Ethics of Scientific Writing and Plagiarism

Troy Moon
Vanderbilt University Medical Center

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What Makes Clinical Research Ethical?
Objective of Clinical Research

- To develop generalizable knowledge to improve health and/or increase understanding of human biology.
  - Subjects who participate are the means by which we gather that knowledge

- By placing some persons “at risk” of harm for the good of others, clinical research has the potential for exploitation of human subjects.
In your opinion, what are characteristics of ethical research?
Ethical Considerations of Clinical Research

- Ethical requirements for clinical research aim to minimize the possibility of exploitation by ensuring that research subjects are not merely used but treated with respect.

- For the past 70 years, the main sources of guidance have included for example:
  - Nuremberg Code
  - Declaration of Helsinki
  - Belmont Report
  - Council of International Organizations of Medical Sciences (CIOMS)

- Many were written in response to specific events or to avoid a future scandal
Current Guidelines and Documents?

- **Nuremburg**
  - Response to Nazi atrocities
  - Focused on consent and risk-benefit ratio

- **Declaration of Helsinki**
  - Responses to weaknesses of Nuremburg
  - Focuses on risk-benefit ratio and independent review

- **Belmont Report**
  - Response to US scandals (ie, Tuskegee)
  - Focus on informed consent and vulnerable populations

- **CIOMS**
  - Current international guideline standard which summarizes others
Framework to Address their Limitations


8 Ethical Requirements for Clinical Research

- These 8 requirements provide a systematic framework for determining if research is ethical.

- Meant to guide development, implementation, and review of individual protocols.

- Intended to describe the ethical standards specific for clinical research.

- Assumes the fundamental philosophy of previous guidelines.
8 Ethical Requirements for International Clinical Research

1) Social or Scientific Value
2) Scientific Validity
3) Fair subject selection
4) Favorable risk-benefit ratio
5) Independent review
6) Informed consent
7) Respect for study participants
8) Collaborative Partnerships
1) Social or Scientific Value

- To be ethical, clinical research must be valuable.
Only when society will gain knowledge, which requires the sharing of results, either positive or negative, can exposing human subjects to the risks of clinical research be justified.
2) Scientific Validity

To be ethical, research must be conducted in a methodologically rigorous manner.

CIOMS: “scientifically unsound research on human subjects is unethical in that it may expose subjects to risks or inconvenience for no purpose”
Scientific Validity: Methods

- Must be valid and feasible
- Have a clear objective
- Designed using accepted principles and reliable practices
- Have sufficient power to test the objectives
- Have a strong statistical analysis plan

*Results have little “value” if the protocol is performed in a sloppy inaccurate manner*
3) Fair Subject Selection

- Selection encompasses decisions about who will be included both by:
  - Inclusion and exclusion criteria
  - Strategies for recruiting subjects
Groups should not be excluded from a research opportunity without a good scientific reason or susceptibility to risk that justifies their exclusion.
Fair Subject Selection

- Efficiency cannot override fairness in recruiting subjects
- As much as possible; those who bear the risks and burdens of research should be in the position to enjoy its benefits.
- Those who may benefit, should share in the risks and burdens
4) Favorable Risk-Benefit Ratio

- Research inherently entails uncertainty about risks and benefits.

- Clinical Research can only be justified if 3 conditions are fulfilled:
  - Potential risks are minimized
  - Potential benefits are enhanced
  - Potential benefits are proportionate to, or outweigh the risks
5) Independent Review

- Investigators have inherently multiple and legitimate interests
  - Conducting high quality research
  - Completing the research expeditiously
  - Protecting subjects
  - Gaining funding
  - Advancing careers

- These interests can sometimes be in conflict
Independent Review

- Review of the study protocol by individuals not affiliated with the research helps to minimize these potential conflicts.

- For some research with few or minimal risks the review can be expedited, but for much of clinical research the review should be done by a full committee of individuals with a range of expertise who have authority to approve, amend, or terminate the study.
Independent Review

- Independent review provides social accountability
  - Provides assurance to society that a study is ethically designed and the risk-benefit ratio is favorable.
6) Informed Consent

- The purpose of informed consent is 2-fold:
  - Ensures that individuals control if they are enrolled or not
  - Participation is in-line with the persons values, interests, and preferences
Informed Consent

- Informed consent embodies the need to respect persons and their autonomous decisions.

- Enrollment without informed consent is to use persons inappropriately in ways they may not agree to.
7) Respect for Study Participants

- Ethical requirements do not end once the informed consent is signed.

- Individuals must be treated with respect from the time they are approached for enrollment (even if they refuse to participate) until after their participation ends.
Respect entails 5 different activities

1) Respect for privacy

2) Permitting participants to change their minds

3) Provision of new information gained during course of the study to the participant

4) Welfare of the participant should be monitored throughout the course of the study. If adverse events are experienced then appropriate treatment must be offered.

5) Their must be some mechanism to inform participants of the results of the study
8) Collaborative Partnerships

A collaboration between researchers in a donor country and researchers in a recipient country.

- Minimizes exploitation
- Helps to ensure the study has a lasting impact
- Helps to convince policy makers to allocate scarce resources based on results
6 Components of a Collaborative Partnership

1) Investigators should represent both countries and approvals should come from both donor and recipient country.

2) Shared responsibility for defining the research priorities, design of the study, and dissemination of results. Includes defined plans for sharing of data and specimens.

3) Mutual respect: recognition of the host community’s values, culture and practices.

4) Fair distribution of the tangible rewards of the research (i.e; sharing of intellectual property, appropriate authorship, and appropriate recognition of all partners).
Plagiarism in the Scientific Community: Ethical, Linguistic and Cultural questions...
“Research misconduct is defined as **fabrication**, **falsification**, or **plagiarism** in proposing, performing, or reviewing research, or in reporting research results.”

US Office of Science and Technology Policy (OSTP), Federal Research Misconduct Policy  
[Federal Register: December 6, 2000 (Volume 65, Number 235)]
Plagiarism???

“What did you put down for the definition of plagiarism?”

http://www.cartoonstock.com/directory/p/plagiarism.asp

Sonia M.R.Vasconcelos
Plagiarism

“Appropriation of another person’s ideas, processes, results, or words without giving appropriate credit.”
(US Office of Science and Technology Policy, 2000)

“The unauthorized use or close imitation of the language and thoughts of another author and the representation of them as one's own original work.”
(Random House Unabridged Dictionary, © Random House, Inc. 2006)
But can words and ideas really be stolen?

According to U.S. law, the answer is yes. The expression of original ideas is considered intellectual property, and is protected by copyright laws, just like original inventions. Almost all forms of expression fall under copyright protection as long as they are recorded in some way (such as a book or a computer file).

All of the following are considered plagiarism:

- turning in someone else’s work as your own
- copying words or ideas from someone else without giving credit
- failing to put a quotation in quotation marks
- giving incorrect information about the source of a quotation
- changing words but copying the sentence structure of a source without giving credit
- copying so many words or ideas from a source that it makes up the majority of your work, whether you give credit or not (see our section on “fair use” rules)
3/23/2011

New tool against plagiarism

Plagiarism constitutes a breach of scientific integrity. After discovering plagiarism in several recently submitted proposals, the Swiss National Science Foundation (SNSF) has acquired a plagiarism detection software.

In recent times plagiarism has often been an issue of concern in both literature and education. This trend has been in evidence at the SNSF as well, where plagiarism has been detected in several recently submitted applications. Information technology has introduced the possibility of copying and pasting from other sources, but it also offers means of detecting such offences. For this reason, the SNSF acquired a plagiarism detection software in 2010. The software compares text not only with the internet, but also disposes of a database of articles taken from all major science publications.

Definition of plagiarism

It is difficult to provide an exhaustive and universal definition of plagiarism. However, in research circles it is recognised as an act that contravenes good scientific practice and constitutes a breach of scientific integrity. The SNSF condemns plagiarism and defines it as "the appropriation of someone else’s results or insights as one’s own” (Regulations of the National Research Council on handling scientific misconduct by applicants and grantees). Thus an act of plagiarism constitutes the use of someone else’s ideas or text as published in an article, manuscript or application without clearly mentioning the author and publication to the reader. In this context, applicants are advised to make reference to the code of conduct of their university or the document published by the Swiss Academies of Arts and Sciences “Integrity in scientific research” (available in German and French), published in 2008.

(From: SNSInfo print no 12 / March 2011)
After reading the paper, Aguirre and his colleague, Juan Braga, looked back through published papers by Imam "to find that many of the microphotographs illustrating coralline algae from diverse localities and ages in these papers are microphotos of algae from different other regions and ages published by several other authors”…

For the past 20 years, an Egyptian researcher based in Saudi Arabia has been publishing papers on various topics related to fossil algae using the same plagiarized pictures over and over again, an article in the current issue of Revista Española de Micropaleontología claims.

Julio Aguirre, from the University of Granada, alleges that Mostafa Mansour Imam has "repeatedly been plagiarizing pictures of diverse organisms previously published by other authors" in papers on microfacies, foraminifera, and coralline red algae from Eocene, Miocene, and Pliocene sediments of several areas of Egypt and Libya.

"Imam has been using the same pictures in the different papers that he has published concerning different areas and rocks of different ages,” Aguirre said.

Aguirre was alerted to the pattern while reviewing a paper submitted by Imam to the journal. The manuscript dealt with red algae from the Miocene in Egypt, but
Plagiarism in Cambridge physics lab prompts calls for guidelines

Jim Giles

A string of plagiarized papers remains unaltered in the literature, after researchers and journal editors ignored warning signs of the problem, an investigation by Nature has found.

At least eight papers written between 1997 and 2001 by Yung Park, a materials scientist who worked at the University of Cambridge, UK, and the Korea Advanced Institute of Science and Technology (KAIST) in Daejeon, are plagiarized, according to documents examined by Nature. Park has also published at least two pairs of papers with significant overlap in separate journals.

Four of the plagiarized papers have been removed from online journals, or marked as plagiarisms, following investigations into Park’s publications by his former colleagues in Korea and by researchers.

http://www.nature.com/nature/journal/v427/n6969/full/427003a.html
SPECIAL REPORT

Taking on the cheats

The true extent of plagiarism is unknown, but rising cases of suspect submissions are forcing editors to take action. Jim Giles reports.

The fight against plagiarism is about to take a decisive turn. Academic publishers have told Nature they hope that software designed to catch cheating students could soon be used to unmask academics who plagiarize other researchers’ — or their own — work.

Big publishers such as Elsevier and Blackwell, which between them publish more than 2,500 journals, have been prompted to act by reports that plagiarism is becoming more common. “We’re hearing about it more frequently from editors,” says Bob Campbell, president of Blackwell Publishing in Oxford, UK.

Self-plagiarism, in which authors attempt to pass off already published material as new, is a particular problem. In an increasingly competitive environment where appointments, promotions and grant applications are strongly influenced by publication record, editors are noticing many more cases, says Scott Dineen, director of editorial services at the University of Sheffield, UK.

And although most cases are never discovered, almost all of the editors and publishers contacted by Nature agreed that self-plagiarism is on the rise.
“A recent analysis turned up numerous examples of plagiarism on the arXiv server (see Nature 444, 524–525; 2006). Ginsparg says that it’s not uncommon for scientists with a poor command of English to plagiarize introductions or background paragraphs from earlier work, often adding an appropriate citation.”

(Turkish physicists face accusations of plagiarism, Nature, 449, 8, 2007)
My experience with editing of hundreds of manuscripts has led me to believe that many researchers, at least in Iran, plagiarize because they simply do not know that it is an illegitimate act. Sometimes a non-native English speaking author may insert words or even sentences from a previously-published article simply because s/he is declined to sacrifice quality and accuracy of the work for want of linguistic expertise. (Editorial, *Hepatitis Monthly*, 8, 2008).
Um estudo do Instituto de Estudos Sociais e Económicos de Moçambique (IESE) revela ter encontrado “plágio significativo” em 75% das 150 teses de mestrado e licenciatura analisadas nas cinco principais universidades moçambicanas.

O estudo, intitulado “Plágio em cinco universidades de Moçambique: amplitude, técnicas de detecção e medidas de controlo” teve incidência em teses de fim de curso de estudantes da Universidade Eduardo Mondlane (UEM), Universidade Pedagógica (UP), Instituto Superior de Ciência e Tecnologia de Moçambique (ISCTEM), Universidade São Tomás de Moçambique (USTM) e Universidade Politécnica, tendo concluído que apenas ¼ é que tiveram uma autenticidade imaculada. “O presente estudo examina 48 teses de licenciatura e 102 teses de mestrado de cinco das maiores universidades. Das
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Neonatal conjunctivitis in the New Zealand Midland region

Samuel Newlands, John Dickson, John Pearson, Chris Mansell, Graham Wilson

ABSTRACT

AIMS: To assess the incidence of chlamydial and gonorrhoeal neonatal conjunctivitis (CON and GON), across six district health boards in the greater Midland region of New Zealand.

METHODS: All positive nucleic acid amplification test (NAAT) eye swabs for Chlamydia trachomatis and NAAT and bacterial eye swabs for Neisseria gonorrhoeae in infants under one year of age were retrieved from three laboratories from 2013–2016. Incidence density rates were calculated using births information from Statistics New Zealand. A subgroup analysis of Waikato and Tairāwhiti cases were further analysed.

RESULTS: Calculated rates for the Greater Midland region are CON, 145.9 per 100,000 births/year and GON, 3.79 per 100,000 births/year. For Tairāwhiti and Waikato, the incidence of CON is 2.5 times greater in Māori than non-Māori (95% CI 1.3–5.1, P<0.01). There was no significant difference in mean NZDep13 for Māori vs non-Māori. Mean maternal age at birth was 20.

CONCLUSIONS: Greater Midland region rates of CON and GON are higher compared to other international reported rates. For Tairāwhiti and Waikato, rates of CON are significantly higher in Māori than non-Māori, although there is no difference in mean NZDep13 scores between Māori and non-Māori. CON appears to be a condition of babies of young mothers with higher deprivation.

Neonatal conjunctivitis (NC) or ophthalmia neonatorum refers to any conjunctivitis occurring in the first 28 days of life.\(^1\) NC is the most common infection of any kind in neonates, occurring in up to 10% of live births.\(^2\) NC is identified as a specific entity distinct from conjunctivitis in older infants because it is often the result of infection transmitted from the mother to the infant during delivery.\(^3\)

... is resistant to usual topical treatments and may be associated with pneumonitis.\(^3\) In mothers who have proven STIs, the transmission to infants developing conjunctivitis is estimated to be around 15% for chlamydia\(^3\) and 30–50% for gonorhea.\(^6\) But the rate of transmission is unknown for those who have been treated.

Since 2010, two district health boards (DHBs), Lakes and Tairāwhiti have consis...
Chapter 1. Introduction

Condition Background

Condition Definition

Ophthalmia neonatorum is conjunctivitis in infants during the first month of life. Ophthalmia neonatorum can be caused by infection with *Neisseria gonorrhoeae* (*N. gonorrhoeae*), *Chlamydia trachomatis* (*C. trachomatis*), or other bacteria or viruses.\(^1\) This report specifically evaluates ocular prophylaxis for gonococcal ophthalmia neonatorum (GON), which occurs when gonococcal infection is transmitted to newborns during delivery by mothers infected with *N. gonorrhoeae*.\(^2\) Ophthalmia neonatorum is caused far less often by *N. gonorrhoeae* than by other bacteria or viruses and is rare in the United States; however, prevention is important because GON is associated with a high risk of corneal perforation and blindness which can occur within 24 hours.\(^3\)
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*Klebsiella pneumonia*: An unusual cause of ophthalmia neonatorum in a healthy newborn

Jaya B. Kumar, MD, Evan Silverstein, MD, and David K. Wallace, MD, MPH

Ophthalmia neonatorum is one of the most common infections during the neonatal period. *Chlamydia trachomatis* and *Neisseria gonorrhoea* must be ruled out, given their high virulence and systemic complications. We describe a case of ophthalmia neonatorum from *Klebsiella pneumonia*. Gram-negative organisms have been reported in hospital-acquired conjunctivitis (HAC), but we are unaware of any published reports of *K. pneumonia* conjunctivitis in an otherwise healthy full-term infant born in the United States who has received prophylaxis. It is important to promptly identify and treat *Klebsiella* conjunctivitis because it can lead to severe complications.
Ophthalmia Neonatorum Caused by Multidrug-Resistant Neisseria gonorrhoeae

Yariv Fruchtman MD², David Greenberg MD¹, Eilon Shany MD³, Rimma Melamed MD¹,², Nehama Peled MSc⁴ and Matityahu Lifshitz MD²

¹Pediatric Infectious Disease Unit, Departments of Pediatrics D² and ³Neonatology, and ⁴Clinical Microbiology Laboratory, Soroka University Medical Center and Faculty of Health Sciences, Ben-Gurion University of the Negev, Beer Sheva, Israel

For Editorial see page 164

Ophthalmia neonatorum is a frequent form of infection in the first month of life and represents a threat to vision [1]. The most common infectious agents are: Chlamydia trachomatis, Neisseria gonorrhoeae and herpes simplex virus [1]. The infection is usually restricted to the eye but can also spread systemically and cause arthritis, septicemia and meningitis [1].

N. gonorrhoeae was a more common cause of conjunctivitis in the past, but due to the widespread use of 1% silver nitrate following the observations of Credé in 1881, its prevalence as a causative agent of ophthalmia neonatorum has decreased in the industrial world from 10% to 0.3% [2]. As a result of extensive antenatal and postnatal care in industrialized countries and screening for sexually transmitted diseases, prophylaxis has been largely abandoned, including at our medical center.
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Thank You

Questions?