Ministry of Health and Sports

Data Management Practices: Data Ownership, Data Collection

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Case: Falsified data

- Case scenario: falsified data.docx

Outline of the presentations

- Data in research
- Data Ownership issues
- Data collection: how researchers should collect, store, protect the research data to maintain its integrity, validity and accuracy.

Data ???

Data in Research

data when referring to research projects means **the all** of the information **collected and generated** in the course of a research project.

What is research data?

Data that has formed the basis of your research output.

The University of Sydney

Research data can be observations, survey answers, scripts, photographs, notebooks,

Data: addition to research findings

- **Sponsored projects –**

  Need to consider financial data and administrative data (subject to retention requirements)

  - **Financial data –**budget information, record of expenditures
  - **Administrative data –**project proposals, required approvals

Why Data Management Practices important?

- In order to conduct research responsibly
- **Researchers' obligations**:
  - *Obligations toward other researchers*
  - *Obligations toward oneself*
  - *Obligations* toward the public

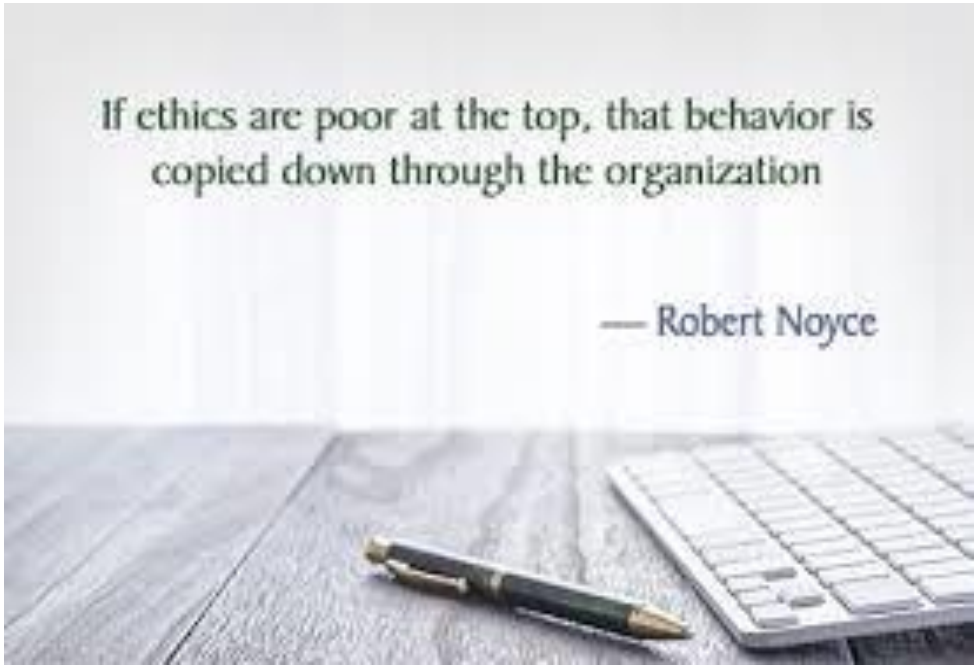
Ref: On Being a Scientist A Guide to Responsible Conduct in Research: Third Edition

Obligations toward other researchers

- new research builds on previous results
- Irresponsible actions can impede an entire field of research or send it in a wrong direction
- Imbedded in this trust is a responsibility of researchers to mentor the next generation who will build their work on the current research discoveries.

Obligations toward oneself

- **maintaining a reputation as a productive and honest researcher, adhering to professional standards builds personal integrity in a research career.**



Obligations toward Public

- Some scientific results directly affect the health and well-being of individuals, thereby society
- Science also is used by policy makers to make informed decisions on such pressing issues
- new knowledge speaks to our sense of wonder and paves the way for future advances.

Can you rely on the drugs that your doctor prescribes?

Silent on many questions

So, how valuable is a guideline for the management of hepatitis C, in which eight authors declared FCOI with recommended drug producers? How reliable are the recommendations from a committee that did not document how evidence was evaluated or include a public or patient representative?

https://theconversation.com/can-you-rely-on-the-drugs-that-your-doctor-prescribes-98128

JAMA Network

JAMA Internal Medicine

Search All

March 2017

Conflict of Interest in Seminal Hepatitis C Virus and Cholesterol Management Guidelines

Akilah A. Jefferson, MD, MSc[1]; Steven D. Pearson, MD, MSc[1,2]

» Author Affiliations | Article Information

JAMA Intern Med. 2017;177(3):352-357.
doi:10.1001/jamainternmed.2016.8439

Data Ownership ??

Data Ownership

Should the person who conducts the research own the product ?

- imposed by
  - Funders (Government/ Private)
  - research institutions
  - data sources
- No absolute rules -highly recommended that researchers determine data ownership before they embark on a study

Ownership according to Grants and Contract

- **Grants**–researchers must carry out the research as planned and submit reports, but control of the data remains with the institution that received the funds
- **Contracts**–researcher to deliver a product or service, which is then usually owned and controlled by the government

******claims of funders can do vary considerably, researchers must be aware of their obligations to them before they begin collecting data.***

Research institutions.

- **Support for research is typically awarded to research institutions, not to individual researcher**
- **As the recipients of research funds, research institutions have responsibilities for budgets, regulatory compliance, contractual obligations, and data management**
- **research institutions claim ownership rights over data collected ; this means that researchers cannot automatically assume that they can take their data with them if they move to another institution**

The Bayh-Dole Act 1980

- allowed universities to have control of the intellectual property, such as patents, generated from federally funded research.
- With a patent in hand, universities could exclusively license the patent to businesses, recent inventions, in the form of new drugs and computer technologies, have also helped the public.
- The law has encouraged new relationships between academic researchers and companies,

Data collection (data acquisition)

Data are used;

- **to confirm or reject research hypotheses,**
- **to identify new areas of investigation,**
- **to guide the development of new investigative techniques, and more;**

. Science and practices today cannot exist without data.

Data collection (data acquisition)

- Different collection techniques for Different types of research, it can vary !!
- How to ensure the overall integrity (both the process & information)
  1. Appropriate methods
  2. Attention to detail
  3. Authorized
  4. Recording

Appropriate methods

- **study design**
- **Experimental design**
- **Appropriate statistical tests**
- **Data collection techniques**

➢inappropriate methods in research compromises the integrity of research data

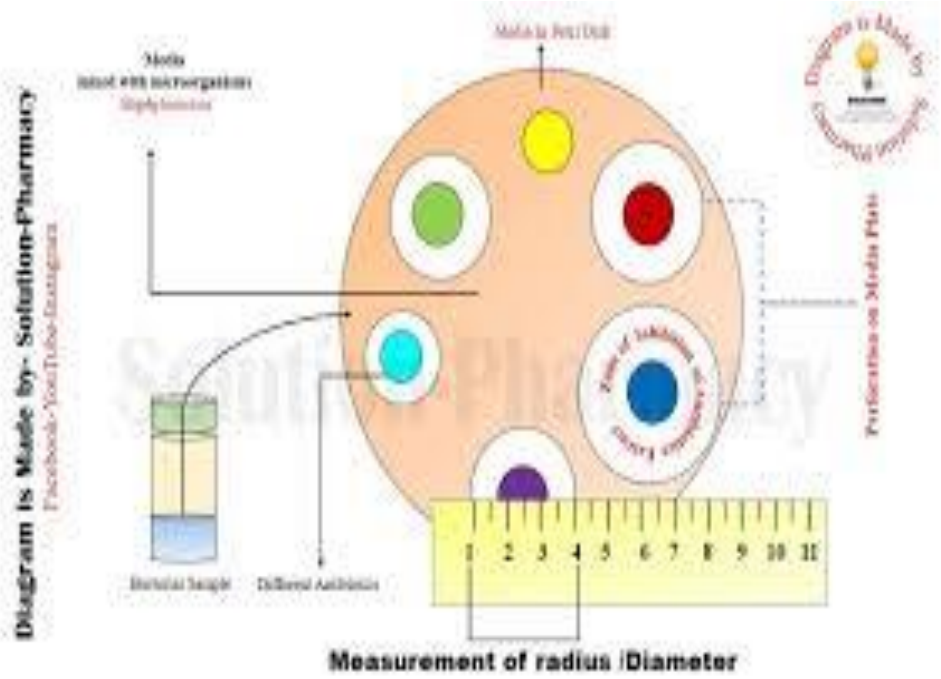
Data Acquisition Techniques

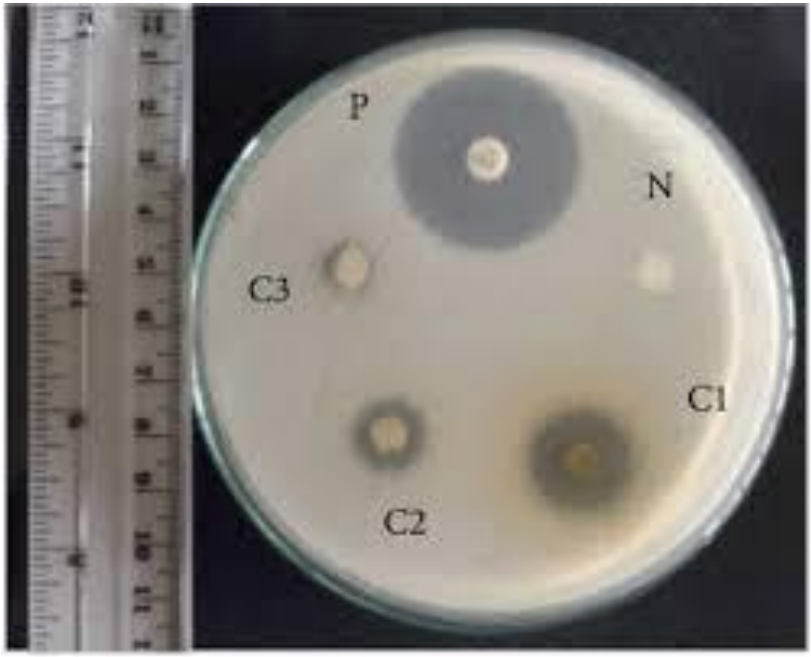
- **experiments ,**
- **published literature sources**
- **surveys (SAQ, Google form, Survey monkey)**
- **interviews**
- **Observations**
- **documents and records**

Data acquisition: process of converting acquired data from different tools to scientific result.

- **Methods can also be compromised by bias—choosing one method or set of experimental conditions so that a particular conclusion can be drawn**

E.g; Scenarios in real practice



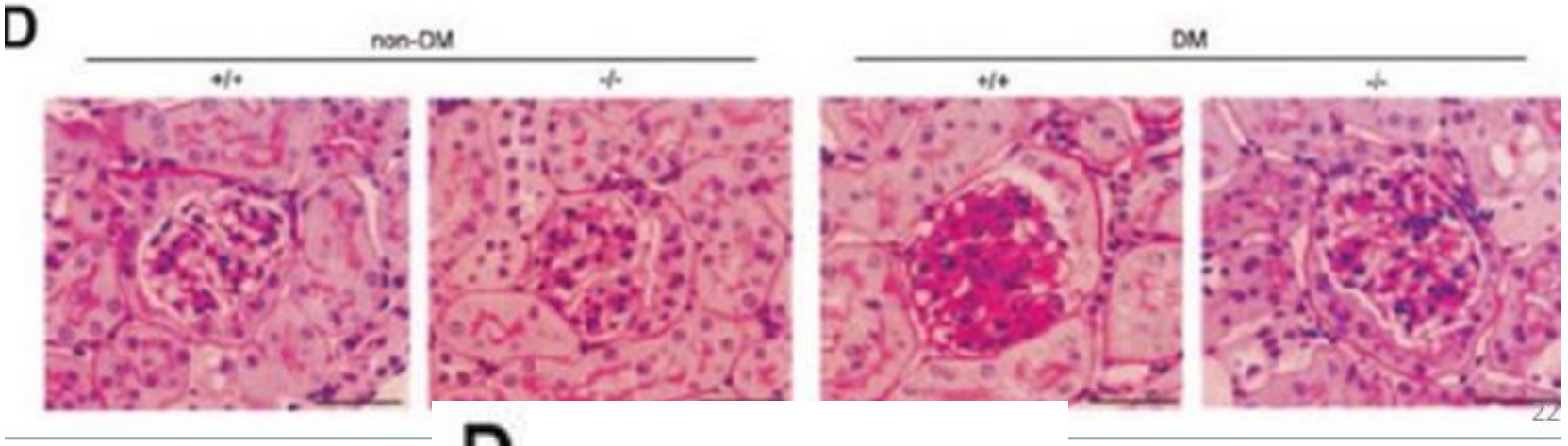


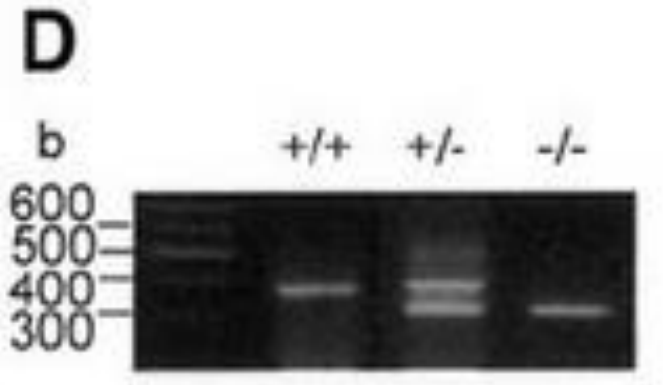
Attention to detail

E.g;

Manuscript submission:

The editors requested the original data, images, figures





Authorized

➢**Obtaining appropriate permissions**

Researchers have a responsibility to know when permission is needed to collect or use specific data

E.g;

- **human (and animal) subjects in research**
- **hazardous materials and biological agents**
- **information contained in some libraries, databases, and archives**
- **information posted on some Websites**
- **published photographs and other published information**
- **other copyrighted/patented processes or materials**

Data sources

- source of data are seeking some control over data derived from them. Countries' data, entities with unique databases, claimed ownership of research results based on their data.
- Make sure you can answer these questions
  - **Who owns the data I am collecting?**
  - **What rights do I have to publish the data?**
  - **Does collecting these data impose any obligations on me?**

Recording data

- **to document** what was actually done and the results that were achieved
- Hard-copy evidence–a bound notebook with numbered pages on which **date and time of research** can be clearly enumerated
- Kept in a way that will **enable someone else to repeat** each experiment
- **Do not change records** in **a bound notebook without noting the date and reasons for the change**

E.g;

Electronic evidence

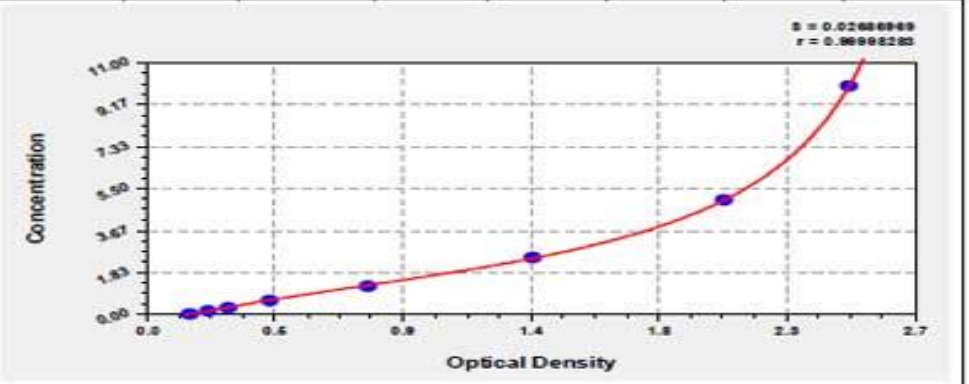
- **validated to assure that it was actually recorded on a particular date and not changed at some later date.**
- **It is easy to change dates on computers and thereby alter the date a particular file seems to have been created. If you collect your data electronically, you must be able to demonstrate that they are valid and have not been changed.**

1. Raw Data: Paste your reader OD raw data below

	1	2	3	4	5	6	7	8	9	10	11	12
A	1.716	1.757	1.84	1.8	0.96	1.013	0.313	0.346	0.655	0.667	1.44	1.409
B	1.438	1.462	1.79	1.801	0.984	0.97	0.334	0.322	0.214	0.267	1.255	1.239
C	0.967	1.014	1.794	1.746	0.958	0.948	0.312	0.312	0.157	0.146	0.233	0.255
D	0.586	0.606	1.791	1.822	0.955	0.906	0.325	0.305	0.091	0.082	1.791	1.822
E	0.319	0.347	1.462	1.493	0.562	0.59	0.171	0.173	0.334	0.322	0.334	0.322
F	0.167	0.186	1.484	1.472	0.589	0.588	0.175	0.169	0.958	0.948	0.086	0.09
G	0.094	0.103	1.445	1.424	0.587	0.573	0.175	0.168	0.589	0.588	0.313	0.342
H	0.086	0.09	1.531	1.478	0.584	0.536	0.091	0.086	0.175	0.168	0.962	1.012

Fill Sample Data | Clear Data

	0.156	0
	0.231	0.168

Standard Curve	
Exponential Association	Rational Function: y=(a+bx)/(1+cx+dx^2) Coefficient Data: a = -0.5122547 b = 3.005744204 c = 0.923589601 d = -0.419016288

Data Protection

- data must be protected for later use, to confirm research findings, to be reanalyzed by other researchers
- Data Confidentiality: Some data may be subject to privacy restrictions (human subjects or confidential business information), a safe place that is accessible only to authorized personnel, using random codes

***PI has the primary responsibility for its protection*.**

Research Misconduct: Concerned Data Management

- **Fabrication** is making up data or results.
- **Falsification** is manipulating or changing or omitting data or results.
- **Plagiarism** is the appropriation of another person's ideas or words without giving appropriate credit.

How big is the problem?

- 163 biostatisticians surveyed.
- 51% knew of at least one fraudulent project during the last 10 years.
- 31% were involved in a fraudulent project.
- 13% directly asked to fabricate or falsify data.

"You are completely free to carry out whatever research you want, so long as you come to these conclusions."

http://www.thejabberwock.org/blogl/finalist3.gif

Ranstam et al.; Control Clin Trials. 2000

Misconduct in data management

Research Misconduct	Self Report %	Observed %
Making up research data	10.4	34.6
Changing research data without mentioning it.	5.4	30.8
Dropping "outliers" without mentioning it	7.2	36.1
Selecting only those data that support your hypothesis	9.0	47.0

- Different forms of fraud (e.g., fabrication and falsification of data, deceptive reporting of results, suppression of data, and deceptive design or analysis)
- fraud is not a negligible phenomenon in medical research

ELSEVIER

Controlled Clinical Trials

Volume 21, Issue 5, October 2000, Pages 415-427

Controlled Clinical Trials

Fraud in Medical Research: An International Survey of Biostatisticians

Jonas Ranstam PhD [a], Marc Buyse ScD [b], Stephen L George PhD [c], Stephen Evans MSc [d], Nancy L Geller PhD [e], Bruno Scherrer PhD [f], Emmanuel Lesaffre PhD [g], Gordon Murray PhD [h], Lutz Edler PhD [i], Jane L Hutton PhD [j], Theodore Colton PhD [k], Peter Lachenbruch PhD [l], for the ISCB Subcommittee on Fraud

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Hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID-19: a multinational registry analysis

Mandeep R Mehra, Sapan S Desai, Frank Ruschitzka, Amit N Patel

Summary

Background Hydroxychloroquine or chloroquine, often in combination with a second-generation m[illegible]ide, are b[illegible] widely used for treatment of COVID-19, despite no conclusive evidence of their benefit. Although [illegible]nerally [illegible]e whe[illegible] used for approved indications such as autoimmune disease or malaria, the safety and bene[illegible]f th[illegible]treatment regimens are poorly evaluated in COVID-19.

Methods We did a multinational registry analysis of the use of hydroxychloroquine [illegible]oquine with[illegible]thout a macrolide for treatment of COVID-19. The registry comprised data from 671 hosp[illegible]s in s[illegible]ntinents. We included patients hospitalised between Dec 20, 2019, and April 14, 2020, with a positive laboratory [illegible]g for SARS-CoV-2. Patients who received one of the treatments of interest within 48 h of diagn[illegible]e included in [illegible]f four treatment groups (chloroquine alone, chloroquine with a macrolide, hydroxychlor[illegible]ne alone, or hydroxychloroquine with a macrolide), and patients who received none of these treatments formed [illegible] control gr[illegible]. Patients for whom one of the treatments of interest was initiated more than 48 h after diagnosis or [illegible]ile they we[illegible]on mechanical ventilation, as well as patients who received remdesivir, were excluded. The main outc[illegible]of in[illegible]t were in-hospital mortality and the occurrence of de-novo ventricular arrhythmias ([illegible]stained o[illegible]ed ventricular tachycardia or ventricular fibrillation).

Findings 96 032 patients (mean age 53·8 years, 46·3% women[illegible]OVID-19 were hospitalised during the study period and met the inclusion criteria. Of the[illegible] patie[illegible]were in the treatment groups (1868 received chloroquine, 3783 received chloroquine with[illegible]macro[illegible]e, 3016[illegible]eived hydroxychloroquine, and 6221 received hydroxychloroquine with a macrolide) and [illegible]4 pati[illegible]in [illegible]e control group. 10 698 (11·1%) patients died in hospital. After controlling for multiple c[illegible]f four[illegible]ctors ([illegible] sex, race or ethnicity, body-mass index, underlying cardiovascular disease and its risk fact[illegible]diabetes[illegible]derlying lung disease, smoking, immunosuppressed condition, and baseline disease severity), wh[illegible]mpared wi[illegible]ortality in the control group (9·3%), hydroxychloroquine (18·0%; hazard ratio 1·335, 95%[illegible]1·22[illegible]457), hydr[illegible]ychloroquine with a macrolide (23·8%; 1·447, 1·368–1·531), chloroquine (16·4%; 1·365, [illegible]318–1·531), [illegible]hloroquine with a macrolide (22·2%; 1·368, 1·273–1·469) were each independently associated [illegible]n an increased [illegible]f in-hospital mortality. Compared with the control group (0·3%), hydroxychloroquine (6[illegible]; 2·36[illegible]·935–2·900), hydroxychloroquine with a macrolide (8·1%; 5·106, 4·106–5·983), chloroquine (4·3%; [illegible]51, 2[illegible]0–4·596), and chloroquine with a macrolide (6·5%; 4·011, 3·344–4·812) were independently associate[illegible]an inc[illegible]d risk of de-novo ventricular arrhythmia during hospitalisation.

Interpretati[illegible] We w[illegible]unable[illegible]nfirm a benefit of hydroxychloroquine or chloroquine, when used alone or with a macro[illegible]on in[illegible]spital outcomes for COVID-19. Each of these drug regimens was associated with decreased in-hospita[illegible]reased frequency of ventricular arrhythmias when used for treatment of COVID-19.

Funding William[illegible]vey Distinguished Chair in Advanced Cardiovascular Medicine at Brigham and Women's Hospital.

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P[illegible]d Online [illegible]22, 2020 https://doi.org/10.1016/S0140-6736(20)31180-6

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See Online/Comment https://doi.org/10.1016/S0140-6736(20)31174-0

Brigham and Women's Hospital Heart and Vascular Center and Harvard Medical School, Boston, MA, USA (Prof M R Mehra MD); Surgisphere Corporation, Chicago, IL, USA (S S Desai MD); University Heart Center, University Hospital Zurich, Zurich, Switzerland (Prof F Ruschitzka MD); Department of Biomedical Engineering, University of Utah, Salt Lake City, UT, USA (A N Patel MD); and HCA Research Institute, Nashville, TN, USA (A N Patel)

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RETRACTED

THE LANCET

COMMENT | VOLUME 395, ISSUE 10240, P1820, JUNE 13, 2020

Retraction—Hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID-19: a multinational registry analysis

Mandeep R Mehra • Frank Ruschitzka • Amit N Patel

Published: June 05, 2020 • DOI: https://doi.org/10.1016/S0140-6736(20)31324-6 • Check for updates

Our independent peer reviewers informed us that Surgisphere would not transfer the full dataset, client contracts, and the full ISO audit report to their servers for analysis as such transfer would violate client agreements and confidentiality requirements. As such, our reviewers were not able to conduct an independent and private peer review and therefore notified us of their withdrawal from the peer-review process.

We always aspire to perform our research in accordance with the highest ethical and professional guidelines. We can never forget the responsibility we have as researchers to scrupulously ensure that we rely on data sources that adhere to our high standards. Based on this development, we can no longer vouch for the veracity of the primary data sources. Due to this unfortunate development, the authors request that the paper be retracted.

? Value and belief

? Researcher's reputation

? Public belief/ perception of science

How to Ensure Data integrity ?

DRAFT

Research Data Management Plan (RDMP template)

The Data Management Plan can be used in a number of ways to assist with data management planning.

These include:

- To identify a series of issues and underlying questions that should be considered when planning a research project and initiate discussions within a project (team)
- For the development of a data management plan
- To raise awareness of good practice when planning for data management during the life cycle of a research project.

Research Data Management Plans (RDMP)

Helps you think constructively about your research data

- Compulsory for all research projects at the University
- Part of the HDR progress plan

Use the RDMP checklist if you haven't done an RDMP before, then submit a formal RDMP via the online RDMP tool

Research Data management Plan RDMP

- template

Case: Falsified data

- Case scenario: falsified data.docx

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Thank you