Ethics in Statistics : Case Study

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- We are in sections 1.4 of the textbook
- In this handout, you'll examine a particular medical study involving multiple ethical violations.
- The American Statistical Association had prepared a set of Ethical Guidelines for Statistical Practice. The guidelines are "intended to help statistics practitioners make decisions ethically"
- Ethical considerations - from the American Statistical Association:
  - Professional integrity
  - Integrity of data and methods
  - Responsibilities to Science/Public/Funder/Client
  - Responsibilities to Research Subjects
  - Responsibilities to Research Team Colleagues
  - Responsibilities to Other Statisticians or Statistics Practitioners
  - Responsibilities Regarding Allegations of Misconduct
  - Responsibilities of Employers

References

- Ethical Guidelines for Statistical Practice, URL: https://www.amstat.org/ASA/Your-Career/Ethical-Guidelines-for-Statistical-Practice.aspx, ASA, 2018.
- Andrew Wakefield: the fraud investigation, Brian Deer, https://briandeer.com/mmr/lancet-summary.htm
- Lancet MMR Autism Fraud, https://en.wikipedia.org/wiki/Lancet_MMR_autism_fraud

A summary of the ASA Ethical Guidelines are given on the next page. The letters and numbers match those set by the ASA in the printed version of the guidelines.

For each of the descriptions below, at least one of the ASA Ethical Guidelines was violated.

Match each description with at least one of the ASA Ethical Guidelines. Also, match each Guideline with at least one of the descriptions.

The lead researcher in the study is called "The Researcher".

Summary of some ASA Ethical Guidelines for Statistical Practice

A. **Professional Integrity and Accountability**

1. Identifies and mitigates any preferences on the part of the investigators or data providers that might predetermine or influence the analyses/results.

2. Employs selection or sampling methods and analytic approaches appropriate and valid for the specific question to be addressed, so that results extend beyond the sample to a population relevant to the objectives with minimal error under reasonable assumptions.

B. **Integrity of data and methods**

1. Acknowledges statistical and substantive assumptions made in the execution and interpretation of any analysis. When reporting on the validity of data used, acknowledges data editing procedures, including any imputation and missing data mechanisms.

4. Reports the sources and assessed adequacy of the data, accounts for all data considered in a study, and explains the sample(s) actually used.

7. In publications and reports, conveys the findings in ways that are both honest and meaningful to the user/reader. This includes tables, models, and graphics.

8. In publications or testimony, identifies the ultimate financial sponsor of the study, the stated purpose, and the intended use of the study results.

C. **Responsibilities to Science/Public/Funder/Client**

3. Applies statistical sampling and analysis procedures scientifically, without predetermining the outcome.

D. **Responsibilities to Research Subjects**

5. Considers whether appropriate research-subject approvals were obtained before participating in a study involving human beings or organizations before analyzing data from such a study and while reviewing manuscripts for publication or internal use. The statistician considers the treatment of research subjects (e.g., confidentiality agreements, expectations of privacy, notification, consent, etc.) when evaluating the appropriateness of the data source(s).

H. **Responsibilities of Employers, Including Organizations, Individuals, Attorneys, or Other Clients Employing Statistical Practitioners**

4. Recognize the results of valid statistical studies cannot be guaranteed to conform to the expectations or desires of those commissioning the study or the statistical practitioner(s).

5. Recognize it is contrary to these guidelines to report or follow only those results that conform to expectations without explicitly acknowledging competing findings and the basis for choices regarding which results to report, use, and/or cite.

6. Recognize the inclusion of statistical practitioners as authors or acknowledgement of their contributions to projects or publications requires their explicit permission because it implies endorsement of the work.

1. The Researcher was paid to find evidence of a link between the measles-mumps-rubella (MMR) shot and autism. The Researcher was paid by a lawyer who hoped to pursue a class action lawsuit against drug companies which manufacture the MMR shot. Some of the money paid for the research came from a public legal defense fund.

2. The published research paper fails to acknowledge funding from the lawyer and the underlying motivation for the study (an undisclosed conflict of interest).

3. The Researcher additionally received funding for the research to prove the MMR shot caused a previously unheard of syndrome, autistic enterocolitis. The Researcher asserted the existence of the syndrome before the research in which The Researcher claimed to discovered the syndrome.

4. The Researcher filed a patent for single measles vaccine (monovalent vaccine) nine months before the research was completed. Part of the published research included speculation that the polyvalent MMR vaccine was dangerous, but a monovalent vaccine would not be.

5. The children in the study were pre-selected through anti-MMR campaigners and other similar anti-vaccination groups.

6. The Researcher changed, misreported, and misrepresented the diagnoses and medical histories of the children. No children in the research paper matched the diagnoses and medical histories of any of the children in the study. In particular, several children had symptoms prior to receiving the MMR shot; several never had, or developed, symptoms. The UK General Medical Council panel ruled that key elements of the research paper were intentionally dishonest.

7. The Researcher did not gain pre-approval for the medical study from the ethics board.

8. The published research paper had 13 co-authors. The paper was drafted and revised by The Researcher. The other 12 co-authors did not know the children. One co-author was a well known researcher in the field, whose reputation, in part, got the paper published.

9. In your opinion, which of these ethical violations is the most serious? Would you recommend disciplinary actions be taken against The Researcher?