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Data Misuse and Manipulation: Teaching New Scientists that Fudging the Data is Bad

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ABSTRACT: Academic laboratories and private research organizations have something in common. Much of the data processing is done by students or associates who have little to no formal ethics training. Yet their work is complicated, demanding, and critical to the success and integrity of the overall project. Any unwarranted "data trimming" could alter results for the worse, discard real findings, or sully the reputation of the lab or company. One way to encourage good behavior in data analysis is to connect the individual's role to the wider effort of the lab, the field, and the scientific enterprise. By doing so, the underlying responsibilities of the data analyst are highlighted.

We have designed an introductory lecture for new scientists and staff to emphasize these responsibilities in an effective and engaging manner. The lecture is organized around four themes: (1) discovering data manipulation; (2) setting objective rules for eliminating outliers, (3) understanding the far-reaching effects of improper data analysis, (4) confronting injurious scientific fraud in biomedical science. These issues are illustrated with well-publicized episodes and personal anecdotes. Finally, we examine the reactions of the students and employees to the lecture and make recommendations for future refinements.

KEY WORDS: Data manipulation, data trimming, consequences of fraud, outliers, scientific integrity, tutorial lecture, data analysis responsibilities, undergraduates

I. INTRODUCTION

In small biotech companies and academic research labs, data are often processed and analyzed by individuals who are new to the science profession. They may or may not have had a formal ethics class that covered the etiquette of handling data. They may or may not have spent time in graduate schoo—and even if they have, they may not have received specific instructions regarding the proper handling of data. In both industry and academia, there are many scenarios in which young scientists may feel pressured to manipulate or "fudge" data. This is especially, but not exclusively, the case when the data in question take the form of images in which the opportunity for "cleaning up" the data before it is seen by a supervisor or senior investigator is pervasive. This situation should cause concern, as industrial and academic work products may show up in filings to the FDA and other regulatory agencies. Analyzed data from academic groups almost always finds its way to published papers and/or grant proposals to the

National Institutes of Health (NIH) or other governmental and non-governmental funding agencies. The results of scientific research and the conclusions drawn may even appear in the popular press.

In an effort to introduce concepts and consequences of data manipulation, we have devised a lecture on the ethics of data misuse and manipulation that is intended to initiate healthy discussion and to set forth some guiding principles in a way that is accessible, provocative, entertaining, and nonthreatening to young scientists (college age or beyond). The lecture is organized into four main themes: (1) discovering data manipulation, (2) setting objective rules for discarding outliers, (3) understanding the consequences of data misuse for the scientific enterprise, and (4) understanding the consequences of data misuse (up to and including outright fraud) for the health and safety of the public. Throughout the lecture, using various means, we convey to the audience that their responsibility as data analysts has ramifications far beyond their immediate lab or company setting.

II. AUDIENCE

We delivered our lecture to two groups: employees at a small biotech company and an undergraduate level Global Health and Technology class at a leading university. The lecture delivered at the biotech was offered as part of a professional development educational series. Attendees were approximately 20 employees of varying levels of education (some college through PhD) and diverse scientific backgrounds. The Global Health and Technology class was made up almost entirely of undergrads (31 students). Reading material related to cases of data fraud were provided to the class (Kohn 1988; Stewart and Feder 1987; Braunwald 1987; Boffey 1986)[1–4] prior to the lecture; none was provided to the company employees.

Following each lecture, a brief survey was sent to the lecture attendees to collect and quantify the responses and reactions of the participants. The survey was administered via a Google form and all responses collected were anonymous.

III. LECTURE BY SECTION

A. Discovering Data Manipulation

The lecture began with a discussion of Mendel and his experiments breeding peas and cataloguing the passing of dominant and recessive traits to subsequent generations (Figure 1).[5] These fundamental studies establish what is now known as Mendelian genetics. That is, if traits are encoded strictly by the combination of two alleles, the phenotype corresponds to that of the dominant allele (e.g., smooth rather than wrinkled peas) unless both alleles are recessive. In such case, (homozygous recessive) the recessive phenotype (e.g., green rather than yellow color) appears. Thus, according to theory, in a given a population of heterozygous peas (designated Yy), the dominant phenotype should appear in the frequency 3:1 (from YY, Yy, or yY) compared with the recessive phenotype (only possible if yy) in a cross-breeding experiment. From his empirical

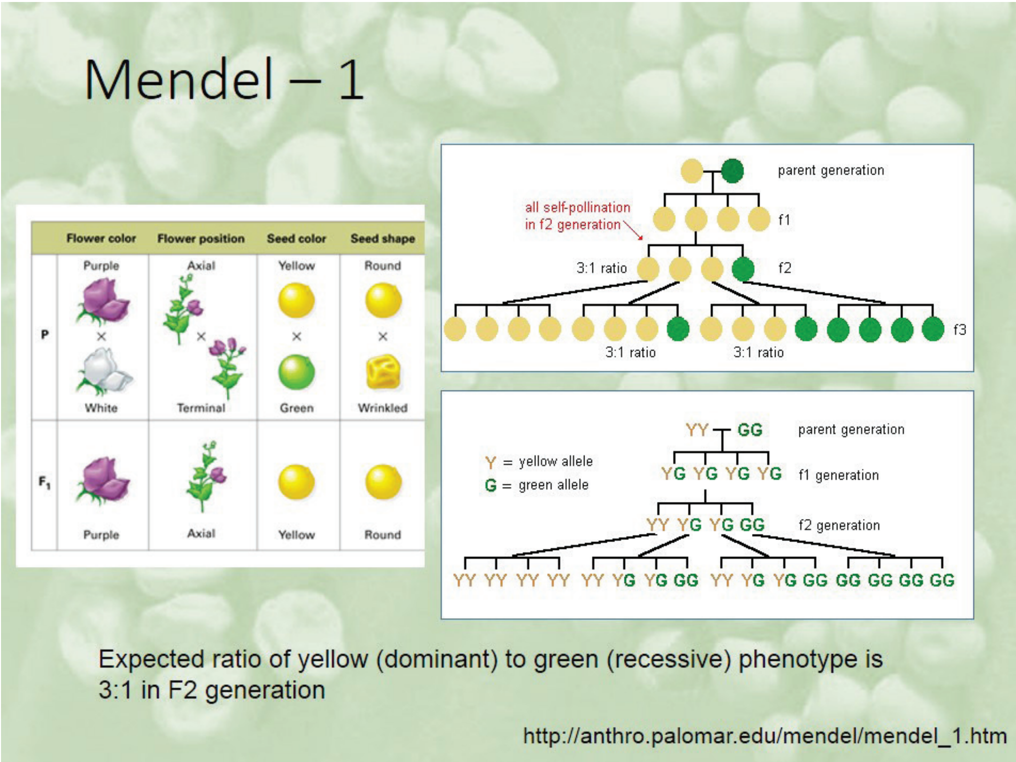

FIG. 1: Mendel's peas and the pattern of inheritance. Images reprinted with permission from Dennis O'Neil, Copyright 1997.[5]

studies, Mendel reported a ratio of 3.009:1, which agrees very well with the theoretical ratio. There were a number of attempts in the early 1900s to replicate Mendel's findings. Despite using larger sample sizes than Mendel, researchers were not able to achieve Mendel's level of adherence to the theoretical value.[6]

In the 1930s, the renowned statistician, R.A. Fisher, examined Mendel's results. Given the number of trials Mendel reported for each trial (600), Fisher predicted that of the peas in the f2 generation exhibiting the dominant phenotype, no better than 367 of 600 would be identified as heterozygotes (Yy).[7] Mendel reported 399 of 600 – essentially a perfect result according to theory. Fisher's prediction cast doubt on Mendel's results.

It is now widely believed that Mendel "trimmed" his data to more closely coincide with his expectations. His reported numbers are remarkably close to the 3:1 ratio that he anticipated for dominant to recessive phenotype in the f2 generation of a cross of homozygous recessive with homozygous dominant (Figure 2).[6,8]

The story of Mendel and his experiments is instructive. It highlights two distinct ways that data manipulation can be discovered. First, another party may attempt a replication study and will be unable to replicate the findings. Second, statisticians may examine the

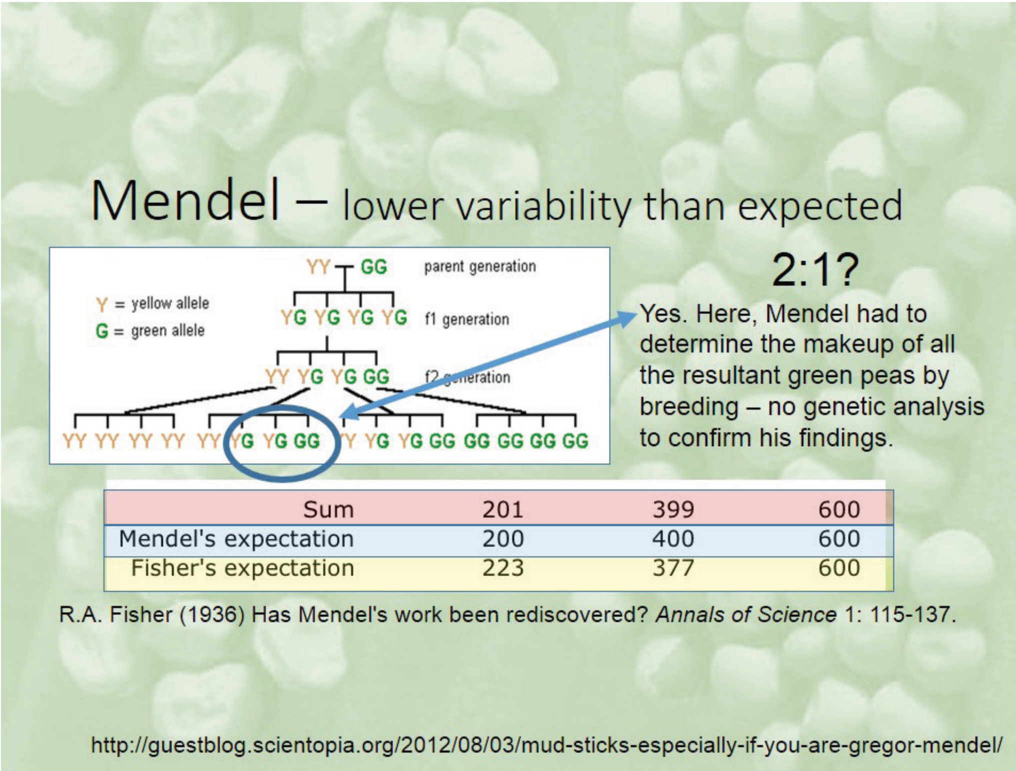

FIG. 2: Mendel's peas and the pattern of inheritance; comparison to Fisher's prediction. Reprinted with permission from Dennis O'Neil, Copyright 2010.[8]

precision of the reported results as RA Fisher did with Mendel's data. If the precision is too good for the number of trials performed, people will suspect manipulation. Perhaps Mendel or his associates authentically felt they were discarding ambiguous findings that could not be classified. Whether Mendel did or did not manipulate the results, and if he did, whether or not the manipulations were intentional, is not really of concern to us here. The value of Mendel's story is in its accessibility to anyone with a basic knowledge of biology. People are broadly familiar with the work and the concepts. They serve as a useful entry point to the broader discussion of numbers, data, discarding data, statistics, and replication. They do so without alienating or confusing anyone in the intended audience. The broad familiarity with Mendel's story and the acknowledgement of its far-reaching implications in education and science, make it a suitable introduction to the methods, ethics, and implications of data manipulation.

As a means of engaging the audience and encouraging critical thinking, throughout the lecture, we posed hypothetical situations under the heading, "You are the Data Analyst." As an example of the questions meant to encourage discussion, this first section of the lecture includes the following scenario:

The study protocol requires you to weigh each animal. Of a cohort of 10, you forget to weigh 1 animal. Your choices are the following:

A) Write in the *mean of the existing animals* as the weight for the animal you didn't weigh.

B) Tell the lab coordinator or study director that you forgot to weigh an animal.

Participants instinctively understand that B is the safer choice. But there is a subtlety to this answer that bears discussing. Substituting the mean value for a missing one will affect the outcome by decreasing the apparent variance of the sample. Taken to the extreme, this course of action would certainly arouse suspicions during a close statistical review of the results.

The main lessons of this section of the lecture are that once data are published in any capacity, one should be aware that

- Someone will try to replicate the findings.
- A statistician somewhere, sometime, will question the data—especially if they seem implausible.

B. Outliers

Certainly, results of faulty trials can and should be discarded at times. After all, experimenters should not be captives to uncalibrated measurement devices or flawed processing algorithms. But, there must be an objective method for discarding data. A very simple rule might be that values that are more than two standard deviations from the mean are "outliers." Consider the following "parametric images" derived from positron emission tomography (PET) scans (Figure 3) (K. Cosgrove, personal communication). Parametric images are detailed maps of a particular physiological parameter—in this case, volume of distribution of an injected tracer— that are calculated from the original PET data at each voxel in the original image. The volume-of-distribution images of brain inflammation shown on the right side of Figure 3 are typical of five healthy subjects to enter a new study. Cold colors indicate that little inflammation was found. Images of a sixth healthy subject from the same study are shown on the left. Images from the sixth subject are visually quite different from the other five sets of images produced and, if correct, suggest a very high level of inflammation, which is inconsistent with the subject being a healthy volunteer. A quantitative comparison of all six data sets is shown in Figure 4. Is this a clear case of an outlier?

The individual with high distribution volume (imaged sixth, but positioned on the left of Figure 4), indicating inflammation, is clearly more than two standard deviations (SD) above the mean (close to five!) Would a careful data analyst throw out the data and attribute the values to a faulty experiment? Hopefully not. As Figure 4 reveals, the subject with a high volume of distribution of the tracer belongs to a different genotype than the first five subjects scanned (labeled 2–6 on Figure 4). "High binders," as they are now called, take up a lot of the tracer even in the absence of a pathology. This discovery, made simultaneously by scientists at the NIH in Bethesda (Kreisl et al, 2010) and at Imperial College in London (Owen et al, 2010), is one of the biggest in the PET field in recent times.[9,10] Different genotypes for the protein that binds the injected tracer used to identify

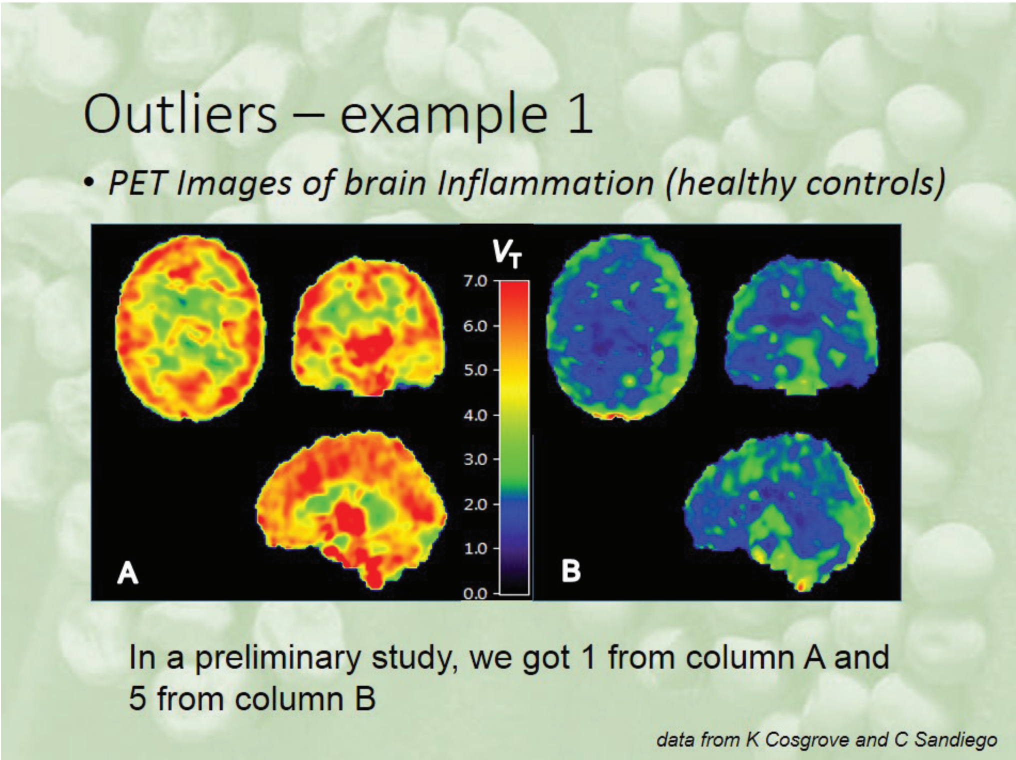

FIG. 3: Parametric images of brain inflammation in two healthy volunteers using the PET tracer, 11C-PBR28. (Personal communication of unpublished data from K Cosgrove.)

markers of inflammation result in distinct classes of individuals: high, low, and mixed binders. Each class must be evaluated separately. Had our hypothetical analyst thrown out the high binder, s/he might have been throwing away part of a seminal discovery.

The most compelling story of scientists reporting remarkable findings by not throwing away troublesome data may be that of Arno Penzias and Robert Wilson (Figure 5). In 1964, Penzias and Wilson were experimenting with a supersensitive, 6-m (20 ft) horn antenna.[11,12] Despite their best efforts, they could not rid their measurements of a steady noise. In 1978, Penzias and Wilson were awarded the Nobel Prize for Physics for their joint discovery of the Cosmic Microwave Background Radiation (i.e., the “noise” left over from the Big Bang).[13]

Through these two examples, we show that choosing the proper criteria for eliminating data from a cohort can be complicated. Criteria for exclusion usually emerge only after the research team has acquired sufficient experience with the particular data set to know what is real and what is artifact. Most of all, this is not a decision to be undertaken by an individual without full knowledge of the principal investigator (PI), as well as her goal and intent for the research. These are decisions to be made by the research team as a whole.

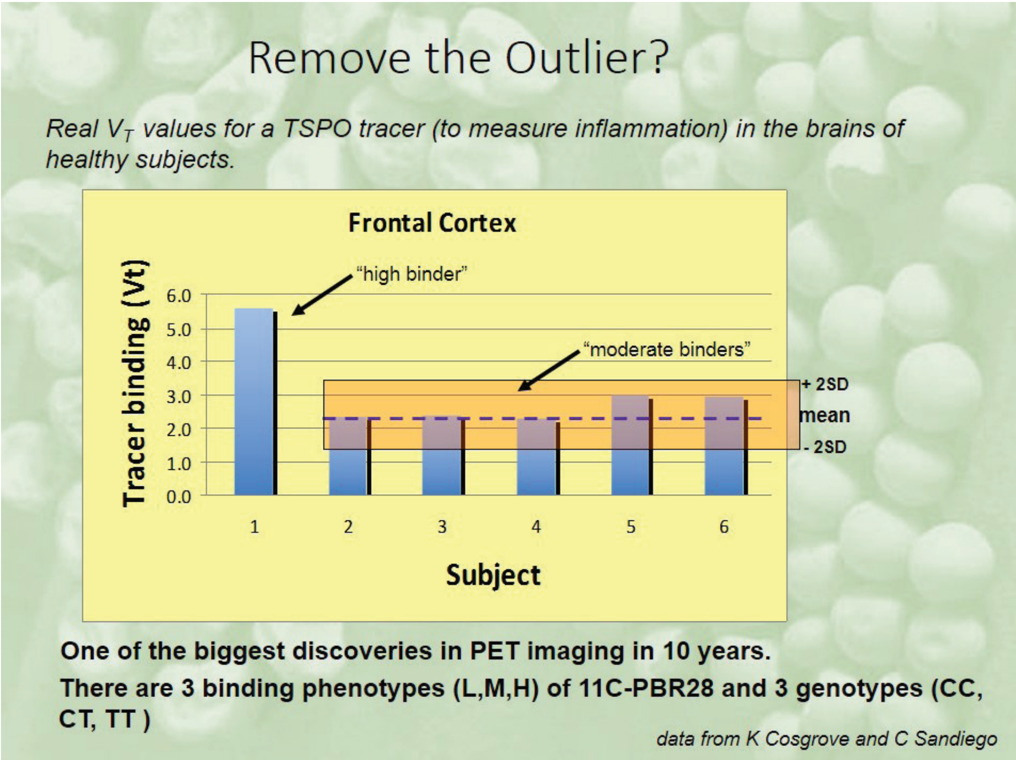

FIG. 4: Distribution volume values representing inflammation for six volunteers in a study of brain inflammation. Subject one is many standard deviations from the mean. Should the data be discarded? (Data from K Cosgrove.)

Lessons:

- Objective rules are required for the elimination of outliers.
- Rules are to be determined by the research team under the guidance of the primary investigator (PI).
- If outliers are discarded, this should be mentioned and explained in reports of the research and published papers.

C. Integrity of the Scientific Literature

It is important to convey to people who are new to science that their work does not exist in a vacuum. Nor is it without consequences beyond their immediate project. As already mentioned, the data analyzed by the intended audience of our tutorial lecture often find their way into journal articles, scientific reports, and grant proposals. To drive home the possible impact of their reported research, we examine the well-publicized case of Robert Slutsky, whose publishing misdeeds were uncovered at UCLA in the 1980s

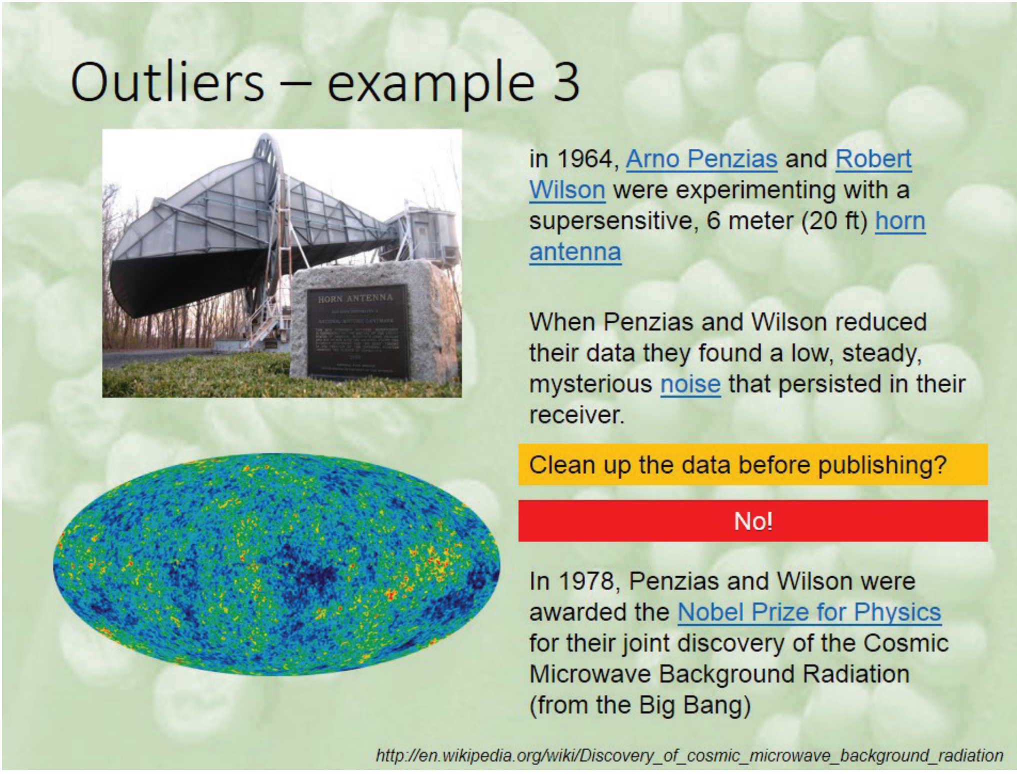

FIG. 5: Penzias and Wilson won the Nobel Prize in 1978 for discovering the residual radiation from the Big Bang. Had they "cleaned up" their data to remove unexplained noise, the discovery might have been lost.[13]

(Figure 6). Slutsky was a rising star at UCLA Medical School. By 1984, Slutsky already had 137 citations listed in PubMed (the public index of biomedical journal articles). In 1985, Slutsky's data fabrication was reported in the LA Times.[14] Subsequently, he was forced to resign his position and ultimately retract many of his published papers. But, retractions are not published on the front page of the LA Times, and not everyone gets the word at the same time. Figure 6 shows the persistent damage that Slutsky's work might have had by comparing the number of times his papers were cited to the times a comparable "control group" of papers were cited in the same period following publication.[15] It is important to keep in mind that every time a researcher cites Slutsky's work they may be operating from an incorrect assumption. The consequence of establishing a hypothesis based on a fraudulent result could be the faulty design of an experiment that can produce only ambiguous or even useless results, further resulting in the poor allocation of funds and other limited resources.

It may be minimally comforting to note that in Figure 6 the citations of Slutsky's work drop off more rapidly than do the citations to the control papers. Unfortunately, this

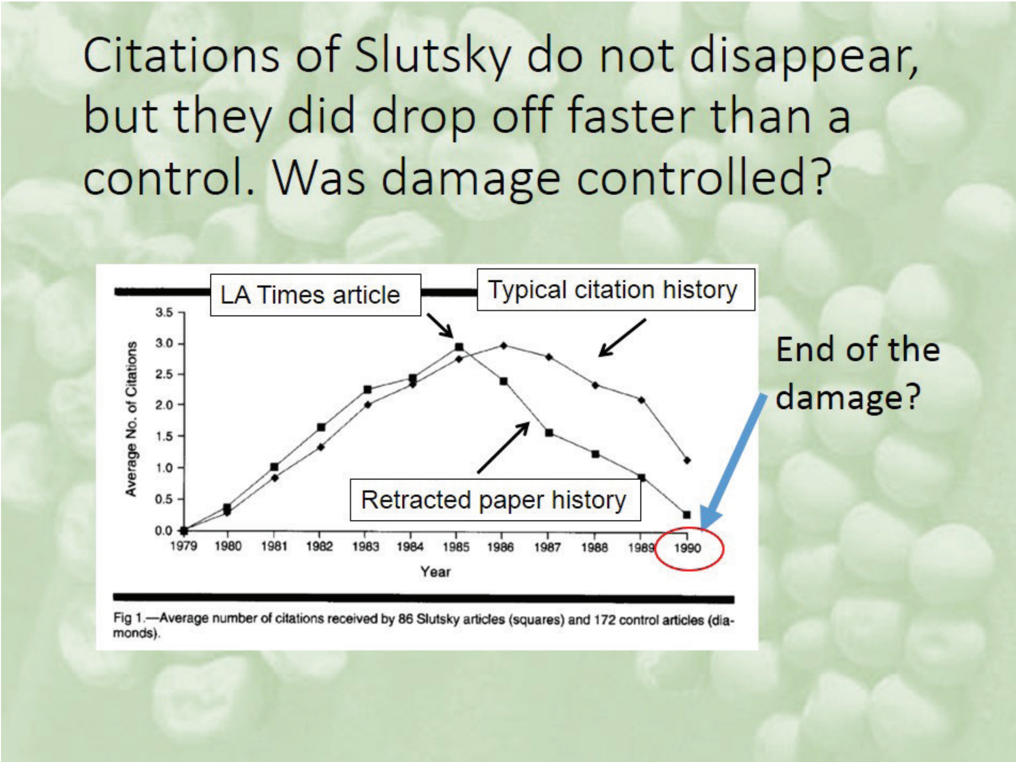

FIG. 6: Pattern of journal article citations for Slutsky's work compared to the average journal article. Note the timing of the LA Times article. Reprinted with permission from The Journal of the American Medical Association, Copyright 1994.[15]

figure from Whitely et al may paint too positive a picture.[15] The plot of citations to Slutsky suggests that the damage to the scientific literature is fully contained and had no echoes beyond 1990. And yet, with a quick and inexhaustive search of Google Scholar, we were able to find a review paper in the prestigious journal *Circulation* that referenced one of Slutsky's *retracted* papers as late as 1995![16] This is very serious. Review papers are often the starting place for formulating new ideas and proposals. One cannot know everything about a field, especially when entering a new one. Thus, scientists seek out review papers as a way to familiarize themselves with a field and to look for timely areas of new research. Researchers base grant proposals to funding agencies on what they know, combined with what they glean from the literature. Fraudulent or misleading information in the published literature can have far-reaching and costly consequences that are hard to contain.
Lessons:

- The scientific literature is poisoned by fraud.
- A poisoned scientific literature is very damaging to the scientific enterprise.
- The poison is hard to deracinate.

D. Consequences for Real People

Finally, we come to the most sinister aspect of data fraud and the effect it has on real people. We started out discussing data "manipulation" and have now progressed to "fraud." The two must be seen as existing on a continuum. It is the authors' opinion that what starts out as simple data "trimming" can easily progress to out-and-out fraud if uncorrected and unchecked. The expectations and accolades for a high-profile scientific finding that cannot be replicated can be its own source of pressure for the offending data manipulator to take even bolder steps toward outright fraud.

In 1998, a paper was published in the prestigious British medical journal *The Lancet*. In that paper, Andrew Wakefield et al. claimed an association between "developmental disorders" and the vaccination for measles, mumps and rubella (MMR).[17] The claim was made based on a population of 12 children, between the ages of 3 and 10, and a supposed causal connection between MMR and autism in 8 of the 12.[17] The key points of the subsequent chronology are recounted in an article by Rao and Andrade.[18]

Immediately following the publication of *The Lancet* article, a large meta-analysis of existing data on autistic children was conducted. The resulting publication the following year, also published in The Lancet, was based on a cohort of 498 children with autism.[19] The authors of this extensive study of children in England found no relationship between the onset of autism in their cohort and the time of MMR vaccination. This, and other large studies, should have served as a sufficient refutation of the earlier 1998 study. Unfortunately, as we see in Figure 7, the impact of the 1998 publication appears to have been quite out of proportion to its size.[20]

Following the publication of the 1998 claim, the MMR vaccination rate dropped precipitously in the UK after having achieved an apparent steady state rate >90% for 6 consecutive years. The unsubstantiated claim was picked up by the media and (anti-vaccination) advocacy groups. In 2004, 10 of the 12 authors of the 1998 paper issued a retraction of their *interpretation*. They said,

> *We wish to make it clear that in [the 1998 Wakefield et al.] paper no causal link was established between MMR vaccine and autism as the data were insufficient. However, the possibility of such a link was raised and consequent events have had major implications for public health. In view of this, we consider now is the appropriate time that we should together formally retract...*[21]

Wakefield was investigated by *The Lancet* for having financial ties to law firms suing vaccination makers. But at the time of the retraction in 2004, he was exonerated. The scientific transgression that was the primary focus of the 2004 investigation by *The Lancet* was an accusation that researchers had *selected* which subjects to report rather than the printed claim that the 12 patients reported had appeared consecutively. This is at least data trimming if not worse. It was not until 2010 that *The Lancet* issued a *full* retraction of the paper. Unfortunately, whether the paper was a case of data trimming or out and out fraud for money, the damage was done. As Eggertson stated,

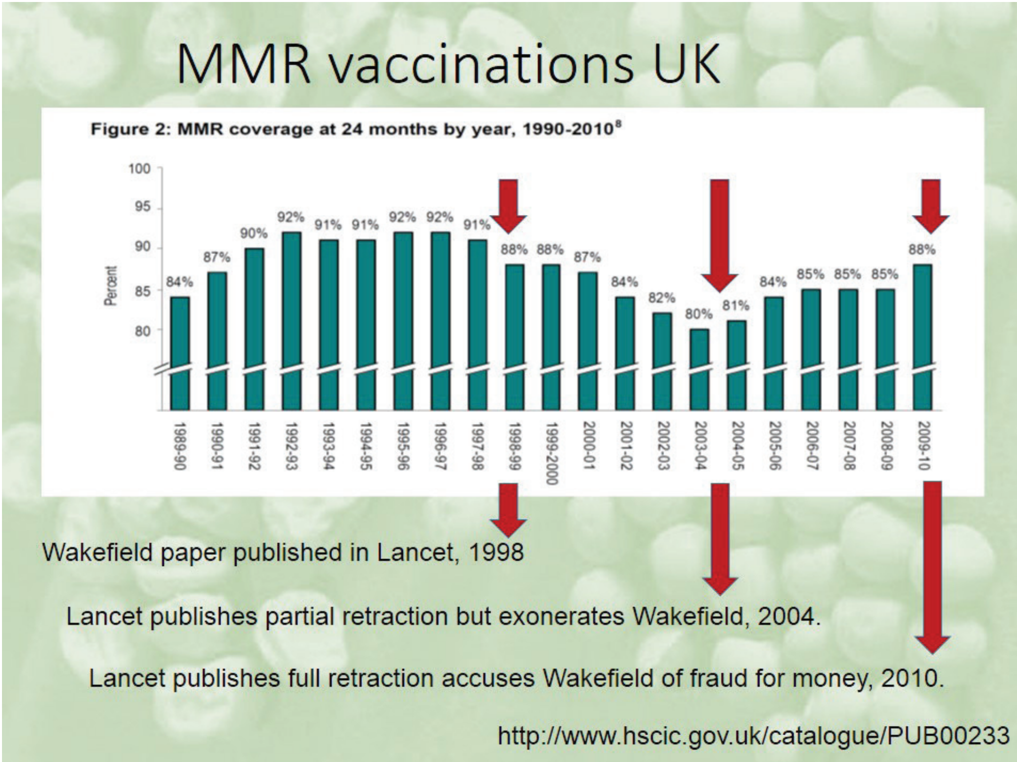

FIG. 7: Timeline of Lancet paper in 1998 claiming association between MMR and autism and sequelae overlaid on timeline of the MMR vaccination rate in the UK.[20]

> *Despite the retraction, many autism advocacy groups and parents continue to defend Wakefield, as they are making clear on blogs such as the Age of Autism, in electronic comments responding to articles about the retraction, and on the website of Generation Rescue, a group founded by actors Jenny McCarthy and Jim Carrey.*[22]

If anyone needs evidence that low MMR vaccination rates have real consequences in terms of harm to people, one need only read the news. Measles outbreaks have been proliferating. Figure 8 shows the growing incidence of outbreaks as reported in *The Wall Street Journal* in 2013.[23] In that same article, the influence of the popular (but sometimes unscientific) media on a guardian's decision to vaccinate a child is captured in this quotation:

> *One of the infected was Ms. Jenkins, whose grandmother, her guardian, hadn't vaccinated her as a young child. "I was afraid of the autism," says the grandmother, Margaret Mugford, 63 years old. "It was in all the papers and on TV."*[23]

The data in Figure 8 only go through 2013. There have since been even larger outbreaks of measles in California. As with the situation in the UK, unscientific support for the anti-vaccination movement is strongly implicated.[24]

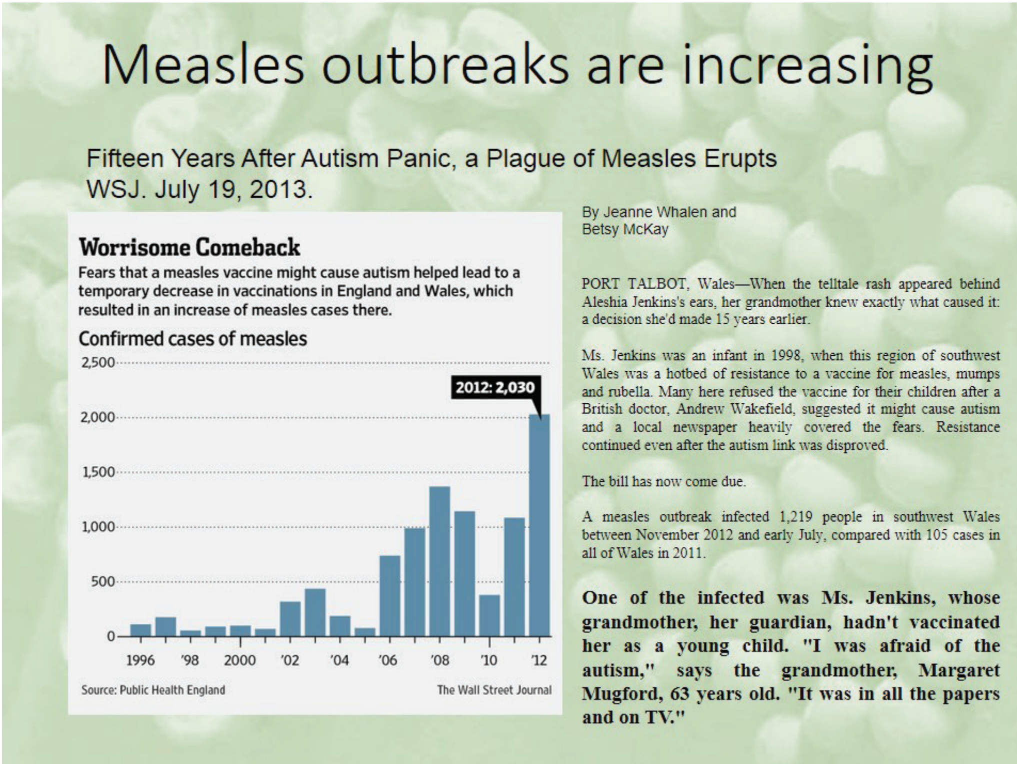

FIG. 8: Growth of Measles outbreaks in the UK from 2006 to 2013 with excerpts from Wall Street Journal article, reprinted with permission from Dow Jones and Co., Inc., Copyright 2015.[23]

The drop-off in vaccination rates for MMR and the resultant outbreaks of what had been an eradicated disease, measles, is a sad illustration of the large deleterious impact that misdeeds in the scientific literature can have on the public. The fact that measles outbreaks are increasing due to loss of herd immunity a full 16 years after the publication of a large-scale refutation of Wakefield,[19] 12 years after a retraction by 10 of Wakefield's co-authors and 6 years after a full retraction by the journal, indicates just how long-lasting the effect can be.

Lessons:

- Mishandling of data can hurt real people.
- Fraudulent data take on lives of their own.
- The consequences can be far-reaching.
- Money can be a temptation to commit fraud.

IV. REACTIONS OF THE INTENDED AUDIENCE

To help us evaluate the effectiveness of the lecture, we wrote and distributed a brief, 13 question survey to all attendees. The survey is provided in a file labelled "Follow-up questionnaire for “Mendel Fudged his Data”” Appendix 1. We hypothesized that the reactions of listeners might break down according to general training areas (science and engineering vs. humanities) training levels (those who attended graduate school vs. those who had not) or based on whether or not an individual reported having received specific ethics training.

Twenty-nine lecture attendees completed the survey. From self-reported demographics, the respondents break down as follows: 62% were current students; 90% of the audience chose to respond and 10% preferred not to respond; 10% had a PhD or other doctoral degree, 17% had a master’s degree, 14% had a bachelor’s degree, 10% had completed 4 years or more of college, 28% had completed 3 years of college, 10% had completed 2 years of college, and 11% had completed 1 year of college; 50% had a degree in engineering, 16% had a degree in the humanities, and 34% had a degree in the natural sciences. When asked if they had taken an ethics course previously, 55% of the respondents said yes.

The majority of survey respondents found the lecture to be entertaining (86% agree or strongly agree) (Figure 9a) and the material accessible (90% agree or strongly agree) (Figure 9b). After attending the lecture, 79% of respondents agreed or strongly agreed that they had a better understanding of research misconduct in data analysis and 90% agreed or strongly agreed that the lecture was relevant to them and their job and/or coursework (Figure 9c). When asked if the seminar changed the way attendees think about their responsibilities at work, in class, and/or in their research, 54% agreed (40% neither agreed nor disagreed). Only 21% agreed that after attending the seminar they have changed the way they approach data analysis (48% neither agreed nor disagreed and 24% disagreed). After attending the seminar, 34% of respondents agreed that they have or will do further research on the topics covered in the seminar.

When breaking the respondents down by current student status, no strong differences between groups appeared except when attendees were asked if have done or will do further investigation into the topics covered within the seminar: 50% of current students but only 9% of non-students agreed that they will do further research. There were no strong differences in responses between those respondents who had previously taken an ethics course and those who had not.

Our test audiences were attentive, engaged, and asked relevant questions. Many said that they had learned new things about the proper and ethical handling of research data, whether or not this was a primary responsibility associated with their daily work. One attended stated, “I attended the seminar. I work in HR. Thus, scientific data analysis doesn’t specifically apply to me in my everyday job. However, I really enjoyed the seminar, learned a lot, and found the information was presented in an understandable and accessible way. I’m glad I attended!” Notably, some audience members said that they would follow up with further research of their own. Almost all respondents of all educational backgrounds and levels answered that the lecture was accessible and entertaining.

V. IDEAS FOR FUTURE MODIFICATIONS

Among the most compelling results of our survey is that inclusion of timely, non-threatening and accessible anecdotes can impart the gravity and also relevance of data

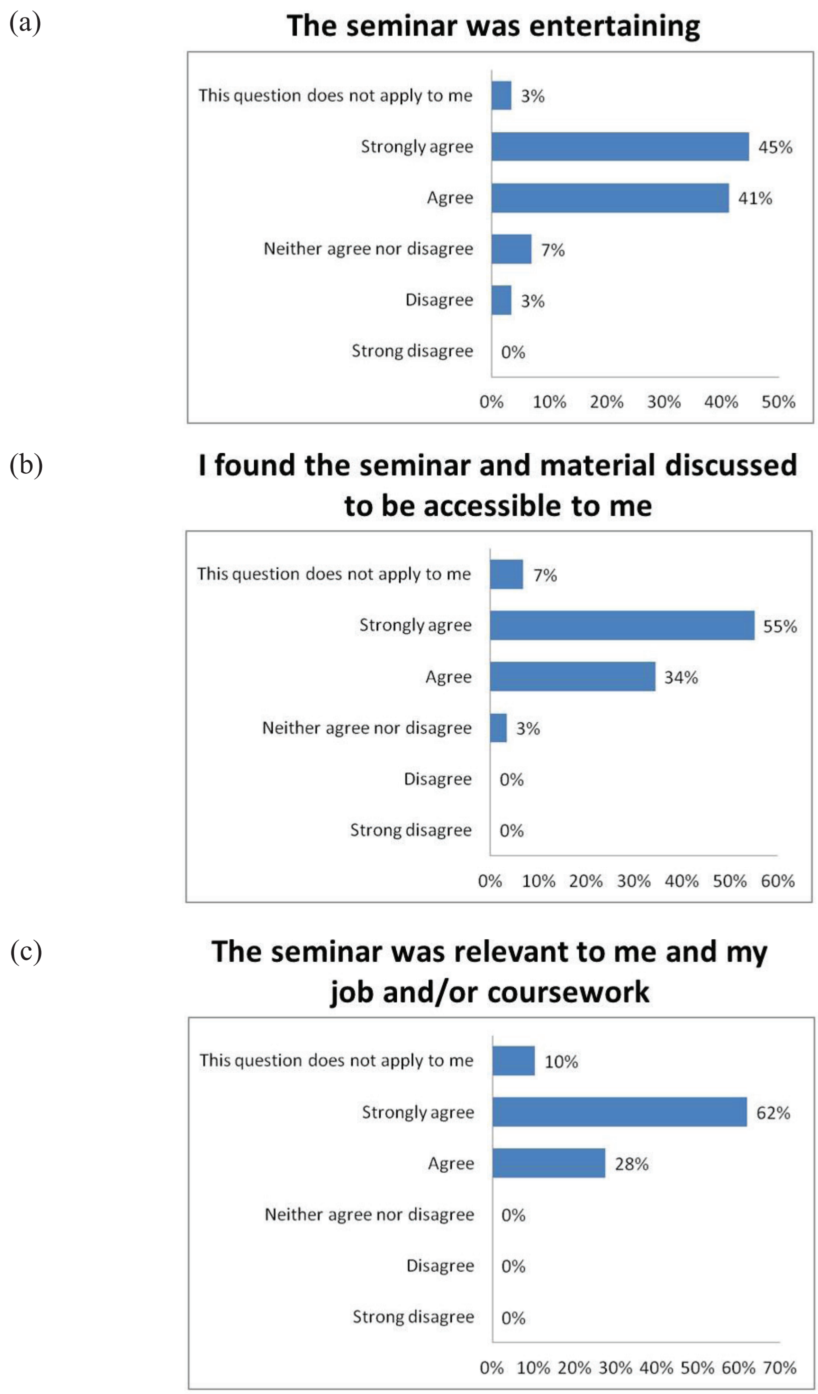

FIG. 9: Lecture attendees who responded to the survey found the lecture to be entertaining, accessible, and relevant.

manipulation to an audience. Unfortunately, these anecdotes are readily available in the popular press which is rife with tales of scientists and physicians who promote studies and treatments that are substandard or ineffective.[25] Organizations such as the Pew Research Center frequently publish on the societal perception of science, scientists and physicians.[26] These reports suggest that societal opinions of science can be greatly informed by an individual's perception or experience with a few, but notable, cases of scientific fraud and manipulation. Negative associations that the public makes with science could have consequences for governmental funding of scientific research and science, technology, mathematics, and engineering (STEM) education.

VI. CONCLUSIONS

The NIH defines research misconduct as "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results [...]".[27] It is important to note that anyone can participate in—and be guilty of—research misconduct. Our lecture educated the attendees on research misconduct through historical examples, well-publicized events, and personal anecdotes.

Our primary goal was to get people thinking about the ethics of data manipulation and to recognize that each analyst "alone in a cubicle" has a responsibility to the project, the PI, and all those who may use the results of the immediate project. The scientific enterprise is a network of many interconnected efforts depending on many results and interpretations that have come before. Everyone engaged in science, whatever the level, is dependent on the integrity of what they read and learn from the literature. Sometimes, scientific findings have direct impact—far beyond the confines of the project—upon the health and well-being of the public. As such, no manipulation of the data not agreed upon prior to the study should be undertaken without thoughtful discussion and consent of the research team under the guidance of the PI.

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