Comparison of instructions to authors and reporting of ethics components in selected African Biomedical Journals: 2008 and 2017

by

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Declaration

I declare that I carried out this thesis. This work has not been submitted for a previous degree at any other tertiary institution and is not being currently considered for any other degree at any other university.

I declare that all citations, references and borrowed ideas have been acknowledged.

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Date: 2022

I hereby declare that I supervised the student who conducted the study contained herein and confirm that the student has my unreserved permission to submit it for assessment.

Prof. Douglas R. Wassenaar

Supervisor

Date: 2022

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Abstract

Journal editors are expected to provide instructions to prospective authors to describe human participants' protection measures before, during and after data collection for any original research. However, little is known about authors' adherence to editors' instructions in African biomedical or health journals. Therefore, the study was designed to review and investigate changes in editors' instructions to authors and authors' reporting of research ethics information, based on the recommendations of the International Committee of Medical Journal Editors (2018) and Committee on Publication Ethics (2018) in selected African biomedical journals between the years 2008 and 2017.

A review of twelve selected African biomedical journal websites and online articles were reviewed in Eastern, Southern, and Western African [ESWA] countries. Data were collected using a pretested schema and checklist from the selected journal websites, and online articles published in 2008 and 2017 were analysed using descriptive and inferential statistics.

Findings showed that more than half of the journals (58.3%) mentioned elements of ICMJE and COPE guidelines in their instruction to authors. Half of the editors requested prospective authors to disclose ethics approval issues in their manuscripts. One-third of the journals (33.3%) requested information from authors on informed consent. Only 16.7% of the journals assessed requested information on protecting research participants from prospective authors. There was a significant increase in the instructions to authors on the request for information on the protection of research participants between 2008 and 2017.

Instructions to authors in the selected journals showed requests for information on ethics approval, informed consent, and human participant protection as requirements for publishing in 2008. There was an improvement in these requirements in 2017, and more authors complied with these requirements.

Contents

CHAPTER ONE

INTRODUCTION

1.1 Background

Research is “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalisable knowledge” (US Department of Health and Human Services, 2016 p. 131). This includes epidemiological studies, biomedical research, clinical trials, and health services research (Baily, 2008), as well as studies of behavioural, social, and economic determinants of health (Institute of Medicine [US] Committee on Health Research and the Privacy of Health Information, 2009). Health research may collect biological samples from participants, respondents, or patients, analysed or used for diagnostic, treatment, or research purposes (Institute of Medicine [US] Committee on Health Research and the Privacy of Health Information, 2009).

The goals of biomedical and health research are targeted toward better health and patient care through innovative research, translating findings into practice, and informing policy decisions (European Commission Scientific Panel for Health, 2016; Brownson, Kreuter, Arrington & True, 2006). Research holds out the potential risks to the safety and well-being of participants, respondents, or patients involved in such research despite its potential benefits. Although no research is risk-free, there are limits to the risks to which research participants or respondents could be exposed. This is through the oversight of Research Ethics Committees (RECs). Providing oversight functions of research activities from inception through implementation and evaluation as approved by RECs is critical to ensuring that participants’ safety is at the centre of the research (Coleman & Bouësseau, 2008).

Due to abuse and exploitation of research participants in the past, ethics codes and guidelines have been developed, which subsequently led to the formation of Ethics Review Committees (ERCs), Research Ethics Committees (RECs) or Institutional Review Boards (IRBs) as the case may be (Navaneetha, 2011; Perkins, Choi, & Kimball, 2007; Schroter, Plowman, Hutchings, & Gonzalez, 2006).

According to Belhekar, Bhalerao and Munshi (2014), “ethical considerations have changed from no rules to very strict regulations” (p. 129) in biomedical research. Some examples of the regulations and guidelines are the Nuremberg Code (Nuremberg Code, 1949), The Belmont Report (1978), Declaration of Helsinki (DoH) (2013) [principles B-15, B-30], the Council of International Organizations for Medical Sciences [CIOMS] (CIOMS, 2016) and Title 45, Part 46 of the Code of the Federal Regulations (45 CFR 46) (US Department of Health and Human Services, 2016). These regulations and guidelines address ethics approval of research protocols, consent or assent, voluntariness, social value, scientific validity, human participants’ protection measures and community engagement. Independent ethics review of research protocols as well as obtaining the informed consent of human participants are some of the safeguards intended to protect individuals taking part in research (Emanuel, Wendler, Killen, & Grady, 2004; Emanuel, Wendler, & Grady 2000; Health Research Authority, 2018; Sumathipala, Siribaddana, Hewege, Lekamwattage, Athukorale, Siriwardhana, Murray, & Prince, 2008).

RECs, by design, have the responsibility to promote the dignity, rights and well-being of participants and support ethical research that may benefit participants and society (Health Research Authority, 2018). Human participants’ protection measures and how research should be conducted and reported are spelt out in documents and guidelines (Belhekar et al., 2014; Sumathipala et al., 2008; Myles & Tan, 2003; Yank & Rennie, 2002) mentioned above.

Progress in health or biomedical research depends not only on the generation of information through research but also on its dissemination through various means (Brownson, Kreuter, Arrington & True, 2006; Nass, Levit, & Gostin, 2009). Publishing research findings in a peer-reviewed scholarly journal is one channel for sharing findings with the research community and the general populace, thus contributing to the current body of medical and scientific knowledge. As stated by Ruiz-Canela, Martínez-González, Gómez-Gracia, and Fernández-Crehuet (1999) “publication of the results of biomedical research is not a mere formality in science” (p. 1114). Ruiz-Canela and colleagues noted also that publication of research outcomes “is the culmination of a long process, and careful attention to every step in that process is important” (Ruiz-Canela et al., 1999, p. 1114). Thus, journal editors have a responsibility to ensure that manuscripts submitted to them or articles published

therein meet current ethical standards by spelling out basic requirements in instructions to authors (Bhat, Shah, & Sherighar, 2017; Wu, Howarth, Zhou, Ji, Ou, & Li, 2017).

1.2 Statement of the Problem

To ensure uniformity in the requirements for publishing results of research involving human participants, the International Committee of Medical Journal Editors [ICMJE] (2018) and Committee on Publication Ethics [COPE] (2018) made recommendations for the conduct, reporting, editing, and publication of scholarly work in journals. In these documents, editors are expected to instruct prospective authors to describe human participants' protection measures before, during and after data collection for any original research. These instructions aim to improve openness by ensuring that all research details are made known. Instructions also help fairness, replicability of the methodology, assurance that valid informed consent was obtained where relevant and disclosure of any conflicts of interest (Bhat, Shah, & Sherighar, 2017). Similarly, Navaneetha (2011) pointed out that it is the responsibility of authors to inform readers whether their studies were implemented in accordance with the international ethics guidelines such as the Declaration of Helsinki, ICMJE; World Association of Medical Editors (WAME), and COPE (Navaneetha, 2011).

A review of two journals in India in 2006 found that 29.5% of published articles mentioned obtaining REC's approval, and 46.9% reported that informed consent was obtained (Bavdekar, Gogtay, & Wagh, 2008). Bavdekar and colleagues noted that 34.1% of the published articles neither obtained REC's approval nor informed consent, while only 7.41% reported REC's approval, informed consent or assent (Bavdekar et al., 2008). In a related study, Bavdekar, Gogtay, & Chavan (2009) found that instructions to authors were contained in the journals reviewed; however, 38% did not provide clear instructions to their prospective authors about reporting REC approval, and 56% did not provide instructions concerning reporting of informed consent. Only three journals gave clear instructions on reporting assent. Bhat and colleagues (2017) analysed 74 biomedical journals in India for the type of information provided in the "instructions to authors" section and adherence to the ICJME recommendations. Among the 71 journals with an "instructions to authors" section, 53 adhered to ICMJE recommendations. In a scoping review of some published articles, Makhoul, Chehab, Shaito and Sibai (2018) reported that not all articles reviewed followed ethical

practices. Makhoul and colleagues (2018) observed that 48.2% obtained institutional approval, 54.9% obtained access to the community/research site, and 53.7% obtained informed consent/assent from the research participants.

However, little is known about the editors' instructions or authors' adherence to editors' instructions in Africa's selected biomedical or health journals. Thus, this study was designed to investigate the changes in editors' instructions to authors in selected biomedical journals in Africa between 2008 and 2017. Moreover, the study will assess authors' adherence to instructions in these journals.

1.3 Justification

In line with available reporting guidelines for research and publication, assessment of editors' instructions and authors' level of adherence to instructions is important. In addition, this study was designed to assess changes that may have occurred in the instructions for and reporting of research ethics information in 12 selected biomedical journals in Africa in the years 2008 and 2017. It will also help determine the proportion of selected articles in these journals that gave appropriate authors' instructions and reported ethics approval, informed consent/assent, and other human participants protection measures in 2008 and 2017. The study could help show whether there is any difference in frequency of human participants' protection information disclosed by authors in papers published in the selected African biomedical journals in 2008 and 2017.

1.4 Broad Objective

The broad objective of this study was to review instructions to authors in 12 selected African biomedical journals and investigate whether changes have occurred in editors' instructions to authors and authors' reporting of research ethics information in selected African biomedical journals between the year 2008 and the year 2017 based on the recommendations and ethical standards of ICMJE (2018) and COPE (2018).

1. The research questions for this study were:

1.6 Research Questions

1. Were authors required to mention ethics approval in their manuscripts in 2008 and 2017?
2. Were authors required to mention whether informed consent was obtained from participants in 2008 and 2017?
3. Is there any difference in human participants' protection information disclosed by authors in papers published in the selected African biomedical journals in 2008 and 2017?

1.7 Hypotheses

The following hypotheses were tested for significance:

$H_1$1: There will be a significant difference in the human participants' protection information in the instructions to authors between selected African biomedical journals established in the years 2000 and below and those established in the years 2001 and above

$H_1$2: There will be a significant difference in mentioning ethics approval by authors of published articles in selected African biomedical journals in the year 2008 and the year 2017

$H_1$3: There will be a significant difference in mentioning informed consent requirements by authors of published articles in selected African biomedical journals in the year 2008 and the year 2017

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

In the academic world, after the completion of research and analysis of data, the researcher should translate the research questions, hypotheses, methods or design, results or findings, and conclusions into an understandable format with a high level of integrity and honesty (Wong, & Hui, 2015). This translation of research ideas and results is done, in part, through publication in peer-reviewed journals and feedback to participants and participating communities where possible.

Publication of research findings in journals is not just a means of disseminating scientific knowledge, findings and information to a broader society. It also serves as a basis for growth in scientific knowledge in the field, creating a cascade in which new information is synthesised and passed on to the world of readers (Sharma, & Verma, 2018). Also, other information might be discredited or overtaken by newer strong empirical findings.

For any research to be considered ethical, such research must observe, adhere to and respect all the ethical principles guiding the conduct of research, especially research involving humans. Likewise, for manuscripts to be considered worthy of publication, such manuscripts must adhere to the ethical principles guiding the publication of scientific research, in particular, biomedical research (COPE, 2018; ICMJE, 2018). Deviation from these standards of practice is one variant of the general rubric of research misconduct (World Conference on Research Integrity, 2010). This means that authors submitting manuscripts to biomedical journals need to state clearly whether the research in their manuscripts follows the ethical standards of the protocol as approved by the necessary REC, in line with existing international guidelines (COPE, 2018; ICMJE, 2018).

2.2 Ethics of Publication

The ethics of biomedical or scientific publication comprise a set of guidelines or rules that articulate authors' norms. In recent years increasing attention has been focused on this because of reported cases of research misconduct due to mounting pressure exerted on academics to publish as one of the major criteria for career progression (National Academy of Sciences, 2017; Wager, 2012a; World Conference on Research Integrity, 2010; Wright, 2016)

Science advances daily and is regularly updated through research findings and evidence-based publications (Mandal, Ponnambath, & Parija, 2016). Medical, biomedical, and other scientific journals are avenues through which researchers communicate or share new knowledge or findings with the medical, scientific world and the general populace (Avanzas, Bayes-Genis, Pérez de Isla, Sanchis, & Heras, 2011). Research findings add to existing knowledge, inform appropriate interventions and foster further research (Mandal et al., 2016). These academic publications are recognised and used as metrics or means of evaluating “scholarly performance leading to academic achievement, promotion of designation status” (Aitkenhead, 2013; Chattopadhyay, 2014; Mandal, Ponnambath, & Parija, 2016 p. 100)

However, using publication alone as a measure of academic excellence could be misleading because many journals are of a low standard. Articles published therein do not go through peer-review rigour (Chattopadhyay, 2014) – more recently known as ‘predatory publishing’. Kurt described predatory journals as dishonest, ill repute, with questionable integrity, and “low academic standards” (Kurt, 2018 p.1). Angadi & Kaur (2020) and Wright (2016) noted that high pressure to publish for promotion purposes and the ‘publish or perish’ syndrome among scientists, philosophers and academics, although not new, are some enabling factors for publishing in predatory journals. Authors gave reasons for submitting manuscripts to predatory journals that were sub-categorised into four themes by Kurt (2008), namely “social identity threat, pressure to publish, lack of awareness and lack of research proficiency” (p.1). Therefore, the predatory journals ' tactics entice early-career faculty members, scientists and doctoral students desperate to publish rapidly to increase their publications. The subtle nature of the operation of predatory publishers makes it easy to attract and exploit unsuspecting young authors and researchers. These journals aggressively send unsolicited adverts on emails, promising short publication turnaround time and

charging publication fees. These publications lack peer-review evidence, taking advantage of an open-access model (Gogtay, & Bavdekar, 2019).

Thus, this kind of assessment potentially increases the pressure on researchers to manipulate research outcomes, leading to fake and misleading research content (Mandal et al., 2016) or publishing in low-impact journals. Several ethical problems have been identified in publishing medical or biomedical research because of pressure to publish for career advancement or reward (Wager, 2012a; Wright, 2016).

Therefore, ethical standards have been established to improve quality publications, build trust in the scientific enterprise, and to ensure that authors get appropriate credit for their ideas (BioMed Central, 2019). These standards guard against data fabrication and falsification, plagiarism, multiple submissions, redundant publications and improper author contribution or attribution (BioMed Central, 2019). They also seek to ensure that internationally accepted ethical standards have been applied to human (and animal) research subjects/participants.

2.3 A review of Selected International Guidelines on Editing, Implementing, Reporting, and Editing Research

2.3.1 Committee on Publication Ethics (COPE)

Editors of various journals came across different cases of research misconduct at various stages - from manuscript development to manuscript submission for publication to their scholarly journals. Their concern about research misconduct led to the formation of COPE. The concerned editors had their first meeting in April 1997, where they shared their experiences regarding research misconduct observed from various manuscripts submitted to them for publication. During this first meeting, these editors had a first-hand understanding of the magnitude of the problem, and the need to find a solution to this problem became more evident. Mike Farthing, the initiator of the first meeting of concerned editors, that later metamorphosed into COPE, stated that COPE was an experiment (COPE, 2018). After broad consultation and workshops at its annual meeting in 1999, the second report featured COPE's Guidelines on Good Publication Practice to identify and investigate cases bordering on scientific misconduct. The guidelines have since witnessed some transformation from "The Code of Conduct" launched in 2000, which spelt out minimum standards for editors

publishing scholarly papers, to “Core Practices” published in 2017. According to COPE, the “Core Practices” applies to all editors, journals, and publishing houses but should not replace other existing international and national guidelines or codes (and should be used alongside such documents). As of 2019, COPE membership exceeds 12,500 from 103 countries (COPE, 2021).

2.3.2 International Committee of Medical Journal Editors (ICMJE)

The ICMJE, formerly known as the Vancouver Group, was created by editors of various biomedical journals in 1978 (ICMJE, 2018). They proposed certain minimum standards/recommendations centred on unifying journals for optimal manuscript format, preparation, and ethical practices in publishing (ICMJE, 2018). Their original recommendations have been expanded in content and scope with a 2017 revision (Enhancing the QUAlity and Transparency Of health Research [EQUATOR] - Network, 2018). The objective of their document is to assist authors, editors, and others in reviewing and publishing to create clear, unbiased articles that can be reproduced (EQUATOR - Network, 2018). According to the ICJME, the recommendations were also developed to “assist authors, editors, and others involved in peer review and biomedical publishing create and distribute accurate, clear, reproducible, unbiased medical journal articles” (ICJME, 2018, p. 1). With the recent revision, the additional statements expanded on the initial recommendations. They focused more on the editorial policy and ethics, which should guide biomedical publications and dealt with several problematic recommendations. The provisions in these recommendations have been the reference point for most journals, especially medical and biomedical journals. This implies that ICJME’s recommendations are unifying requirements for journal editors to consider for editorial policy and ethics for publishing in medical and biomedical journals.

2.3.3 The World Medical Association Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects (WMA)

The World Medical Association (WMA) has issued a code that all physicians follow and adhere to general guiding principles. Despite the novel idea of the Declaration of Geneva, the tone or vague language used in the initial document did not allow for precise interpretations in medical and biomedical ethics (WMA, 2013). To distinguish

between practice and research as a physician, the association reconsidered the issue in 1953. The product of this long year of debate was a document titled “Ethical Principles for Medical Research Involving Human Subjects”, approved at its general meeting in Helsinki in 1964, known as the ‘Declaration of Helsinki’ until now. This Declaration has been amended several times (1979, 1983, 1989, 1996, 2000, 2008 and now 2013) and now has 11 Sections (A-K) and 37 Paragraphs (WMA, 2013).

Two paragraphs in section J are of special interest, which focus on ‘Research Registration and Publication and Dissemination of Results’ (WMA, 2013). The two paragraphs clarify the requirements for publication. According to paragraph 35, every research study involving human participants must be duly registered in a database accessible to all before the recruitment of participants. Also, in paragraph 36, it is clearly stated that researchers, sponsors, authors, editors and publishers have ethical obligations concerning the dissemination and publication of research findings. Thus, researchers have the duty to make public the findings from their research, whether positive or negative and observe guidelines regarding publications, failing which such reports or manuscripts should not be accepted for publication.

2.3.4 Summary of the Guidelines

To help writers, editors, and reviewers, organisations involved in publication ethics recommend and provide guidelines. The goal is to produce and publish research papers that are accurate, understandable, reproducible, and objective.

To inform and assist editors and publishers, COPE aspires to provide thought leadership on publication ethics and useful resources (Smith, 2022). The guidelines covered these issues: study design and ethical approval, data analysis, authorship, conflicts of interest, peer review, redundant publication, plagiarism, responsibilities of editors, media relations, advertising, and how to handle misconduct (Wager, 2012b). These recommendations, however, are meant to be advisory rather than prescriptive and change over time.

ICMJE created guidelines for authors who want to submit their manuscripts to journals that are ICMJE members. These recommendations outline the obligations of authors, contributors, reviewers, and editors. Preparing a manuscript, submitting it, and dealing with editorial matters associated with publication in medical journals are also covered

and drafted. ICMJE created uniform guidelines for manuscript submission to biomedical journals, which are now followed by most journals (ICMJE, 2022). The Declaration of Helsinki is a statement of ethical standards for medical research involving human beings were created by the World Medical Association (WMA). The emphasis is on the fact that medical research involving human subjects must adhere to generally accepted scientific principles, based on a thorough knowledge of the scientific literature, other pertinent sources of information, adequate laboratory and, when necessary, animal experimentation, and be supported by adequate data (WMA, 2018).

2.4 Roles and Responsibilities of Editors

Because of some cases of unethical practices and misconduct observed in manuscripts submitted for publication, publishers and editors should be concerned about publication ethics (Singhal & Kalra, 2021). Beyond the science of manuscripts submitted, journal editors have a duty to pay particular attention to allegations of misconduct and ethical issues in manuscripts submitted or published in their journals (Wager, 2012a; Wright, 2016).

The main responsibilities of journal editors, especially of scientific journals, are as stated below: to provide information to prospective authors who submit manuscripts as part of the content of their journals, to source and assign competent and ethical peer reviewers who comment on the suitability of manuscripts for publication, and to update the journal's readers and the scientific community and the public in general (Editorial Policy Committee, Council of Science Editors, 2018). Editors encounter various problems while performing their duties, seen as acts of omission or commission. The most common ones are poorly managed peer review, slow review of manuscripts, financial gains, dealing with alleged scientific misconduct, and confidentiality, among others.

Editors and reviewers are expected to look for ethical issues when prospective authors submit manuscripts to their journals. These include falsification, fabrication and duplication of data, gift and ghost authorship, statements on obtaining approval from ethics review committees and informed consent from participants or respondents, plagiarism, conflicts of interest, non-disclosure, and 'salami' slicing (Polonioli, 2017; Avanzas et al., 2011). Salami slicing is splitting data generated from the same

research or study into multiple or smaller publishable units or slices (Karlsson, & Beaufils, 2013; Menon, & Muraleedharan, 2016). Menon & Muraleedharan (2016) noted that there are circumstances when salami slicing can be justified. However, they pointed out that such justification is risky from the academic viewpoint; logical conclusions that could have been made if complete data were reported will be missed, which impedes scientific advancement. Authors' desire or external pressure to have many publications for academic career progression usually drive this practice (Durani, 2006; Karlsson, & Beaufils, 2013; Samp, Schumock, & Pickard, 2012; Spielmans, Biehn, & Sawrey, 2010).

With the availability of various international guidelines on publication ethics, editors of biomedical journals are well-positioned to collectively champion sound authorship practices and raise, where necessary, publication practice standards through implementing these consensus guidelines on publication ethics. This can partly be achieved by stating clearly in the authors' instructions how their journals operate and what standards and practices are required.

According to the Editorial Policy Committee of the Council of Science Editors (2018), it is the responsibility of the journal editor to provide prospective authors with guidelines for preparing and submitting manuscripts and a clear statement of the journal's policies on the criteria for authorship. Examples of editorial standards that journal editors may require of prospective authors include information on sources of research funding (which is to be included in the acknowledgement section of the manuscript). Others include authors' statements in the manuscripts about human participants' protection information, where applicable, e.g. that a relevant REC approved the research protocol for research that involves human participants (Uddin, 2018). Others include a statement that the study was conducted with the understanding and appropriate informed consent or assent of each participant or respondent (Uddin, 2018) and the list of contributors who meet the journal's criteria for authorship as authors (Tarkang, Kweku, & Zotor, 2017).

Uddin (2018) also noted that editors are in the best position to decide whether to reject manuscripts lacking regarding the above. It was stressed further that if there are manuscripts submitted from countries with no REC, and the protocols did not go through equivalent review and approval, editors are at liberty to judge whether such manuscripts are publishable, based on their experience. If editors eventually decide

to permit publication under these conditions, the manuscripts should be supported by a statement explaining their circumstances (Uddin, 2018).

2.5 Instruction to Authors - Requirements

An author is an individual who has made sufficient intellectual contributions to the conception or development of research. He or she must have contributed to data collection, analysis, and interpretation of data. Such individuals must be actively involved in the drafting, revising and approving of the final draft manuscript to be published. Also, he or she must have agreed to take responsibility for what is published to ensure that queries relating to the correctness or integrity of any part of the manuscript are aptly examined and resolved (ICMJE, 2018; Council of Science Editors, 2019). In the biomedical research domain, many journals have adopted this definition. The committee defines authorship by the following four criteria:

1. substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data
2. drafting the article or revising it critically for important intellectual content
3. final approval of the version to be published and
4. agreement to be accountable for all aspects of the work to ensure that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

According to ICJME (2018), all individuals listed as authors are expected to meet all four conditions for authorship. If anyone does not meet the four conditions, their contribution should be acknowledged in the manuscript.

In line with international best practices on the publication of scholarly work, instructions to the author should be provided by journal editors, as mentioned above. These instructions highlight the step-by-step activities to be followed in preparing manuscripts. These instructions aim to foster transparency and encourage detailed information on the implementation of the research, methodology and disclosure of ethical issues (Bhat, Shah, & Sherighar, 2017).

For uniformity and promotion of this aim, the ICMJE published recommendations for the conduct, reporting, editing, and publication of scholarly work submitted to biomedical journals (ICMJE, 2018). These recommendations are set to regulate manuscript format and minimise the likelihood of scientific misconduct and unethical practices. They have been reviewed with the recent version released in December 2018 (Bhat et al., 2017). As noted by Cornelius, when instructions to authors are adhered to by prospective authors, they tend to improve the quality of manuscripts and enhance adherence to international publication standards (Cornelius, 2012). So, authors are encouraged to utilise the ICMJE recommendations and individual journals' instructions to authors (Bhat et al., 2017).

2.6 Roles and Responsibilities of Authors

Apart from the recognition or credit bestowed on an author, publishing may also have academic, social, and financial implications (ICMJE, 2018). Therefore, authors or contributors to any published work or article should take responsibility and accountability for such works or articles. The ICMJE (2018) guidelines recommended that anyone who contributed substantially to an article should be recognised and given credit as an author. Nevertheless, ICMJE (2018) stressed further that the person listed as an author must understand his or her role in being held responsible and accountable for the published article. As pointed out on the PLOS Medicine journal website (PLOS Medicine, 2019), all authors listed in the submitted manuscript should take public responsibility for such content.

Furthermore, any published article is stored permanently in the journal archives and can be accessed and used for different purposes (Simera & Altman, 2009). While some users or readers of articles might be comfortable with a superficial reading of article conclusions and findings, more scholarly readers will meticulously read through them and apply them to their clinical or scientific practices. Since readers use these articles for different purposes, authors must adequately report research methodologies and findings to meet their needs. When authors adhere to and follow these reporting guidelines, quality articles will be published which will ideally withstand scientific scrutiny (Simera & Altman, 2009).

2.7 Reporting Standards

Research documentation and reporting of research findings in primary research is a major concern in biomedical literature (Dickersin, & Chalmers, 2011; Glasziou, Altman, Bossuyt, Boutron, Clarke, Julious, Michie, Moher, & Wager, 2014; Levine, Adachi, & Thabane, 2017; Li, Mbuagbaw, Samaan, Jin, Nwosu, Levine, Adachi, & Thabane, 2017). The EQUATOR network anchored the development of reporting guidelines and supported disseminating such guidelines (EQUATOR Network, 2014).

A reporting guideline is a simple and structured tool developed for health researchers and useful while writing manuscripts. It provides researchers and authors with the necessary information to make a manuscript understandable, replicable, and ideally used by physicians to make clinical decisions and can be included in a systematic review (EQUATOR Network, 2019). These guidelines include the Animal Research: Reporting In Vivo Experiments (ARRIVE) guidelines for animal studies, Consolidated Standards of Reporting Trials (CONSORT) guidelines for clinical trials, Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines for systematic reviews, Standards for Reporting Diagnostic accuracy studies (STARD) guidelines for diagnostic or prognostic studies and Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines for observational studies (EQUATOR Network, 2014). There is evidence in the literature on the usefulness of reporting guidelines which led to significant improvement in the transparency and completeness of publications (Plint et al., 2006; Simera & Altman, 2009; Smidt et al., 2006)

2.8 Human Participants' Protection Information Provided by Prospective Authors

Research, whether clinical or biomedical, which involves human participants or subjects, is critical for the advancement of human health and welfare (Grady, 2015; Munung, Che, Ouwe-Missi-Oukem-Boyer & Tangwa, 2011; Sumathipala, Siribaddana, Hewege, Lekamwattage, Athukorale, Siriwardhana, Murray & Prince, 2008). Therefore, such research must follow the guidelines, codes, rules and regulations designed to protect human subjects or participants and ensure that such research is conducted ethically (Grady, 2015; Munung et al., 2011). All international

guidelines, codes, rules and regulations on the ethical conduct of research focus their attention on the protection of human subjects or human participants in research.

These documents stipulate that research protocols or proposals must be submitted to an ERC, REC, or IRB for review and approval before the commencement of such studies. They are expected to provide an oversight function during the study. This ensures that human participants' protection measures are adequate to protect potential participants. These guidelines further recommend that prospective research participants be provided with appropriate information regarding the study that will be adequately understood and give their consent to participate in the research.

Similarly, publishers and journal editors are expected to comply with the recommendations on protecting human participants in research. Paragraph 36 of the Declaration of Helsinki (2013) recommendeds that research manuscripts or reports failing to comply with the accepted guidelines for ethical reporting should not be accepted for publication (https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects; Munung et al., 2011). According to ICMJE (2018), prospective authors must state in their manuscripts that their research was conducted in line with the national or institutional ethical standards (www.icmje.org). Unfortunately, failure to report these ethical procedures in scientific publications continues to occur (Schroter et al., 2006), and other studies have shown that investigators are not paying sufficient attention to reporting these ethical procedures (Abdur Rab et al., 2008; Chaturvedi & Somashekar, 2009; Sumathipala et al., 2008). Whenever authors fail to report obtaining ethics approval from appropriate RECs and obtaining informed consent from participants or respondents, it may suggest that they consider these processes insignificant or hindrances to their study (Ruiz-Canela et al., 1999).

2.9 General objectives

Based on the above overview, the general objectives of this study are to

1. Determine whether authors of 12 selected African biomedical journals were required by editors to mention ethics approval in their manuscripts in 2008 and 2017

2. Determine whether authors of 12 selected African biomedical journals were required by editors to mention whether informed consent was obtained from participants in 2008 and 2017
3. Identify the difference in human participants' protection information disclosed by authors of 12 selected African biomedical journals in papers published in these journals in the years 2008 and 2017

CHAPTER THREE

METHODOLOGY

3.1 Study Design

The study comprised an online review and a cross-sectional survey of selected African biomedical journals' websites.

3.2 Study Area

The study involved a review of selected biomedical journals and online articles on websites in Africa. These journals were selected from the African Journals OnLine (AJOL). According to the information on its website, "AJOL is a Non-Profit Organisation that (since 1998) works to increase global & continental online access, awareness, quality & use of African-published, peer-reviewed research" (AJOL, 2022). By 'journal', the researcher refers to non-predatory journals. Although there is no agreed-upon definition of what the term "predatory" means, scholars, researchers, journalists and data experts came up with some guiding definitions. "Predatory" journals and publishers are "entities that prioritise self-interest at the expense of scholarship and are characterised by false or misleading information, deviation from best editorial and publication practices, a lack of transparency, and/or the use of aggressive and indiscriminate solicitation practices" (Grudniewicz et al., 2019 p 211). Another perspective from Shamseer et al. is that predatory journals "actively solicit manuscripts and charge publication fees without providing robust peer review and editorial services" (Shamseer et al., 2017 p 1).

3.3 Sources of Data

The sources of data for the study were selected websites of 12 biomedical journals in Africa, that is, a minimum of 12 selected biomedical journal websites in Africa (Eastern, Southern African and Western African [ESWA] countries) and selected published articles at a 2-timepoints of years 2008 and 2017.

The study focused on the "instructions to authors" sections. It investigated the reporting of human participants' protection measures in the selected published

biomedical research within this same period and whether changes occurred in the instructions to authors of selected biomedical journals, specifically between 2008 and 2017. This period was chosen because requirements for reporting human participants' protection measures from prospective authors have been given more attention (International Committee of Medical Journal Editors, 2017). In addition, the electronic version of selected published articles on the selected biomedical journal websites was assessed, reviewed and analysed. Collected information was documented, and changes that occurred between the years 2008 and 2017 on the websites and published articles were assessed (based on the recommendations of ICMJE and COPE). A schema was developed, and a checklist was employed to harness this information (Appendices I & II).

3.4 Sampling Techniques and Selection Process

A purposive sampling technique was adopted to select a minimum of 12 African biomedical journal websites (four journals from each region [ESWA] countries). They were chosen because most of the articles in these journals are published in English, unlike those in journals in the North African published mainly in Arabic. However, additional suitable journals were considered for inclusion if they had a searchable online presence. After searching for possible online access to other journal websites, no other suitable African biomedical journals were found. The 12 biomedical journals represent the population of relevant African biomedical journals.

3.5 Inclusion and Exclusion Criteria

Inclusion criteria

The inclusion criteria for the selected journals were as follows:

1. Journals indexed in African Journals OnLine (AJOL)
2. Biomedical journals based in Africa
3. Journal online presence on or before 2008 to date
4. Full open access to articles
5. Journal website and articles in English

6. Published research conducted in Low and Middle-Income Countries

Exclusion criteria

The exclusion criteria for the selection of journals for this study were as follows:

1. Journals with no websites by the year 2008
2. Journals in Physical and Biological Sciences and Animal Research
3. Journals written in French or Arabic

3.5.1 Procedure for the selection of articles

The researcher visited the selected journals' websites, went through the journals' archives, and randomly selected articles within the specified years. If a chosen article had no full open access, another was selected to replace it. The original research was targeted for review as they were expected to observe all ethical considerations for the studies.

3.6 Instrument for Data Collection

An observation checklist and a schema were developed and used for data collection for the study. Tables were developed to capture information based on the literature reviewed and guided the documentation of variables assessed in all selected journal websites and articles.

3.7 Validity and reliability of the instrument for data collection

Validity of the instrument

The instrument's validity was ensured through an extensive literature review to identify necessary variables in the final instrument for data collection. The draft instrument was given to the researcher's supervisor for review. Other ethicists were also consulted to help review the instrument regarding the issues relating to editors' instructions to authors and authors' reporting of research ethics information.

Reliability of the instrument

The draft instrument was pre-tested using two similar biomedical journals, which were not included in the study. Subsequently, the data generated from the pre-test was analysed using descriptive statistics. The data was then subjected to Cronbach's Alpha statistical test for the correlation coefficient. Cronbach's Alpha measures internal consistency: how closely related a set of items are as a group. In this test, a result showing a correlation coefficient greater than 0.50 is reliable. The closer the value of the reliability test to 1, the more reliable the instrument. The correlation coefficient generated for the instrument was 0.8 suggesting good reliability.

3.8 Data Collection Process

Twelve African biomedical journal websites (four journals from each region mentioned above – East, Southern and West Africa [ESWA] countries) were selected. All biomedical journals were reviewed for eligibility regarding the year established and whether they are still active in production. Archives of the journal websites were accessed for review. Many biomedical journals were excluded for not meeting the review criteria, especially fully open access. The following information was reviewed using the schema and checklist: the journals, year of establishment, last active year, location or country, instruction to author, articles and type of study, human participants protection related information (Appendices I & II).

3.9 Data Analysis

As part of the data analysis plan, a data summary proforma was used for documentation (Appendix III). Statistical analysis was performed using the IBM/SPSS (version 23). Descriptive and inferential statistical analyses such as the Chi-square test were employed for data analyses. Guided by the research questions and hypotheses, these data were analysed, and journal data of 2008 and 2017 were compared. The data were analysed and presented in descriptive (frequency tables, charts) and inferential statistics (t-Test and Chi-square). Data on human participants' protection information in the instructions to authors were generated and scored. The

two categories were cross-tabulated and analysed using the Chi-square test. The decision rule is that if $p \leq 0.05$, the null hypothesis will be rejected in favour of the alternate hypothesis. Three hypotheses were tested; however, the first hypothesis measured the difference in the human participants' protection information in the instructions to authors between selected journals with a historical perspective comparing those established in the years 2000 and below with years 2001 above.

3.10 Ethical Considerations

Before the commencement of this study, an application for exemption from ethics review was submitted to the Biomedical Research Ethics Committee, University of KwaZulu-Natal, South Africa. The exemption was requested because all the data (journals and journal articles) were already in the public domain. Ethics review exemption was granted (BREC REF: EXM698/18) (Appendix IV).

CHAPTER FOUR

RESULTS

The results below set the context for the main findings according to the study questions and objectives. The study was designed to determine whether authors were required to mention ethics approval in their manuscripts in 2008 and 2017. It also investigated whether the authors were required to mention whether informed consent was obtained from participants in 2008 and 2017. Lastly, the study examines possible differences in authors' frequency reporting human participants' protection information in papers published in the selected African biomedical journals in 2008 and 2017.

4.1 Regional distribution of reviewed journals

Twelve selected biomedical journal websites in ESWA countries, four journals from each of these regions and selected published articles in these regions in the year 2008 and year 2017 were reviewed. A total of 72 articles were reviewed for 2008 and 2017 (Table 4.1). About half of the journals were established before the year 2000 and are still published before 2000 and are still active. Two journals are based in Ethiopia, one in Kenya and one in Tanzania from the East African region. Three journals are based in South Africa from the Southern Africa region, while the last is in Zambia. In the West Africa region, three journals are based in Nigeria, while the last one is based in Ghana.

Table 4.1: Regional distribution of indexed journals and articles

Region	**AJOL indexed journal**	**The proportion of articles indexed by year**			
		2008 (N=72)		**2017** (N=72)	
		№	**%**	**№**	**%**
Eastern Africa	*Ethiopian Journal of Health Development*	6	8.3	6	8.3
	African Health Sciences	6	8.3	6	8.3
	Ethiopian Journal of Health Sciences	6	8.3	6	8.3
	Tanzania Journal of Health Research	6	8.3	6	8.3
Southern Africa	*African Journal of Infectious Diseases*	6	8.3	6	8.3
	South African Journal of Child Health	6	8.3	6	8.3
	South African Medical Journal	6	8.3	6	8.3
	Medical Journal of Zambia	6	8.3	6	8.3
West Africa	*African Journal of Reproductive Health*	6	8.3	6	8.3
	African Journal of Biomedical Research	6	8.3	6	8.3
	Nigerian Health Journal	6	8.3	6	8.3
	Ghana Medical Journal	6	8.3	6	8.3

The following section presents the results according to the main study questions, starting with question 1.

4.2 Instructions to authors requesting information on ethical approval in manuscripts for publication

Question one aimed to determine whether authors were required to mention ethics approval in their manuscripts. Results related to question one are set out below.

The details of the instructions to authors section in the selected African biomedical journals' websites as of 2019 are presented in Table 4.2.

Elements of ICMJE and COPE guidelines were mentioned in 58.3% of these journals' instructions to authors. Half (50.0%) of the journals requested prospective authors disclose issues relating to *ethics approval* in their manuscripts.

Less than half (41.7%) of these journals gave instructions to prospective authors to provide information on *authorship* in their manuscripts, 16.7% requested information on *the acknowledgement of sources,* while 33.3% requested information on *originality and plagiarism*. All the assessed journals instructed prospective authors to provide appropriate *referencing* styles for their manuscripts. Only one journal (8.3%) requested data fabrication and falsification information. In contrast, all the assessed journals did not require data sharing information (Table 4.2).

Table 4.2: Details of instructions to authors in the selected African biomedical journals

Items	**№**	**%**
Years the journals were established		
≥2001	6	50.0
≤2000	6	50.0
ICMJE/COPE mentioned		
Yes	7	58.3
No	5	41.7
Disclosure of ethical approval obtained		
Yes	6	50.0
No	6	50.0
Other ethics and human participants protection information		
Authorship		
Yes	5	41.7
No	7	58.3
Disclosure on the acknowledgement of sources		
Yes	2	16.7
No	10	83.3
Originality and plagiarism		
Yes	4	33.3
No	8	66.7
References		
Yes	12	100
Data fabrication and falsification		
Yes	1	8.3
No	11	91.7

4.3 Instruction to authors requesting information on informed consent obtained from participants

Question two aimed to determine whether authors were required to mention whether informed consent and other ethics and human participants protection information were obtained from participants. The details of these instructions in the selected African biomedical journals' websites as of 2019 are presented in Table 4.3.

About a third (33.3%) requested authors to indicate how *informed consent* was sought. Half (50.0%) of the journals required information on *conflict of interest.* Only 16.7% of the assessed journals requested information on the *protection of research participants* from authors. None of the assessed journals requested information from authors about the c*onfidentiality* of data provided by the participants (Table 4.3).

Table 4.3: Details of instruction to authors to mention whether informed consent was obtained from participants and ethics and human participants protection information in 2008 and 2017

Items	**№**	**%**
Disclosure of informed consent obtained		
Yes	4	33.3
No	8	66.7
Other ethics and human participants protection information		
Yes	12	100
Disclosure of conflict of interest		
Yes	6	50.0
No	6	50.0
Disclosure of data sharing		
No	12	100
Protection of research participants		
Yes	2	16.7
No	10	83.3
Confidentiality		
No	12	100

4.4 Difference in the human participants' protection information disclosed by authors and sourced from the reviewed articles

Question three aimed to identify the difference in human participants' protection information disclosed by authors in papers published in the selected African biomedical journals in 2008 and 2017.

Human participants' protection information disclosed by authors and sourced from the reviewed articles in the selected African biomedical journals is presented in Table 4.4. Findings showed that in the year 2008, original articles (44.4%) top the list of reviewed articles, followed by cross-sectional surveys (33.3%). In 2017, cross-sectional surveys constituted 44.4% of the articles, 38.9% were original. In 2008 and 2017, the ICMJE and the COPE guidelines were not mentioned in any of the articles reviewed. In the 2008 articles reviewed, *ethics approval* was disclosed in about half (52.8%) of the articles compared to 81.9% of articles reviewed for 2017. There was also an increase (from 61.1% in 2008 to 72.2% in 2017) in the articles that disclosed that *informed consent* was obtained in the 2-timepoints of 2008 and 2017 (Table 4.4a).

Other ethics and human participants' protection-related information were disclosed in all articles reviewed. For instance, in 2008, *conflict of interest* appeared in 6.9% of the articles reviewed and increased to 43.1% in 2017. In 2008, information on the protection of participants was not provided in any of the articles but only in one of the 2017 articles reviewed. In 2008, information on *confidentiality* was provided in only 8.3% of the articles, and the proportion rose to 33.3% for 2017. In the 2008 articles, information on *authors'* contributions was not provided; however, 27.8% of the articles reviewed for 2017 disclosed this information (Table 4.4b). Information about the *privacy of data* collected was provided in 9.7% of 2008 articles reviewed and decreased to 5.6% in 2017 articles. Acknowledgement of sources of data was provided in less than half (43.1%) of the 2008 articles reviewed, while it increased to 51.4% in the 2017 articles.

Information on *originality and plagiarism* was not provided in all the articles reviewed. All the articles had references provided. From the 2008 articles reviewed, only 8.3% of these articles mentioned some information on the *anonymity* of research participants, while 15.3% of articles reviewed in 2017 had information on this. Information on *voluntariness* was provided in 4.2% of the articles reviewed for 2008

and 11.1% of the articles reviewed for 2017. There was no *information on minimising risk or harm* in the articles reviewed for 2008, while 2.8% of the articles reviewed for 2017 reported this. Similarly, the was no information on *data management* for the articles reviewed for 2008, while only one article had such information among the articles reviewed for 2017 (Table 4.4c).

Table 4.4a: Comparison of human participants' protection-related information by year of review

Items	**2008 № (%)**	**2017 № (%)**
Types of articles reviewed		
Review	2 (2.8)	2 (2.8)
Original	32 (44.4)	28 (38.9)
Cross-sectional survey	24 (33.3)	32 (44.4)
Clinical trials	6 (8.3)	4 (5.6)
Prospective	5 (6.9)	1 (1.4)
Purposive	1 (1.4)	0 (0)
Descriptive	1 (1.4)	0 (0)
Longitudinal	1 (1.4)	0 (0)
Retrospective	0 (0)	1 (1.4)
ICMJE/Cope mentioned		
No	72 (100)	72 (100)
Ethics approval required		
Yes	38 (52.8)	59 (81.9)
No	34 (47.2)	13 (18.1)
Informed consent required		
Yes	44 (61.1)	52 (72.2)
No	28 (38.9)	20 (27.8)

Table 4.4b: Comparison of human participants' protection information by year of review

Items	**2008 № (%)**	**2017 № (%)**
Other ethics and human participants protection information		
Yes	72 (100)	72 (100)
Conflict of interest		
Yes	5 (6.9)	31 (43.1)
No	67 (93.1)	41 (56.9)
Protection of participants		
Yes	0 (0)	1 (1.4)
No	72 (100)	71 (98.6)
Confidentiality		
Yes	6 (8.3)	24 (33.3)
No	66 (91.7)	48 (66.7)
Authorship		
Yes	0 (0)	20 (27.8)
No	72 (100)	52 (72.2)
Privacy		
Yes	7 (9.7)	4 (5.6)
No	65 (90.3)	68 (94.4)
Acknowledgement of sources		
Yes	31 (43.1)	37 (51.4)
No	41 (56.9)	35 (48.6)

Table 4.4c: Comparison of human participants' protection information by year of review

Items	**2008 № (%)**	**2017 № (%)**
Originality and Plagiarism		
No	72 (100)	72 (100)
References		
Yes	72 (100)	72 (100)
Anonymity		
Yes	6 (8.3)	11 (15.3)
No	66 (91.7)	61 (84.7)
Voluntariness		
Yes	3 (4.2)	8 (11.1)
No	69 (95.8)	64 (88.9)
Minimisation of risk or harm		
Yes	0 (0)	2 (2.8)
No	72 (100)	70 (97.2)
Data management		
Yes	0 (0)	1 (1.4)
No	72 (100)	71 (98.6)

4.5 Hypotheses

The following alternate hypotheses were tested:

Hypothesis One

The first alternate hypothesis states that there would be a significant association in the human participants' protection information in the instructions to authors in selected African biomedical journals established in or before 2000 and in 2001 and after (Table 4.5a).

The calculated p-values for all the key human participants' protection information were greater than 0.05. Therefore, based on these values, there was no significant association between the human participants' protection information in the instructions to authors in the selected journals and the year they were established. The year the journals were established did not affect the human participants' protection information in the instruction to author those journals. Therefore, the alternate hypothesis was rejected (Table 4.5a).

Table 4.5a: Association between human participants' protection information in the journals and years of establishment

Year of establishment	Human Participants Protection Information				
	Ethical Approval				
	Yes № (%)	**No № (%)**	**Total № (%)**	X^2	**p-value**
≥2001	2 (33.3)	4 (66.7)	6 (50.0)	1.333	0.567
≤2000	4 (66.7)	2 (33.3)	6 (50.0)		
Total	6 (50.0)	6 (50.0)	12 (100.0)		
	Informed consent				
	Yes № (%)	**No № (%)**	**Total № (%)**	X^2	**p-value**
≥2001	2 (33.3)	4 (66.7)	6 (50.0)	0.000	1.000
≤2000	4 (66.7)	2 (33.3)	6 (50.0)		
Total	6 (50.0)	6 (50.0)	12 (100.0)		
	Conflict of interest				
	Yes № (%)	**No № (%)**	**Total № (%)**	X^2	**p-value**
≥2001	3 (50.0)	3 (50.0)	6 (50.0)	0.000	1.000
≤2000	3 (50.0)	3 (50.0)	6 (50.0)		
Total	6 (50.0)	6 (50.0)	12 (100)		
	Protection of research participants				
	Yes № (%)	**No № (%)**	**Total № (%)**	X^2	**p-value**
≥2001	1 (16.7)	5 (83.3)	6 (50.0)	0.000	1.000
≤2000	1 (16.7)	5 (83.3)	6 (50.0)		
Total	6 (50.0)	6 (50.0)	12 (100)		
	Authorship				
	Yes № (%)	**No № (%)**	**Total № (%)**	X^2	**p-value**
≥2001	2 (33.3)	4 (66.7)	6 (50.0)	0.343	1.000
≤2000	3 (50.0)	3 (50.0)	6 (50.0)		
Total	6 (50.0)	6 (50.0)	12 (100)		
	Privacy				
	Yes № (%)	**No № (%)**	**Total № (%)**	X^2	**p-value**
≥2001	1 (16.7)	5 (83.3)	6 (50.0)	0.000	1.000
≤2000	1 (16.7)	5 (83.3)	6 (50.0)		
Total	6 (50.0)	6 (50.0)	12 (100)		
	Acknowledgement of sources				
	Yes № (%)	**No № (%)**	**Total № (%)**	X^2	**p-value**
≥2001	4 (66.7)	2 (33.3)	6 (50.0)	0.000	1.000
≤2000	4 (66.7)	2 (33.3)	6 (50.0)		
Total	6 (50.0)	6 (50.0)	12 (100)		

Table 4.5a: Association between human participants' protection information in the journals and years of establishment (cont'd)

	Originality and Plagiarism				
	Yes № (%)	**No № (%)**	**Total № (%)**	X^2	**p-value**
≥2001	2 (33.3)	4 (66.7)	6 (50.0)	0.000	1.000
≤2000	2 (33.3)	4 (66.7)	6 (50.0)		
Total	6 (50.0)	6 (50.0)	12 (100)		
	Data fabrication and falsification				
	Yes № (%)	**No № (%)**	**Total № (%)**	X^2	**p-value**
≥2001	1 (16.7)	5 (83.3)	6 (50.0)	1.091	1.000
≤2000	0 (0)	6 (100.0)	6 (50.0)		
Total	6 (50.0)	6 (50.0)	12 (100)		

Hypothesis Two

The second alternate hypothesis states that there would be a significant difference in mentioning of ethical approval in the selected journals articles in the year 2008 and 2017 concerning the disclosure of ethical approval by authors.

The calculated p-value for human participants' protection information disclosed by authors in 2008 and 2017 was less than 0.05. Therefore, based on the value, it can be inferred that there was a significant association in the human participants' protection information (ethics approval) disclosed by authors in the selected articles and journals at the two-point years. The two-point years were significantly associated with the authors' disclosure of human participants' protection information. Therefore, the researcher fail to reject the alternate hypothesis (Table 4.5b).

Hypothesis Three

The third hypothesis states that there would be a significant difference in the disclosure of informed consent in the selected journal articles in the years 2008 and 2017 by authors.

The calculated p-value for human participants' protection information disclosed by authors in 2008 and 2017 was greater than 0.05. Therefore, based on the value, the researcher rejected the alternate hypothesis. The null hypothesis was upheld, which says no significant difference in the disclosure of informed consent in the selected journal articles in the years 2008 and 2017 by authors. Therefore, it can be inferred that there was no significant association between informed consent disclosure by authors in the selected articles and journals at the two-point years. The two-point years assessed were not significantly associated with human participants' protection information on informed consent disclosed by the authors (Table 4.5c).

Table 4.5b: Difference between human participants' protection information disclosed by authors in articles published in the selected African biomedical journals in 2008 and 2017

Human participants' protection information	Mean±SD	95% Confidence Interval of the Difference		t-test	p-value
		Lower	Upper		
Ethical approval (2017)	0.82±0.387	- 0.431	- 0.153	- 4.181	0.000*
Ethics approval (2008)	0.53±0.503				

Table 4.5c: Difference between human participants' protection information disclosed by authors in articles published in the selected African biomedical journals in 2008 and 2017

Human participants' protection information	Mean ± SD	95% Confidence Interval of the Difference		t-test	p-value
		Lower	Upper		
Informed consent (2017)	0.72±0.451	- 0.267	0.044	- 1.424	0.159
Informed consent (2008)	0.61±0.491				

4.6 Summary of study findings

Objective one aimed to determine whether authors were required to mention ethics approval in their manuscripts in 2008 and 2017. Elements of ICMJE and COPE guidelines were mentioned in more than half of these journals. Key findings include the following: half of the journals requested prospective authors to disclose issues relating to ethics approval in their manuscripts. Less than half of these journals instructed prospective authors to provide information on authorship in their manuscripts.

Summary of the findings in objective two, which aimed to determine if authors were required to mention informed consent obtained from participants in 2008 and 2017, include the following. About a third of journals requested authors to indicate how informed consent was sought. Half of the journals required information on conflict of interest. Only a few journal editors requested information on the protection of research participants from authors. None of the assessed journals requested information about the confidentiality of data provided by the participants.

Objective three aimed to identify the difference in human participants' protection information disclosed by authors in papers published in the selected African biomedical journals in 2008 and 2017. In 2008 and 2017, the ICMJE and the COPE guidelines were not mentioned in any of the journals reviewed. Most of the year 2017 articles reviewed disclosed *ethics approval* compared to about half of those who declared it in the year 2008 articles. There was also an increase in the articles which disclosed that *informed consent* was obtained between 2008 and 2017. Also, there was an increase in the articles that disclosed other ethics and human participants' protection-related information.

Two of the three hypotheses tested were rejected, while the other showed significant differences in the variable tested.

The first alternative hypothesis was disproved based on the values calculated for hypothesis one. This demonstrates that there was no connection between the protection information for human participants in the guidelines for writers in the chosen journals and the year they were founded. Information on protecting human participants in the instruction to authors in these journals was unaffected by the journals' establishment year.

The researcher does not refute the second alternative hypothesis. The human participants' protection information (ethical approval) reported by authors in the selected articles and journals at the two-point years may be inferred to have been significantly correlated. The authors' disclosure of information about the protection of human participants was substantially linked with the two-point years.

The third alternative hypothesis was disproved. This proves that the null hypothesis was correct. Therefore, it can be concluded that there was no statistically significant correlation between authors' disclosure of informed consent in the chosen articles and journals at the two-point years. The two-point years evaluated had no discernible relationship with the authors' disclosure of information regarding informed consent regarding the protection of human participants

CHAPTER FIVE

DISCUSSION, CONCLUSION AND RECOMMENDATIONS

5.1 Discussion

Academic journals are established for scholarly publication of results from original articles, clinical trials, reviews, comments, and case notes, and are written by investigators, researchers and other experts. Some journals are discipline-specific; as such, they receive manuscripts for publication to disseminate research findings to experts in such disciplines or fields or funding agencies, and secondarily for the general populace. As reported by Brownson and colleagues, advancement in biomedical research does not depend only on the generation of information through research but also on its dissemination through various means (Brownson et al., 2009). Publishing research findings in a journal is one medium for sharing them with the research community and contributes to the current body of medical training, practice, and scientific knowledge. Publication of research outcomes (e.g., biomedical research, clinical trials) is not just a mere scientific formality but the climax of a long process. Every step in this process is important, and careful attention must be paid to each step (Ruiz-Canela et al., 1999).

Beyond disseminating research findings, published articles are meant to guide other researchers on the feasibility of reproducing such research. Thus, journal editors have a responsibility to ensure that manuscripts submitted to them, or articles published therein meet current ethical standards by spelling out basic requirements in their instructions to authors (Bhat, Shah, & Sherighar, 2017; Wu, Howarth, Zhou, Ji, Ou, & Li, 2017). The guidelines and recommendations for writing and sending manuscripts to journals are usually outlined in each journal's "instruction to the authors" section. Most journals and editors should be familiar with international guidelines and recommendations (COPE, 2018; ICMJE, 2018).

5.1.1 Distribution of indexed journals and articles

This is likely to be the first study that compared instructions to authors and reporting of ethics components in selected African biomedical journals between 2008 and 2017.

Twelve biomedical journal websites were assessed for information relating to instructions to authors, and authors' disclosure of human participants' protection measures in selected articles at 2-timepoints (2008 and 2017) were then reviewed.

5.1.2 Instructions to authors requesting information on ethical approval in manuscripts for publication

Journal editors are required to guide and instruct prospective authors for direction to facilitate scientific publication (Bhat et al., 2017). Findings from this study showed that, of the total number of the journals assessed, more than half cited the ICMJE and COPE recommendations in their instructions to authors. This was similar to Bhat and colleagues' (2017) findings and those of Mathur, Dhillon, Kalra, Sharma and Mathur (2013). Most of the journals assessed in their study adhered to the ICMJE recommendations. Findings from this study showed that half of the journal editors instructed prospective authors to disclose issues relating to *ethics approval* in their manuscripts. This was similar to Jaykaran, Yadav, Chavda, and Kantharia (2011), where instructions requiring REC approval were found in most of the journals assessed.

5.1.3 Instructions to authors requesting information on informed consent obtained from participants

Moreover, about one-third of the journals requested prospective authors to disclose that *informed consent* or assent was obtained from their study participants or respondents. In their studies, Mathur et al. (2013) and Navaneetha (2011) also found that about one-third of the journals surveyed instructed their prospective authors to obtain informed consent from their study participants.

The study also showed that about half of the journals instructed prospective authors to disclose issues about conflicts of interest in their study. In a similar study, Mathur et al. (2013) found that most journals surveyed required their prospective authors to

disclose any conflict of interest. Less than half of the journals instructed prospective authors to provide information on *authorship* in their manuscripts. This finding contrasts with Mathur et al. (2013), who found that authorship criteria were mentioned in all journals reviewed. Also, Wager (2007) reported that only 41% of the indexed journals gave no guidance about authorship in the author instructions.

5.1.4 Difference in the disclosure of human participants' protection information by authors and sourced from the reviewed articles

Findings show that reference to and compliance with the ICMJE and COPE was not mentioned in any of the reviewed journals in 2008 and 2017. More of the reviewed 2017 articles disclosed obtaining ethics approval compared to the 2008 articles. A similar result was found by Schroter et al. (2006), where most authors mentioned ethics approval in their articles. A related study by Myles and Tan (2003) showed a similar trend where most authors mentioned ethics approval in their studies.

This study also showed an increase (from 2008 to 2017) in the proportion of the reviewed articles that mentioned informed consent in the two timepoints reviewed. This finding is similar to Schroter and colleagues (2006) findings' that more than half of the articles reported consent. Another study by Hussein and Elmusharaf (2019) showed, in subtle contrast, that less than half of the articles disclosed obtaining informed consent from their participants.

Other ethics and human participants protection-related information mentioned in all the reviewed articles included conflicts of interests, protection of participants' privacy or confidentiality, authorship contribution, the privacy of data, acknowledgement of data sources, anonymity, and voluntariness. Results showed a steady increase in the proportion of frequencies with which they were mentioned in the year 2008 to 2017. Similar trends were observed in other studies (Bhat et al., 2017; Jaykaran et al., 2011; Mathur et al., 2013; Schroter et al., 2006), although most of these studies did not compare similar journals a decade apart.

5.2 Limitations to the Study

This study is not without limitations. The first limitation is the small sample size of the selected African biomedical journals. This is because of scarce resources and the limited scope of the thesis. The second limitation, and related to the former issue, is that it may not be possible to generalise these findings to other biomedical journals. Also, the selection of the journals was somewhat skewed; this is because many journals based in other countries in the three regions did not meet the inclusion criteria and were inactive (stopped publishing) in 2017. Further, it cannot be assured that predatory journals were excluded from this analysis.

5.3 Conclusions

Findings showed that more than half of the journals mentioned both ICMJE and COPE in the instructions to authors, and about half of the editors requested that prospective authors disclose whether ethics approval was obtained for the research. One-third of the editors required information on informed consent, and a few journals requested information on protecting research participants from prospective authors.

Between 2008 and 2017, there was an improvement in instructions to authors in the selected journals' requirements for information on ethics approval, informed consent and human participant protection. However, there is room for even more improvement. The editorial teams of the selected biomedical journals in the African did not pay much attention to authors' instructions on their online pages. Almost all selected journals did not appear to update their sites regularly. For some of these journals, the last update was done approximately ten years before the data were collected on their websites.

5.4 Recommendations

Although not directly supported by this non-interventional descriptive study, these data might assist the African biomedical journals in question to ensure that all reported biomedical research more explicitly complies with international guidelines for publication, such as COPE and ICMJE.

Manuscripts are submitted electronically, and sufficient information concerning editors' online instructions for authors is required. This is a good avenue through which prospective authors can be guided appropriately.

Editors' instructions for authors and writing guidelines should be revised regularly so that prospective authors can access more recent instructions and thus produce higher quality manuscripts. This should be done as frequently as the ICMJE and COPE guidances are periodically revised.

Journals may belong to larger publishing houses; in such instances, publishing houses need to provide instruction and stress the importance of prospective authors to report ethics requirements. Clear and explicit statements on the required human participants' protection-related information for prospective authors should be made so that authors can be appropriately guided in developing quality manuscripts and save more time and resources during the peer review process.

This study explored human participants' protection information in selected African biomedical journals and a sample of their published articles. Future studies could explore possible barriers to reporting such information, for example, interviews with editors. Authors of published work who did not indicate information on ethics approval and informed consent could be interviewed to explore reasons for such omissions.

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Appendix I

2008 or 2017 Journal/Name	Year of first publication/establishment	ICMJE/COPE mentioned?		Ethics approval required?		Informed consent required?		Other ethics and human participants' protection information	
		Yes	No	Yes	No	Yes	No	Yes	No
1									
2									
3									
4									
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9									
10									
11									
12									

Appendix II

2008 Journal/Name	Type of article reviewed 1. Review 2. Original 3. Quasi-experimental 4. Cross-sectional survey 5. Clinical trial etc	ICMJE/COPE mentioned in the article?		Ethics approval mentioned in the article?		Informed consent mentioned in the article?		Other ethics and human participants' protection information mentioned in the article	
		Yes	No	Yes	No	Yes	No	Yes	No
1									
2									
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7									
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12									

Appendix III

Summary of data

2008 or 2017 Journal/Name	Type of article reviewed 1. Review 2. Original 3. Quasi-experimental 4. Cross-sectional survey 5. Clinical trial etc	ICMJE/COPE mentioned in the article?		Ethics approval mentioned in the article?		Informed consent mentioned in the article?		Other ethics and human participants' protection information mentioned in the article	
		Yes	No	Yes	No	Yes	No	Yes	No
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12									

Appendix IV

Ethics Exemption letter

UNIVERSITY OF
KWAZULU-NATAL
INYUVESI
YAKWAZULU-NATALI

RESEARCH OFFICE
BIOMEDICAL RESEARCH ETHICS ADMINISTRATION
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Website: http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx

10 December 2018

Dr IO Dipeolu (217075680)
School of Applied Human Sciences
College of Health Sciences
oludipeolu@yahoo.com / 217075680@stu.ukzn.ac.za

Dear Dr Dipeolu

Protocol: Comparison of instructions to authors and reporting of ethics components in selected African Biomedical Journals: 2008 and 2017
Degree: M.Soc.Sci (Health Research Ethics)
BREC REF: EXM698/18

I refer to your application to BREC received on 28 November 2018 and wish to advise you that exemption of ethics review has been granted for this study.

This exemption will be **noted** at the next Biomedical Research Ethics Committee meeting to be held on **11 December 2018.**

Yours sincerely

[redacted]

Prof V Rambiritch
Chair: Biomedical Research Ethics Committee

cc: Prof D Wassenaar (supervisor)