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"A case study evaluating the effectiveness of adherence clubs in Gugulethu as a strategy for mobilizing and engaging men in HIV treatment"

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Thesis submitted in partial fulfillment of the degree of Masters of Public Health

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DECLARATION

I Petronella Ncube hereby declare that the work on which this dissertation/thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

I empower the university to reproduce for the purpose of research either the whole or any portion of the contents in any manner whatsoever.

Signature: Signed by candidate

Date: 24.01.2022

DEDICATION

To my late grandfather, beloved friend, scholar and war veteran Joshua Mahlathini Mpofu, thank you for being my greatest cheerleader even on your deathbed. I will always remember your words of encouragement and how much you couldn't wait to 'ukutshaya ukhwelo' on my second graduation. 'Lala ngoxolo, Bhoza lam'.

ABSTRACT

The existing global literature shows that men living with HIV need efficient antiretroviral treatment (ART) delivery. Adherence clubs (ACs) have been identified as one way to improve retention of stable patients living with Human Immunodeficiency Virus (HIV). ACs are among several strategies that have been said to potentially assist in the engagement and mobilization of men in HIV services. However, very few have been evaluated to see whether they are effective in this regard. This qualitative study examines the facilitating factors that help retain and engage men in HIV services by trying to understand the perceived effectiveness of the Adherence Club in Gugulethu. The study employs a qualitative approach to explore the facilitating factors which help retain and engage men in HIV services. A total of 12 participants participated in in-depth telephonic interviews. The participants included stakeholders of the AC such as the health workers (facilitators, nurse, community health worker (CHW) and adherence counsellors), men attending the club and family members who are indirectly involved in supporting participants engagement in the AC as patients. Interviews were conducted in IsiXhosa and for data analysis, they were translated to English, and a thematic analysis was done. The findings show facilitating factors in all stages of the socio-ecological model with the patient level being the vital stage which allows for the integration of other level factors. This study shows that when men properly utilize the different resources provided for their HIV treatment, their engagement and retention in the AC improves. It is therefore key for policy makers to consider planning for male-focused health services to ensure that men view health services as spaces which are inclusive and tailored for them to improve their engagement and retain them in health services.

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My family and their support have helped get me this far and I am very grateful.

ACRONYMS AND ABBREVIATIONS

HIV: Human Immunodeficiency Virus

ACs: Adherence Clubs

PLWHIV: People living with Human Immunodeficiency Virus

CCWs: Community Care Workers

IALARM :“Using Information to Align Services and Link and Retain Men in the HIV Cascade

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Part A: Protocol

Background

Since the epidemic "74.9 million people have been infected by human immunodeficiency virus (HIV) and of those infected, 32 million people have died, 37.9 million people are living with HIV and 24,5 million" are accessing anti-retroviral therapy (ARVs) (1). Further, the Africa region remains with the highest prevalence and incidence rate of HIV with South Africa having the highest number of people living with HIV (PLHIV) (1). Globally, men comprise nearly half of people aged 15 and older living with HIV (2). Researchers argue that men living with HIV compared to women, face challenges in the access of preventive services and antiretroviral therapy (ART), viral load suppression and retention in care (3,4). Similar findings have been found in South Africa (5,6,2). Challenges of 'men who have sex with men' (MSM) have been well documented compared to heterosexual men. The poor access of HIV services by men compared to women represents an under recognised mortality rate. The engagement and retention of men in HIV treatment was very low and there was urgent need for effective interventions within the different transitions throughout the HIV treatment cascade (7). Similar studies highlight that's men despite their dominance in society, experience higher ART related mortality rate and there has not been much done to addresses the gender differences (8,2).

To address the challenges related to HIV care in the clinics and improve better access to HIV services, for the whole populace, Adherence Clubs (ACs) were rolled out in South Africa since 2007. They were also formed to address the clinical challenges hindering ART adherence. These included but were not limited to stigma, long waiting queues and health professional condescending attitudes. The ACs aimed at ensuring support, viral load suppression and retaining people infected with HIV in care. To date, there has been some successes since the roll out of ACs such as peer group support, better retention of (PLHIV), maintenance of viral load suppression and short waiting time at the clinic (9,10). Despite this, there has been some challenges towards ensuring adherence especially with men living with HIV due to cultural norms, masculinity, and stigma (2,10,11). There have been various strategies introduced to try and address challenges related to HIV and men. This study being a sub study of the iALARM Project, will look at the adherence club as a strategy used to engage and mobilise men. IALARM stands for "Using Information to Align Services and Link and Retain Men in

the HIV Cascade". The project is concerned with understanding the effectiveness of different strategies in engaging men living with HIV. This sub-study tries to assess the impact of the ART adherence club in retaining, engaging, and mobilizing men through a qualitative approach which involves everyone as a participant who is part of the club to understand how it facilitates engagement.

Statement of the problem

Studies, evaluating the effectiveness of ACs in ART-have been conducted in Khayelitsha, rural districts, Cape Metro area and Eden district (12,13,14). To the best of our knowledge, no studies have been conducted in other areas of Cape Town, with attention to men. Different residential areas present different HIV prevalence rates and different challenges to the HIV positive residents. Furthermore, women (70-85%) were most participants in most studies that have been done in South Africa whilst men may have unique challenges that result in reported lower adherence rates relative to women (5,6,14,15,16). Therefore, the findings of previous studies on the effectiveness of ACs may not be generalisable to men. Reviews have shown differences in uptake and adherence of men and women in Southern Africa. In the literature, this has been a strategy recognised for its potential to engage men in HIV treatment. However, little is known about its effectiveness in retaining men in care and ensuring better health outcomes. To address this gap in knowledge, this study seeks to evaluate the perceived impact of ACs in engaging and mobilising men in HIV treatment in Gugulethu through a qualitative approach.

Literature review

Globally "37.9million people are living with HIV (1). Furthermore, South Africa has the highest HIV epidemic accounting for 7.7 million PLHIV. Despite the roll out of antiretroviral medication, there has been challenges with adherence. In comparison to women and other countries in other regions, the percentage of men (47%) who are adhering to their medication is low and this indicates challenges with viral load suppression (1,4,5,6). Several studies have found that males have higher mortality after ART initiation even with baseline features and differences in disease severity being controlled for (12; 15).

To explain the above findings, a study review found that, men's failure to engage fully with their treatment is in part due to cultural norms around men such as patriarchy; gender roles and expectations that see men as strong without sickness (1). He also asserts that; it has been observed that clinical settings are perceived as mostly female dominated which often produces discomfort in disclosure and reluctance to show vulnerability. Further, the stigmatising attitudes from nurses who perceive men as undeserving of the same services as women because of being framed 'perpetuators of HIV and sexual violence' impacts on their access and inhibits men from coming to the clinic unless it is an emergency (2,4). The stigma in communities associated with HIV impacts on access to medication and adherence to treatment.

ACs were rolled out in 2007 by the Department of Health to address issues around stigma in clinics around South Africa and help with medication uptake. ACs aim to assist patients with medication adherence through providing easy collection and access to treatment. They aim to reduce viral load and retain patients in HIV care through support rendered by non-clinical staff (17).

There is conflicting evidence on whether the HIV ACs have been able to meet their aims and objectives. With regards to ACs maintaining viral load suppression, a study found that patients in the Eden Municipality District who were satisfied with Adherence club were able to be treatment adherent and retain in care compared to clinical participants (9). Similarly, UNAIDS and Human Sciences Research Council (HSRC) reports that more than 70% PLHIV on ART had achieved suppressed viral loads in South Africa as of 2017 (1,18). Moreover, suppressed viral loads were reported among participants attending an adherence club in Cape Town (19). Further, they found higher susceptibility of viral rebound from younger patients attending the club which in part, was due to the transitioning period from adolescent to adult.

ACs have been found to be effective in the retention of care. A study found that patients improved in retention in care after non- clinical staff led a group supportive role in the ACs in Khayelitsha (13). They further expressed that they felt part of a family that is supportive, helpful, caring and always felt encouraged to take their medication. Similarly, a study found that patient's positive experience at the club compared to the clinic was the mediator and a predictor of a sense of belonging which helped with adherence (10)

Even though there have been some notable successes with the ACs, there are remaining challenges. There are different interacting factors that help bring about the different outcomes stated above and some of these factors can be invisible or visible, but they all provide lessons to different agents in the health system (20). These lessons can be incorporated to improve experience in the adherence club. Therefore, this study is interested in finding out whether this strategy is effective in engaging men in HIV treatment in Gugulethu and if so, what are the facilitating factors and how do they help facilitate the engagement in an ecological system considering how the individual must interact with their environment and the resources within that environment.

Theory and Conceptual Framework:

The Ecological Systems Theory

To understand the individual, one must understand their wider context and consider how numerous system interaction one way or the other exerts its influence on the individual's behaviour (21). Further, another consideration of the ecological perspective is that, both the individual and their environment develop over time. These developments are crucial to our understanding of how the different levels in the system overtly influence the individual and their development (22). There are four levels in this framework; the first level is the individual and their personality; the second level is about relationship and connections; the third level involves structures that inform and shape every level interaction and lastly, the fourth level is about policy and culture that influences all the other levels (21). This theory guides researchers to examine all important aspects that have a bearing on the individual and the environment while accentuating the boundary between them to find appropriate action and attain better management of HIV in men. Further this theory is suitable because it identifies intricacies and interconnections that are essential for health promotion. It shows that multiple levels of influence should always be incorporated in the course for better HIV outcomes. It will help the researcher understand how the individual and the adherence club interact at different levels in society to promote support, access, engagement, and retainment in HIV care. It will also help in analysing levels of influences that could be strengthen for better HIV care engagement and retention in care.

Resource Theory

The ecological model is useful but in practice it often focuses too much on the barriers to a process. However, resources and resourcefulness are also important. This project will include a focus on resources available and mobilised at the club. This theory presupposes that an individual who has access to resources is better able to utilize these resources for their human development, upward mobility and better outlook be it health or career (23). This is because resources enable opportunities and full participation in society. The resources can vary according to social, cultural, and economic capital and these enable any individual to go up the hierarchy or manage any stressors in their environment. These include tangible items such as money, services, and information. The intangible items such as love and status in society. This theory is useful for this research because it helps identify the resources that the adherence club has and how patients use these resources to adhere to their treatment, to feel supported and retain in care. It helps to further explain the interaction between the resources found in the adherence club and the ones in their environment and how this cements the engagement of men in HIV treatment.

Main Research Question:

How does the Adherence club at Gugulethu NY3 Clinic facilitate the engagement of men in HIV treatment?

Study Aims

The study seeks to evaluate the impact of ACs in engaging and mobilizing men in HIV treatment in Gugulethu through an ecological approach.

The objectives are:

- To evaluate the perceived effectiveness of ACs in retention and viral suppression amongst men living with HIV in Gugulethu through qualitative interviews with everyone involved in the club.
- To assess the facilitating factors of adherence and how these helps retain men in HIV care.

Sub questions

- How do the adherence club at Gugulethu NY1 Clinic help retain men in HIV care?

- How does the club interact with the individual to facilitate support and retention in care?
- How do health personnel negotiate challenges to make sure that health care for the participants is not compromised?
- How is the interaction between the club and the family members who the participants have disclosed their status to and how does the interaction assist the participants attending the adherence club.
- Are there any gender or sex differences in the uptake of HIV medication?

Methodology

Study Design

The study design that will be employed is qualitative. Qualitative research is a method that allows the researcher to study selected issues in depth and detail allowing the participants to share their experiences regarding the Adherence Club and what has facilitated their commitment to be adherent (24).

Study Population and Sampling

For this research, purposive sampling will be used. It is a type of "non-probability sampling" in which the participants are selected based on the researcher's judgement (25). The sample will consist of men who are part of the adherence club. The inclusion criteria are men who reside in Gugulethu and attend the HIV adherence club at Gugulethu NY1 Clinic. It also includes facilitators of the adherence club, community health workers, family members, the manager and nurse. The sample size will be a total of 13 people. This research study will sample participants who are directly and indirectly part of the adherence club because it is seeking to understand how different spheres in the socio- ecological context contribute in the facilitation of better health outcomes with interest to men who attend the clubs. Everyone mentioned above plays a significant role in the club therefore they have a unique facilitating factor which will be explored during the interviews. The family members will be interviewed once consent is gained from the participant who is a member of the adherence club. The exclusion criteria will be men who do not reside nor attend adherence club in Gugulethu and family members who do not reside with the male participant attending the club.

Research Setting

The research will be conducted in Gugulethu at the NY1 Clinic. The interviews will be done at the clinic or at the Sonke Gender and Justice office. Due to the safety regulations prompted by COVID-19, the interviews will be through the telephone and/ or mobile phone hence the setting will be at the comfort of their homes.

Recruitment and enrolment

After ethics clearance is obtained from the university and clinic, recruitment will follow. The potential participants will be from Gugulethu community health care clinic. The facilitator of the club will help identify people attending the ART adherence club and will act as a gatekeeper. The researcher will share information about the study so that he is able to brief participants and address as much questions as possible. The facilitator who acts as a gate keeper, will provide the necessary information to the potential participants. The consent forms will be emailed to the facilitator. He will give potential participants the forms and explain the information sheet and the consent forms (Appendix A-B) giving participants enough information for them to make an informed decision. If they have questions about the study which the facilitator feels the researcher can give more clarity, they are free to leave their numbers and they will be contacted for further clarity. Once verbal consent has been obtained, the participants will be asked to leave their details and they will be called to arrange for the interview. Those who have more questions, their numbers will be collected, and I will contact them. With the help of the translator, I will clarify and address any concerns or questions. With his assistance, he will handout the consent form on the day of the interview and the signed consent form copies will be scanned back to me. Alternatively, participants can send a picture of the signed copies.

In terms of other participants such as the health workers and the family members, the facility manager will be emailed and informed about the study. The facility managers email address will be obtained from Sonke Gender Justice that collaborates with our department in research. The researcher will ask permission from the manager for the Adherence club health personnel contact details. They will be then contacted via email or alternatively via their cell phone numbers and asked to participate. The family members contact details will be accessed through the participants from the Adherence club and they will be called and asked to participate. The researcher will ask the club

member to inform their family member so they are aware of the purpose of the call although the researcher will reiterate this again at the beginning of the call. To maintain confidentiality, the family member will be asked to produce their ID /Passport number number/booklet to the translator for verification. The researcher will ask for their consent to participate and reiterate that it is voluntary participation, and they are free to say no.

Study Procedures

After obtaining written informed consent from participants, interviews will be conducted. Obtaining a room at the clinic is a contingency measure for participants who might have not disclosed their HIV status to friends or family hence they are not comfortable with the telephonic interview taking place at their home or any other place outside the clinic. Also, the room is for participants who do not feel comfortable with the translator being in their home so it provides a central comfortable and familiar place since it will be in the clinic. The room could potentially serve as a quiet place that offers no disturbances for participants who are health workers. Permission for a room in the clinic will be obtained from the Clinic Manager, Sister Mavume to allow the participants space to answer questions. Alternatively, a room from the Sonke Gender and Justice office will be acquired. Once interviews have been completed, debriefs will be initiated to allow for participants to ask questions and gain clarity from the researcher or any form of support if they have experienced any emotional harm from the questions.

Data collection

For this study, in-depth telephonic interviews will be employed. Due to Covid-19 safety regulations, the interviews will be conducted under strict safety regulations as highlighted by the Minister of Health. Telephonic interviews will be used to replace the initial face to face interviews. Interviews are an effective way of obtaining substantial amounts of in-depth data systematically (26). The researcher will utilize interviews because they will allow for more depth and understanding of the research question. The researcher will utilise semi structured interview schedule. A semi-structured interview schedule is uniquely flexible, addressing specific dimensions of the research while providing room for participants to offer new questions on the study topic (25). See attached Appendix C. These interviews will aim to explore the participant's experience of the ACs. More so, they will explore the differences the health professionals have noted in men during their

engagement with the services offered at the Adherence club. It will also explore how the individual participant at the club is able to interact with the resources available at the club to optimise better health outcomes and in this case, not have any opportunistic infections.

All potential participants will be contacted individually to arrange for a telephonic interview. Attempts will be made to arrange interviews with community health workers on the day they available at the clinic. The family members will be contacted once consent is given and arrangement will be made. The interviews will be between 45 to 60 minutes in duration. Depending on the participants' preference, the interview will be conducted in English or Xhosa. A member from MCSJ (Movement of Change and Social Justice), Ndumiso (who works closely with men living with HIV in Gugulethu) will be assisting the researcher in translation so that participants can be comfortable in conveying in isiXhosa. All the interviews will be recorded with the participants' consent.

Data analysis

The thematic analysis will be used to analyse the data. Data analysis is described as a "process of bringing order, structure and meaning to the data" that has been collected (26). Thematic analysis is also described as units derived from patterns and fragments emerging from the data to give meaning to what is being explored (27). They also describe thematic analysis as a procedure where data is coded and labelled into categories and finally recurring themes which represent the true elements of the participant's responses. An inductive approach will also be applied for data analysis. In preparation for data analysis, all interviews conducted in isiXhosa will be translated into and transcribed English.

Data safety and management

The researcher will protect the participants by keeping all raw data (transcripts, field notes and informed consent) in a password protected computer. Before storage, all transcripts will be kept confidential by assigning pseudo names. Due to the sensitive nature of the recordings, they will be placed in a different iALARM Dropbox folder. This folder will only be accessed by the primary researcher and supervisors working on this project.

Ethical considerations

Ethical approval is required by the University of Cape Town (UCT) Health Science Faculty's Human Research and Ethics Committee (HREC) and the UCT School of Public Health and Family Medicine. Ethics approval was given for this study, see attached Appendix D. The Western Cape Department of Health (WCDoH) City of Cape Town has already given approval for this sub study. Appendix E shows the letter of approval.

Informed consent and confidentiality

Participants will be invited to the study will be provided with substantial oral and written information regarding the study so they able to decide on whether they would like to participate or not. Potential participants will be offered an opportunity to ask questions and seek clarity on any issues that might be unclear to them. Once everything is clear and they consent, they will be asked to sign a written informed consent form. The study information will briefly describe the study, the research personnel, and the study procedures, and notify the participants about the informed consent. The information sheet and informed consent will outline the research purpose, procedure, risks and benefits and the contact information of the primary researcher, supervisor and HREC office. The researcher will treat information shared during interviews with utmost discretion and this will be explained to all participants. To ensure confidentiality and protection of the participants HIV status, we will ask the club member to provide us with the cell phone number of the family member instead of the shared telephone number at home. Further, the family member that the participant has allowed, will take part in some security questions provided by the participant before the continuation of the interview. This would be 2 questions with information that only the participant, study team and the potential family member knows to confirm their identity. To protect the participants identities and data, pseudonyms will be used and only the research supervisors apart from the researcher will have access to data. Participants' data will be stored in a password secure computer which will be backed up in cases the computer crushes. Access will be controlled by the principal investigator. It will be stored for 5 years after study completion.

Data recording

With the consent of the participants, all the interviews will be recorded. The researcher will get permission from the participants to record because it is a violation of privacy if they record without the participant's consent (26). The researcher will obtain this through a written and verbal consent.

Description of Risks

The study will be conducted in line with the South African Good Clinical Practice guidelines and the principles of the Declaration of Helsinki (1964). The participants will only be included after giving their consent. They will be able to withdraw from the study at any time, even without a reason. The researcher understands that there might be some aspects that they are not free to talk about hence they are free not to answer any question they do not want to talk about. Also, disclosure of their HIV status might be a possible risk which could lead to emotional discomfort. Further, there might be some questions which could further inflict unintended discomfort hence the researcher will facilitate the referral to a counsellor at Sonke. A debrief will happen to attend to any concerns around the study to alleviate any issues that might have risen during the study. They will be made aware of the fact that their withdrawal in the study will have no repercussions on their participation in the club.

Description of benefits

The study findings will assist health professionals to understand the facilitating factors which can help improve situating ACs within a social context directly and indirectly interacting with all the levels in society. Understanding the effectiveness of ART ACs among HIV positive men on ART will augment efforts toward the 90-90-90 vision of South Africa. The focus of this study will help the participants to indirectly benefit from understanding how adherence to treatment is crucial in obtaining the full advantages of ART. If challenges are noted, this will help in recommending changes for the improvement of outcomes and promotion of health.

Researcher Safety

Researchers often at risk by being in deprived communities were they visible stand out as outsiders and being a woman amplifies a situational and an ambient risk (28). They also stress the fact that social research is a team activity therefore to manage these risks, the researcher through the help

of Sonke and MCSJ will be able to manoeuvre around the community to the clinic. Initially it was going to be contact interviews but considering the pandemic, telephonic interviews will ensure the safety of the researcher and the participants.

Rigour

The following will be considered to strengthen the rigour of the study and ensure validity and reliability.

For the research to be trustworthy, certain criteria should be considered (29). The researcher will consider the views of each participant and make sure that they have been accurately acknowledged, represented, and interpreted by doing member checking. The researcher, through ongoing feedback from the supervisor will ensure that the data is debunked efficiently. Also, through a process of mutual feedback, she will share the findings with the participants and ask for their comments to ensure that there was not any misinterpretation.

To ensure confirmability, the objective is to minimize the researchers' bias by acknowledging their own predispositions (29,30). Any bias or preconceived narratives throughout the study will be reflected upon with the supervisors throughout the research process.

In ensuring transferability, thick descriptions of the research context will be provided. This allows the reader to bear in mind whether the findings could be transferable to their situation or not (29,30).

To ensure credibility, the study will attempt to capture the social reality of the participants (29,30). The researcher will gather information from the interviews and different journal sources to gain a broader understanding of the topic of interest which allows triangulation. Member checks will be employed after the data analysis. An audit trail will be kept of all the notes, recordings excluding identifiable data.

Reflexivity

Reflexivity acknowledges the primary role of the researcher in constructing new knowledge as well as the participants (31). Further, it relates to the researcher being aware of their own characteristics and the participants and how this influences the research methodological decision, rationales, and

findings. To reflect on the researcher's position, she plans to record and reflect on her subjectivity and influence over the participants, the data collection and analysis. The research process is influenced by several factors which are intended and unintended consequences hence reflexivity should be facilitated by a consideration of culture, social realities, and researcher's positionality (31). The researcher is also aware of her inexperience with qualitative research therefore she will consistently and persistently reflect with her supervisor's biweekly. Being a black Ndebele speaking woman and interviewing black Xhosa speaking men, she is aware of gender and sex differences hence she will build rapport by interviewing participants in a comfortable and secure place. Because our own positionality might not be clear to us, neither our awareness of prejudice, the researcher will continually be reflexive in her diary and challenge underlying perspectives with my supervisor's guidance. The researcher will work with a member of the MCSJ as mentioned above, who will assist with translation during the interviews and his presence will allow for a level of comfortability for the participants because he speaks IsiXhosa and shares the participants lived reality of being an HIV positive man from the community of Gugulethu. There is reiterateration of the importance of involving the reader in how interpretations were formed in the data analysis leading to the final write up and this will be considered by the researcher (31).

Study Budget

Item	Estimated Cost
Airtime	500
Printing and scanning	200
Total	**700**

Study Time Frame

Activity	Expected Timeline
Protocol submission	October

Data Collection	December
Data transcription	December
Data Analysis	December
Final write up	February

Knowledge dissemination

The results will be disseminated at the Gugulethu-UCT Research indaba that happens every year at Gugulethu. This is a space for the researcher to share the results with the community and different stakeholders. The indaba brings together the community of Gugulethu, NGOs, CBOs, and health systems to share information, build relationships and work towards better health for all. This is important because it is an opportunity for knowledge to be shared and hopefully integrated into health structures to improve adherence in men where it might be a challenge.

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Part B: Journal Ready Manuscript

A case study evaluating the effectiveness of adherence clubs in Gugulethu as a strategy for mobilizing and engaging men in HIV treatment.

Abstract

The existing global literature shows that men living with HIV need efficient antiretroviral treatment (ART) delivery. Adherence clubs (ACs) have been identified as one way to improve retention of stable patients living with Human Immunodeficiency Virus (HIV). ACs are among several strategies that have been said to potentially assist in the engagement and mobilization of men in HIV services. However, very few have been evaluated to see whether they are effective in this regard. This qualitative study examines the facilitating factors that help retain and engage men in HIV services by trying to understand the perceived effectiveness of the Adherence Club in Gugulethu. The study employs a qualitative approach to explore the facilitating factors which help retain and engage men in HIV services. A total of 12 participants participated in in-depth telephonic interviews. The participants included stakeholders of the AC such as the health workers (facilitators, nurse, community health worker (CHW) and adherence counsellors), men attending the club and family members who are indirectly involved in supporting participants engagement in the AC as patients. Interviews were conducted in IsiXhosa and for data analysis, they were translated to English, and a thematic analysis was done. The findings show facilitating factors in all stages of the socio-ecological model with the patient level being the vital stage which allows for the integration of other level factors. This study shows that when men properly utilize the different resources provided for their HIV treatment, their engagement and retention in the AC improves. It is therefore key for policy makers to consider planning for male-focused health services to ensure that men view health services as spaces which are inclusive and tailored for them to improve their engagement and retain them in health services.

Key words

men, HIV/AIDS, adherence club.

What do we already know about this Topic?

The systematic, structural, social, and gendered factors that contribute to men's failure to engage in HIV services. Further, the barriers linked to prevention and treatment of HIV/AIDS among men in South Africa and globally which lead to poor outcomes of men's health compared to women. There has been a need for effective strategies and policies to improve men's engagement with HIV/AIDS services.

How does your Research Contribute to this field?

It shows what works to improve HIV positive men's engagement with HIV services and retention in care, and how these efforts work. The study shows that a multilevel system and resource approach is important in showing and understanding the factors that promote adherence in men living with HIV in South Africa.

What Are Your Research Implications toward Theory, Practice or Policy?

Responsive health system strategies that are aware of men's needs are better able to engage and retain men in HIV services even in unprecedented times like Covid -19. Further, HIV/AIDS intervention programs that account for multilevel, contextual, and cultural consideration, have potential to be effective in engaging more men in HIV care. Therefore, continued support in form of policy and resources for not only men, but health workers, community health workers, families that have men living with HIV/AIDS and communities at large are needed.

Introduction

Since the early stages of the HIV epidemic, it is approximated that "74.9 million people have been infected by the Human Immunodeficiency Virus (HIV). Of those infected 32 million people have died, 37.9 million people are living with HIV and 24,5 million" are accessing antiretroviral therapy (ARVs) (1). Further, the African region remains with the highest prevalence and incidence rate of HIV, with the highest number of people living with HIV reported in South Africa (1). Globally, nearly half of

the people aged 15 and older living with HIV are men (2). Researchers argue that men living with HIV, compared to women, face challenges in the access of preventive services and antiretroviral therapy (ART), viral load suppression and retention in care (3,4). Similar findings have been found in South Africa (2,5,6). The poor access of HIV services by men compared to women results in an under-researched mortality rate. Several studies reported that the engagement and retention of men in HIV treatment was low and there was urgent need for effective interventions within the different transitions throughout the HIV treatment cascade (4, 5, 6, 7, 8). Further, they highlight that, despite their dominance in society, they experience higher ART-related mortality rates and there has not been much done to address the gender differences.

To address the challenges related to HIV care in the clinics and improve access to HIV services, for the whole population, adherence clubs were introduced in 2007 and rolled out in South Africa since 2011 (9,10). They were also formed to address the clinical challenges hindering ART adherence. These included but were not limited to stigma, long waiting queues and health professional condescending attitudes. Further, clubs aimed at ensuring support, viral load suppression and retaining people infected with HIV in care (9,10,11). To date, there have been some successes since the roll out of adherence clubs, including improved outcomes like peer group support, better retention of people living with HIV, maintenance of viral load suppression and short waiting time at the clinic (9,11). Despite this, there have been some challenges towards ensuring adherence, especially among men living with HIV, due to cultural norms, masculinity, and stigma (2, 9, 10). There have been various strategies introduced to address these challenges related to HIV and men. This sub-study uses a qualitative approach to understand the adherence club as a strategy used to engage and mobilise men. It is a sub study of the iALARM project, “Using Information to Align Services and Link and Retain Men in the HIV Cascade”. The broader project is concerned with understanding the effectiveness of different strategies in engaging men living with HIV.

Methods

Study Design

This study is a qualitative thematic exploration of the engagement and retainment of men in HIV services. Interviews were done with male participants attending the adherence club and their family

members as well as staff members involved at the adherence club in Gugulethu. The study used semi-structured in-depth telephonic interviews.

Setting

The study was done within the Klipfontein health sub-district in Gugulethu. The population in Gugulethu is predominantly Black Xhosa speaking individuals. Gugulethu is among the oldest townships with a growing population of more than 100 000 people with many of its residents living in informal settlements (12). It further has an unemployment rate of more than 32% with more than 60% of the resident's monthly household income less than 15000 Rands, making it an economically marginalized peri-urban township (12). Gugulethu has been highlighted as a peri urban setting with one of the highest prevalence rates of HIV in the Western Cape (13).

Data Collection

A purposive sampling method was used to sample 12 participants who are part of the adherence club to understand how different spheres in the socio-ecological context contribute to the facilitation of better health outcomes among men who attend the clubs. Data was collected through telephonic interviews due to Covid-19 precautions. A semi-structured interview guide was used to allow for flexibility and the exploration of the perceived effectiveness of the Adherence Club. They were conducted in a private and quiet place. The interviews were between 30 to 45 minutes long. They were recorded with the participant's consent.

Data Analysis

To analyze the data, a thematic analysis was used. Data analysis is a "process of bringing order, structure and meaning to the data" that has been collected (14). Thematic analysis is described as units derived from patterns and fragments emerging from the data to give meaning to what is being explored (15). This study followed the thematic analysis process of coding and labelling the data into categories and finally recurring themes which represent key elements of the participants' responses. To prepare for data analysis, the recorded interviews which were conducted in isiXhosa were all translated into English. Transcripts were read until an initial code map was established. An inductive coding was used to identify codes relating to the study. The code map was refined and reduced to thematic categories which summarize the main points. They were refined and drafted

down in the findings section. Further, the resource theory and ecological perspective were aided in the data analysis. The resource theory presupposes that an individual who has access to resources is better able to utilize these resources for their human development, upward mobility and better outlook be it health or career (16). The Ecological perspective shows how different levels in the system overtly influence the individual and their development. This theory will aid in understanding how the individual and the adherence club interact at different levels in society to promote support, access, engagement, and retainment in HIV care (17).

Data Rigor

To ensure data quality and trustworthiness of the findings, the same core interview schedule was used on each group of participants (family members, men attending the club and health workers) (12). All participants expressed willingness to take part in the study and were informed about the broader iALARM project. During the design, data collection and analysis phases, the researchers' potential impact of her positionality as a Black Zimbabwean woman was discussed. The field notes captured in the research diary were a guiding tool which helped the researcher observe patterns, emerging themes and how these were answering the research questions. They also assisted during data organisation and the final write up. The findings will be presented in Gugulethu during a community meeting. Ethical approval was provided by the University of Cape Town Faculty of Health Sciences Human Research Ethics Committee (HREC). The HREC REF numbers are 802/2014 and 652/2020.

Findings

Characteristics of the Participants

The total number of participants for this study was 12 people. These included 6 men who are attending the club, 2 family members, and 4 health workers (1 community health worker, 2 club facilitators and 1 adherence counsellor). Men who were interviewed were between the ages of 30 to 50 and had been attending the club since 2017. The health workers were 2 females and 2 males.

Overview of ACs

The ACs are a long-term retention model of HIV care which are facilitated by non-clinical health workers who provide support, peer support, clinical assessment, prepacked 2-month ART medication and referral to a group of 30 stable patients (9,10,32, 11). Moreover, adult patients who have undetectable viral load for at least 12 months as well as a medical condition that does not require regular clinical examination are eligible to be in the AC. Once a year, blood is sampled to assess viral load by the nurse and a clinical consultation is done as a follow up (9, 10,18). The AC is administered by a club manager, nurse, adherence counsellor, CCW and data capture. The CCWs work both in the clinic and club and their role is to manage defaulters and bring them back to the health system (9, 10). During the club session, which is facilitated by the counsellor or manager, male and female participants collect their medication, sign the register, and are invited to engage in different topics to help one another manage HIV. Some of these topics are requested by the club members. The club meets once in two months for an hour and during the Covid-19 period, it was meeting once every 4 months.

The findings will be presented through the socio-ecological model which depicts the intersection of multiple levels in facilitating the effectiveness of an intervention in this case, the adherence club as a strategy to engage and retain men in HIV services. The facilitating factors will be presented in the following levels, patient level, family level, community level and health system level. There is awareness from the health workers that over the years, the number of men engaging in HIV services has increased. They reported that men mostly attend regularly and the number of men who are defaulters is lower than that of women. They also reported that men seem to be comfortable around women at the club, opening and sharing their challenges and experiences and helping each other thus they felt that there are facilitating factors which have helped retain men in HIV services over the years. This is contrary to what is often reported in literature because studies have found that men are either reluctant to engage with HIV services or unable to engage because of the lack of male friendly clinics, responsive care, and competent health providers (37,39, 42,43). Men seem to be doing well in this AC and the findings below will explore factors that might help explain this.

The Patient Level: The Role of Individual Agency and Motivation

'I had to accept my HIV status'. There is acknowledgement that acceptance is a critical entry point, a prerequisite and initial success factor for adherence, from both the health workers and male patients. Most male AC members described acceptance as being difficult and requiring a lot of strength. They further related that after they had accepted their status, they were able to integrate the illness in their daily lives and that incorporating self-management of HIV through continued support from the club had made the journey a lot easier. They also asserted that once they had accepted themselves, they have been part of the club for more than 3 years and they have never had any HIV-related sickness. Furthermore, they had a low viral load, and they wanted it to stay that way. A South African Xhosa speaking male activist who shares more knowledge about HIV in Gugulethu to end stigma started attending the AC in 2011, explained the benefits of accepting his HIV status:

> ***''I have accepted my status; a person can talk negatively about us but it doesn't affect me anymore'' (Participant 2*).**

The above quote shows that there is a mental shift and change in one's behaviour once they have accepted their HIV status and failure to do this potentially results in denialism which acts as a barrier for men's poor performance in accessing health care services. Their willingness to align their behaviour to what assists them to adhere shows their understanding of the responsibilities that come with acknowledging their HIV status.

'Leaving the club means killing myself'. What keeps them coming to the AC is a sense that the club is lifesaving as well as a sense of the agency that the club facilitates. Health workers viewed their patients as individuals desiring a long life. The male patients in the club want to live longer, see their children grow, they want to be there to witness their children graduate and be happy for them. Thus, they are willing to do anything to stay alive and healthy with no HIV induced illness. This involves stopping alcohol or limiting alcohol intake as well as eating healthy food. They are willing to do what it takes to adhere to their medication, and some have even gone as far as limiting their alcohol intake whilst some have stopped drinking. Participant 1, is a South African Xhosa speaking

male patient who started attending the AC before 2017, had to significantly reduce his alcohol intake to continue being adherent explained his motivation for engaging in HIV services:

> ***''I want a life and to be able to live my life well. I cannot leave the club because of what I want with my life. '' (Participant 1).***

Affirming this, a health worker explained that a patient's willingness and agency is the first step towards healing and engagement in HIV care and without that, they cannot do much to convince the patients to see the benefits of the HIV treatment if they are not willing to do so:

> ***''Despite family support, if a patient is not willing to attend the club, nothing can be done to change that'' (Health worker 3).***

This shows the significance of individual commitment and dedication as key to retention in care. Their determination propels adherence despite the changes around the AC as a response to Covid 19. The club has given them hope and they have seen through their own lives, how adhering to their medication can be fulfilling and have important benefits such as living longer and describing themselves as being 'almost HIV free' (Participant 5 and 6) because of the low count. The health workers view their male patients as not defined by their HIV status but as capable individuals who can contribute positively to society.

The Family Level: Family members in support of the ACs

The family members understood the perceived benefits of being in the club and engaging in care. Thus, they play an influential role in helping men who attend the club understand and see that. They are strong supporters of the adherence club in the community. They understood the values of the club relating to acceptance of one's status and dealing with stigma in the community setting. Their influence goes beyond the buddy system. It also involves emotional and financial support. A participants' wife, who also attends the AC at a different clinic in Gugulethu discussed how as a couple they support each other in the face of stigma and other challenges. She described the AC as ;

''Yuhhh, we receive a lot of support from the club, it is very nice. When it is time for collection of your medication, they remind you, they encourage you... they were people who were looking down on us, but they are the ones that are coming to us right now for advice, we are able to tell people about our status and encourage them, they do not believe how much we have accepted our status'' (Family Member 1).

Health workers also saw men who have disclosed to their families engaging better with HIV services compared to those who failed to disclose because families are a source of resourcefulness to patients seen below:

''Yes, it really does because if you cannot come then you have somebody who can come and help you with collecting the treatment but if you did not disclose you are on your own and the problem is today you have an interview and now you have no body to come collect for you but when you disclosed, at least they will be someone who can do that for you. It makes it easier'' (Health worker 4).

Most male patients seemed to agree about the positive impact their family members have in dealing with either financial challenges, stigma or remembering when to take their medication. A South African Xhosa speaking, unemployed male patient who receives some relief from the Club and her sister started attending the AC in 2017. He explained:

''I sometimes work but most of the time, I have no job so my sister buys me groceries which I collect from her every month'' (Participant 5).

This shows that disclosure unlocks doors of support. The positive relationships that men have with their family members provides an important environment which supports the work the adherence club does. Due to this, family members can guide, support and lead men to continue being engaged in care. Their influence is crucial as this bidirectional relationship also gives men something to live for and more reasons to remain in HIV care.

The Community Level: The role of CCWs and gender

CCWs as problem solvers. The role of the community care workers (CCWs) is paramount in the continued engagement of men in HIV care. Their role is to assist both men and women to re-engage those who might have defaulted due to health provider treatment or side effects caused by the medication. Their work is not easy as they describe facing challenges when they approach the patient's home, but their dedication and training assist them in the appropriate actions to take. They related how they visit patients three times to try and intervene and provide solutions. Thereafter, the clinic has a mandate to deal with the cases. A CHW explained reasons for disengagement and what happen during the recall:

> ***''Before you go recall someone, at the start of their treatment, they are usually informed about the dangers of not adhering to their medication so now when you go recall them, you do educate them because they might have forgotten that education that you gave them from the start and some say I forgot my date, I did not know my date, my card got lost and I did not remember my date or I have gone to Eastern Cape…I go there 3 times when I am recalling them, after the third time, the clinic intervenes as a last resort"(Health worker 3).***

In this instance, they oversee cases of those that might have defaulted, and they try to alleviate the discomforts and work around resolving the issues that might have caused them to default. Thus, they can re-engage men in care and act as a bridge that binds the patient's needs and health workers' efforts in retaining both men and women in HIV care. Due to their efforts and the patient's willingness, some come back to the clinic and through consistent commitment, end up at the club again.

The male provider role as facilitator. A community-level factor which has aided most men in the promotion of adherence is the 'provider role' that is part of dominant local ideas about masculinity. Gender norms reward men who can act as the provider in their family. The men attending the club do not want to die because this would mean leaving their families financially vulnerable as a result. They feel responsible for their family's well-being and are willing to remain in care to have more

years with their family. A South African Xhosa speaking male patient who has 2 children and started attending the AC in 2017 explains his motivation:

> ***''I want to be able to live longer, I am not smoking and drinking, my health is very important to me, I have two kids which I am looking out for, I do not want to leave them at that age''*** **(Participant 6).**

The commitment of men towards their HIV treatment is influenced by their gender roles and their view as a provider who must shield their family from any risks that could potentially harm or impede on their success. Consequently, they are willing to take their medication and have the liberty to see their children grow and excel at school.

The Health System Level

Perceived Health Worker Competence. Most men thought that the adherence club staff were well trained to deliver proper, efficient, timely access to HIV related services compared to the clinic and this contributed to their engagement in HIV services. They felt that the clinic staff, compared to the AC staff, was not as efficient and effective. Thus, they preferred adhering to the club rules rather than being sent back to the clinic. Also, health workers reported having training regularly. The male patients also thought that the staff was well equipped and understood how to meet their needs as well as provide guidance and solutions to their arising health problems during the years. Therefore, they judged their competence based on their ability to solve their health-related problems and provide quality care through the timely provision of HIV services and an efficient administration process. Furthermore, they considered their competency through their ability to suggest and connect them with reliable HIV service groups outside the club such as on the ones on Facebook and other HIV awareness raising NGOs in Gugulethu. A health worker below described the health system reason for why men continue in HIV care:

> ***''Efficiency kaloku [you see], they know they have their treatment and us as health workers we treat them well, like normal people and make sure they feel supported so by 9am they are gone from the clinic and done with collecting their medication'' (Health worker 1).***

Some men felt that the gender and competency of the health worker was key to their continued engagement. A club member explained:

> ***''They know how to do their job, they do it lovely and well. They do not act like they are being forced to do their job, they are dedicated and competent, I have no problem with them'' (Participant 5).***

Thus, men at the club trust that they are in good hands because they have staff who treat them with dignity and have their best interest at heart. This also shows that men living with HIV feel more comfortable in discussing certain issues with male health workers as compared to female health workers although they perceive female health workers to be approachable. They are confident that the club staff will continue to provide efficient services to them as they have done in the past compared to the clinic staff. Hence, this provides them assurance and satisfaction that they can always depend on the health system in relation to their HIV services and any issues intersecting from that. Despite the Covid-19 pandemic, the staff was still able to provide quality services and mitigate the effects of the pandemic, which continued to show their responsiveness and commitment to their patients.

Health workers uphold a human rights and patient-centered approach. Most men acknowledged that the health workers at the club uphold their human rights which help them to engage better in care and feel satisfied with the services provided at the club. They reported that they are treated with respect, dignity and this makes them feel 'like they matter'. They also felt that they have never been discriminated against because of their HIV status and they are treated as human beings not defined by their HIV status. They report that this makes them feel comfortable to express themselves when they are in the club because the staff understand that their sickness does not define them. They also enjoyed coming to the club because there is not any differential treatment between men and women as they are all treated equally. They described the health workers as being fair, friendly, and honest. Equality to most men seemed to translate to being valued, seen, and heard in the same way as others. This made it feel like home, a place they can feel content and at ease. Furthermore, they are provided with access to HIV care as well as proper knowledge

regarding HIV and their status is kept confidential and private. An employed South African Xhosa speaking male patient who has an HIV negative wife and child, explained how they are treated:

> ***''They have ububele (kindness), they know how to treat us like humans, they know how to remind us when it is our date to take treatment'' (Participant 3).***

Another male patient also described the treatment at the club:

> ''They do not have favours; they treat us equally'' (Participant 6).

This shows that they appreciate the club staff members because they do not in any way exhibit condescending or self-blaming attitudes towards their HIV diagnosis but rather, they value and respect them. Therefore, the health workers' positive attitude reflects their desire to see them attain better health and remain in HIV care. This also shows that better treatment not only removes a barrier to care, but also produces a positive response, an investment in engaging in care. Therefore, respect engenders trust and helps build a patient and health provider relationship which makes patients see themselves as equal partners in their HIV treatment thus they understand the responsibility required to be adherent and continually engage with HIV treatment.

Perceived quality relationships within the club. All the participants appreciated the positive relationships that they have with the club facilitator, nurses and with women and other men at the club. They all pointed out that these relationships are founded on trust and have thus enriched their experience of the club and given them something to be grateful for. They believed that being with people who understand your illness is motivating and positively contributes to the preservation of a positive outlook towards their HIV status, helping them make better choices with regards to their health and wellness. They also stated that these positive relationships help them understand that they are 'not alone' and they have pillars of strength in the club which they can depend upon.
A Zimbabwean- Shona speaking Christian who attended a different AC before moving to Gugulethu said;

''It is a lot, we are friends there, we can communicate well and have good conversations, we are free to say anything, we know each other''(Participant 4).

This shows the importance of positive relationships as a crucial factor in retaining men in care and engagement in HIV services because they provide beneficial support, quality of care and good information sharing. Positive relationships with health providers seem to enhance men's experiences of the club and help promote their continued positive engagement with HIV services. Further, positive relationships between club members seem to provide a stream of mutual support.

Discussion

A health system that is well supported and funded can deliver HIV intervention programs that are able to meet their goals and promote patient satisfaction. ACs offer informational, emotional, affirmational, and social support through peer group engagement, clinical assessment, prepacked 2-month ART medication and referral for a group of stable patients to reduce pharmacy and patient load in mainstream care and incapacitation of clinicians for new patients. But how ACs work in practice, and what resource factors facilitate their success are not well understood. These resources can be in form of hardware or software factors which help determine the perceived effectiveness of different programs within the health system. Hardware factors are usually seen as more important however aspects of software factors are also important in influencing behaviour towards health promotion. This is what this study is bringing out. Health systems and its programs are conceptualized in terms of its software and hardware factors which contribute to the performance of the health system through structuring the behaviours, relationships and decision making. Hardware factors comprise governance and policy, information systems, medical products, and human resources (19). Whereas, software factors include communication, power, the values and norms and relationships within the AC (19). In the above findings, it is not only the hardware resources that provide facilitating factors for men to remain in care but also the software factors which enhance their experience of the club and therefore assist with continued engagement, retention, and adherence. The positive interaction of hardware and software factors enhance the adherence club performance drivers, contributing to its perceived effectiveness which has been

seen through their quality of care, continuity of care, retention, and high levels of patient satisfaction.

Patient-level factors provide the fertile ground for men to be able to engage with other facilitating factors within the wider ecological system. A study done in Swaziland found that patients' acceptance of their HIV status provided engagement and access to social support, counselling, knowledge and understanding of the health care (20). There have been studies that have reported on non-acceptance and denialism and their negative impact on adherence to HIV treatment, showing the importance of acceptance as a path towards engagement (20,21-24). This study shows male patients' willingness to sacrifice certain foods which they have been advised not to eat, limit alcohol, or stop drinking completely to be able to adhere to their medication and guidelines. Such commitment does not come easy, and it shows the patient's commitment to their treatment. Therefore, the intent and motivation to live longer and see their children grow helps them to maintain adherence to their HIV treatment, allowing them to be continuously engaged in HIV services.

Family members have been described in literature as sources of support and stress in respect to HIV care and support (25-28). In this study, family members are a critical element of the AC itself and should potentially be counted as part of the health system as they are important enablers (or disablers) of male patients attending the ART adherence club. Studies done in South Africa and other parts of the world have highlighted that dealing with HIV necessitates robust social and family support. Disclosure of HIV and AIDS status thus unlocks greater emotional and social support whilst positively impacting on how PLWHIV interact with other HIV-related services on multiple levels (26-29). The study findings show that families offer ways in which individuals can deal with stigma. However, if the stigma exists within the family, it potentially inhibits families from offering adequate support, which often leads to poor outcomes for people living with HIV (25,26). Family members are important supportive stakeholders of the AC. Their awareness and knowledge of the AC's impact on their loved one is influential for men attending the club. Therefore, where disclosure has been made, health workers working collaboratively with families can ensure constant engagement in

care. Where disclosure has not been made, AC facilitators should continuously educate patients on its benefits.

The role of CCWs, sometimes known as community health workers, is another facilitating factor in the uptake of HIV services for men. The findings in this study are like reports from Central America and Asia reporting that CHWs can escalate HIV services uptake (30,31). Similarly, studies in Zambia, Mozambique, Uganda, and Rwanda examining the roles of CHWs found that, through adherence counselling and defaulter tracing, they play an important role which helps improve retention rates (30,31). Moreover, through CHW support, a cohort study done in South Africa reported better viral suppression at six months. Another study found that engaging men as HIV CHWs may improve ART-related outcomes as well as potentially contribute to the 'wider gender transformation agenda in South Africa' (32). The study further points out that this requires more than just hiring more men in care but the emotional and political commitment to encourage 'equitable healthier masculinities. CHWs have been identified as key intermediaries between health services, health workers and patients (30-32). This makes them a bridge which improves the patient-health worker and HIV services relationship (30). Although they have an undeniable impact in the health system, they still face challenges. Mainstreaming CHWs into the wider health sector could help mitigate some of these challenges and continue to improve men's utilisation of HIV services.

The results of this study support the assertion that a responsive health system has a better chance of retaining men in care and maintaining substantial rates of adherence to ART in the Adherence Club (2). A quality relationship between health workers and men allows for a positive experience of the health system which is associated with better adherence for men with programs and services offered at the AC. Several qualitative studies that have observed patient-health worker relationships reported that effective health worker and patient relationships potentially improves adherence to therapy among patients (33,34). Further, there have been studies that have reported on a positive association between the quality of the patient-health worker relationship and self-reported adherence to ART. This provides evidence that software factors of the health system, in this case, interpersonal aspects, may directly correlate with the health and better outcomes of PLHIV (33).

Also, in this relationship, trust in the health worker is seen as the key element and this translates as the provider having the best interests of the client (33, 34). Therefore, trust in the health system provides assurance for men that health programs such as the ART adherence club allocated to engage them in their HIV treatment will work. This is because of their experience of adherence clubs' administration efficiency, good quality service coverage, and provision and timely access of HIV treatment.

Moreover, the relationships between club members are crucial because they promote group cohesiveness which facilitates a 'home feel' and a feeling of 'I am not alone' thereby promoting retention and ART adherence for club members (33-36) and especially for men (37). This study has shown that male patients appreciate their human rights being upheld by the health workers as that brings about a sense of accountability and being seen as 'human being foremost' and not defined by their HIV status. A human rights approach in health is critical because it offers opportunities for access, accountability, agency, and redress for individuals to enjoy their highest attainable standard of health (38). London (2014) asserts that a human rights approach allows for the provision and creation of an institutional culture that accommodates interventions targeted at those mostly affected. This means incorporating interventions focused on the prevention and treatment of HIV among men who are often excluded from the HIV mandate. A patient-centered approach has also been identified in this study as a facilitating factor because it sees the person and not the illness. It focuses on the individual's capabilities and helps tailor services to meet their needs (38). In the AC, there is provision of food, individual sessions for sensitive matters, more individual responsibility, and less guidance and monitoring. A patients' centered approach allows men to be active participants as well as collaborative partners in their own treatment.

This study also found that the skills and competence of health workers contributed to the retention of men in care and facilitated their engagement with HIV services at the health system level. Existing studies found that patients that perceived their health workers as competent and acknowledging them as 'a whole person' was one of the key predictors of ART adherence in primary care settings (33, 34). Friendliness has been shown in this study through the male patients perceiving the health workers as approachable, communicating, and treating them well supporting the notion that male

friendly health systems have a potential to retain men in care (21). Some men in this study felt that being served by a male health worker allowed them to open about their sexuality and problems relating to sex. There have been reports on the positive response received in Khayelitsha that has a men's clinic with male health workers only. To a certain extent, more male health workers might improve men's engagement with HIV services among other health system interventions (2,21). Such clinics can be upscaled and implemented in various places to maintain its sustainability in the continued engagement of men in the HIV cascade.

Although gender norms, masculinity, and patriarchal norms were reported to negatively influence the uptake and engagement of men in HIV services (2,21,39), this study found that gender norms and expectations of men as the head and provider influences their uptake of HIV services positively. The findings show that the power of the provider frame encourages men in their engagement with HIV services. It helps them understand what is at stake when they stop taking their treatment. They understand the risks involved in defaulting which might lead to death and vulnerability of their family economically. Because their families mean a lot to them, they want to continue providing for them and playing their role. A study reports that failure to engage men in HIV services can severely impact households as their role often includes being income generators (40).

The implications of the study for AC design and management suggest that focus should not only be on scaling up treatment, information, medication, and human resource but also training, monitoring, and evaluating health worker service delivery to patients through emphasis on building positive working relationships and communication. This could involve practical role playing that draws attention to rapport building, patient-centered and human rights approaches, power dynamics and how they affect their behaviour and their relationship with the patient. There is a need for interventions to focus on multilevel, contextual, and cultural explanations and move away from individualistic models of male health behaviours and practices to ensure efficient HIV/AIDS programs are created to engage more men in HIV care (41). Patient-centered and human rights approaches have yielded positive experiences for men at the club. The training on how to deliver proper approaches in practice should be made explicit. Every health worker who facilitates the club can be trained on how to manage group facilitation. Families should be recognised as important

stakeholders. AC facilitators should articulate to the club members the benefits of disclosure and family support. As some participants have shared, the club, through the community worker, could work closely with families to ensure constant utilisation of HIV services by men. The role of CCWs is critical. Therefore, continuous timeous support from the clinic is vital for them to mitigate the challenges they might face when they go out to the community.

A limitation of this study is its relatively small sample. The sample size was small to support an in-depth case orientation data analysis of the study investigation. This allowed the researcher to conduct an in-depth exploration of the phenomena of a specific context thereby capturing a rich textured understanding of the participants value cocreation of the AC in Gugulethu NY1. understanding participants value cocreation of the AC in Gugulethu NY1(41). Another limitation is that the study was self-reported and that could potentially open room for bias. The strength of this study is its demonstration of the socio-ecological approach of one strategy in facilitating the engagement of HIV services by men. This shows that strategies used to engage men in HIV services should exist and constructively interact with all levels in the socio-ecological contexts for the strategy to potentially be effective. This study also shows how the club facilitates a safe space for acceptance and family engagement in men staying in care as well as the promotion of their physical health, mental and emotional well-being assisting in their retention, adherence, and engagement in HIV services.

Understanding the drivers of HIV risks and non-adherence involved at each level of the socio-ecological model and mitigating such risks is a critical step in engaging men in HIV treatment hence the adherence club is perceived as an effective strategy (35). The findings in this study show that the different levels of the socio-ecological model have a bearing on men being adherent. Most men in this study have indicated how their willingness to be adherent and the support of their family has been crucial in their journey. The health workers have also indicated that the AC is only once in 2 or 3 months hence the patients and their families do most of the heavy lifting. What has been shown to be a crucial resource is their ability to know and understand the how and when to effectively interact with the resources that the Health Workers have impacted them with despite the impinging socio-ecological factors that might impede on their adherence. This shows that it is not the number

of resources that matter, but the ability to utilize them in ways that speak to their willingness to be adherent no matter the challenges. As the community workers depict the challenges and the causes of the non-adherence, this highlights how even though there are sufficient resources in the club, their motivation and attitude to stay in the club is one of the driving forces for their engagement.

Further research can investigate the role of the CCWs in the engagement and reengagement of men in HIV services. Also, the relationship between the AC and family members and its impact on men attending the club can be explored. Further research will be required to evaluate the implementation of the study findings in a different setting. Moreover, research can focus on evaluating the perceived effectiveness of other strategies developed to engage men in HIV services.

As highlighted in this study, the number of men utilising HIV services in this AC is increasing. However, other studies have found that it still fares lower than women as a result there is a need to improve policy and strategies to purposefully include men in HIV service (8,37, 39,43). There is also a need to improve strategies to engage men globally in the HIV cascade and this will be possible through collaboration of different stakeholders and the knowledge and understanding of which hardware and software factors promote engagement and health seeking behaviors to facilitate their retention and engagement of men in HIV services. Future research can evaluate the perceived effectiveness of other strategies used to engage men in HIV services either through testing or treatment.

Authors note.

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Declaration of Conflicting of Interest

The author declared no potential conflicts of interest.

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Part D: Appendices:

Appendix A: Xhosa translated Information Sheet and Consent Form

UNIVERSITY OF CAPE TOWN
IYUNIVESITHI YASEKAPA • UNIVERSITEIT VAN KAAPSTAD

Title: A case study evaluating the effectiveness of ACs in Gugulethu as a strategy for mobilizing and engaging men in HIV treatment. / *Isihloko: Uvavanyo lohlobo amaqela okubambelela kunyango eGugulethu asebenza ngangayo njengecebo lokuhlanganisa nokubandakanya amadoda kunyango lwentsholongwane kagawulayo.*

PRINCIPAL INVESTIGATOR/*UMPHANDI OPHAMBILI*

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Department/*Isebe*: Social and Behavioral Sciences. Public Health. University of Cape Town

Address/*Idilesi*: University of Cape Town. Health science. Observatory.7708

Phone/*Umnxeba*: 0797803520

INFORMATION SHEET/*IPHEPHA ELINENKCUKACHA*

The project is concerned with understanding the effectiveness of different strategies in engaging men living with HIV. This sub-study tries to assess the perceived impact of the ART adherence club in retaining, engaging, and mobilizing men through a qualitative approach which involves everyone as a participant who is part of the club to understand how it facilitates engagement. This means that family members will potentially be participants for this study but will only be allowed to participate with your consent first.

Efforts will be made by the researcher to ensure that you remain anonymous, and all information provided in the interviews kept confidential. All information collected will be carefully stored and locked away. We would appreciate your participation in the interviews.

Olu phando lujolise ekuqondeni ukusebenza kwamacebo ohlukeneyo okuhlanganisa amadoda aphila nentsholongwane kagawulayo. Olu phononongo luzama ukuvavanya ifuthe elibonakalayo lamaqela okubambelela kunyango lwe-ART ekugcineni, ekubandakanyeni, kunye nasekuhlanganiseni amadoda ngokusebenzisa indlela yovavanyo equalitative ebandakanya wonke umntu njengomthathi-nxaxheba ukuqonda indlela lamaqela aququzelela ngayo intlanganisela. Oku kuthetha ukuba amalungu osapho aya kuba nenxaxheba kwesi sifundo kodwa aya kuvunyelwa kuphela ukuba athathe inxaxheba ngemvume yakho kuqala.

Iinzame ziya kwenziwa ngumphandi ukuqinisekisa ukuba uhlala ungaziwa kwaye lonke ulwazi olunikezwe kudliwanondlebe lugcinwa luyimfihlo. Zonke iinkcukacha eziqokelelweyo ziya kugcinwa ngononophelo kwaye zitshixelwe. Siya kukuvuyela ukuthatha kwakho inxaxheba kudliwanondlebe.

PROCESS/*INKQUBO*

All interviews will be telephonic with the researcher. They will approximately be an hour. The participants will be asked to be in a quiet room so that they communication is clear between them and the researcher. With your permission, the interview will be recorded, and the recording will be safely stored on the researcher's computer. All names will be kept confidential. To protect your identities and data, pseudo names will be used and only the research supervisors apart from the researcher will have access to data Once study is completed, the recording will be kept safe and deleted after 5 years. You will receive a transport voucher to cover expenses incurred by travelling to take part in this study.

Ukuthatha kwakho inxaxheba kudliwanondlebe kuya kwenziwa ngomnxeba nomphandi kwaye kuya kuthatha malunga neyure. Abathathi-nxaxheba baya kucelwa ukuba babe kwigumbi elithe cwaka ukuze unxibelelwano lucace phakathi kwabo nomphandi. Udliwanondlebe luza kushicelelwa ngocoselelo kwaye lugcinwe ngokukhuselekileyo kwikhompyuter yomphandi. Onke amagama aya kugcinwa eyimfihlo. Ukukhusela ubuwena kunye nedatha, amagama obuxoki aza kusetyenziswa kwaye izokuba ngabahleli bophando nomphandi abaya kuba nakho ukufikelela kwidatha. Lwakuba uphando lugqityiwe, ushicelelo luya kugcinwa lukhuselekile kwaye lucinywe emva kweminyaka emi-5. Uyakufumana ivawutsha yokuhlawula iindleko zohambo ukuze ukwazi uthatha inxaxheba kolu phando.

RISKS/*INGOZI*

There are not any physical risks in taking part in this study. If there is any emotional harm induced by the questionnaire, you will be referred to a social worker.

Akukho bungozi ngokwasemzimbeni ekuthatheni inxaxheba kolu phando. Ukuba kukho nawuphi na umonakalo ngokwasemoyeni, uya kuthunyelwa kunontlalontle.

BENEFITS/I*INZUZO*

If you decide to participate in this study, this will assist in the collection of information regarding the perceived effectiveness of ACs in Gugulethu. These findings will help you understand and utilise the full benefits of ACs. The study findings will assist health workers to understand how best to improve your experiences with the adherence club and understand your needs to make your experience at the club better.

Ukuba uthatha isigqibo sokuthatha inxaxheba kolu phando, oku kuya kunceda ekuqokeleleni ulwazi malunga nokusebenza amaqela okubambelela kunyango eGugulethu. Ezi ziphumo ziya kukunceda uqonde kwaye usebenzise izibonelelo eziphelelelyo zeeklabhu zokubambelela kunyango. Iziphumo zophando ziya kunceda abasebenzi bezempilo ukuba baqonde ukuba bangawaphucula njani amava akho kwaye bangaziqonda njani iimfuno zakho ukwenza amava akho kwiklabhu abe ngcono.

WITHDRAWAL/*UKURHOXA*

Your participation in this study is voluntary. No penalty or prejudice will be held against you in the Adherence Club should you choose to withdraw. The reason for your withdrawal will not be asked. Any information that has already been shared will not be used without your consent. All information collected in this study will be kept private and confidential; there will not be any identifiable information.

If you have any concerns or issues at any point during the study, you may contact either the UCT Human Research Ethics Committee hrec-enquiries@uct.ac.za or reach the UCT HREC Chairperson on this number 021 650 1236 , my supervisors on; Christopher Colvin. cj.colvin@uct.ac.za and Nonzuzo Mbokazi. nonzuzo.mbokazi@uct.ac.za .

Ukuthatha kwakho inxaxheba kolu phando kungokuzithandela. Ungarhoxa nanini na ngaphandle kokuchaza isizathu, ngaphandle kokuthintelwa okanye ukohlwaywa okanye ukuthatha kwakho inxaxheba kwiklabhu yokubambelela kunyango. Ukuba ukhetha ukurhoxa, umphandi uzibophelela ukuba angasebenzisi naluphi na ulwazi olunikezileyo ngaphandle kwemvume etyikityiweyo. Lonke ulwazi oluqokelelweyo kolu phando luya kugcinwa luyimfihlo kwaye; awuyi kuchongwa ngegama okanye ngokudibana.

Ukuba unayo nayiphi na inkxalabo okanye imiba nangaliphi na ixesha ngexesha lesifundo, ungaqhagamshelana neUCT Human Research Ethics Committee hrec-enquiries@uct.ac.za okanye ufike kuSihlalo we-UCT HREC kule nombolo 021 650 1236, abaphathi bam; UChristopher Colvin. cj.colvin@uct.ac.za kunye noNonzuzo Mbokazi. nonzuzo.mbokazi@uct.ac.za.

Consent Form/*IFom yeMvume*

I……have gone through the information sheet and I am aware of what the study entails. I understand that my study participation is voluntary therefore I can freely withdraw anytime. By signing, I am confirming that I have had time to ask questions and I am satisfied with the responses. I give my permission for the data collected during the interview to be utilized for research purposes and academic publication.

I consent to take part in this study.

Ngokutyikitya olu xwebu

Ndizifundile iinkcukacha ngolu phando kwaye ndiyazi ukuba isifundo simalunga nantoni. Ndiyaqonda ukuba ukuthatha kwam inxaxheba kolu phando kungokuzithandela kwaye ndikhululekile ukurhoxa nanini na. Ngokutyikitya ndiqinisekisa ukuba ndibenethuba lokubuza imibuzo kwaye ndonelisekile ziimpendulo neenkcazo endizinikwe. Ndinika imvume yam kubaphandi ukuba basebenzise ulwazi endilunika kudliwanondlebe ngeenjongo zophando kunye neenjongo zokupapashwa kwezemfundo.

Ndiyavuma ukuthatha inxaxheba kolu phando.

Participant's signature _____ Date/Umhla _____

Witness signature _____Date/Umhla _____

Investigator's signature _____ Date/Umhla _____

Consent for a Family member to participate

I……give consent to my family member who I have disclosed to and is aware of my HIV status to be contacted and interviewed for the purposes of this research study. I am comfortable with sharing their contact details with the research team

Imvume yokuba ilungu loSapho lithathe inxaxheba

Ndinika imvume kwilungu losapho endithe ndalichaza kwaye ndiyazi ngemeko yam ye-HIV ukuba kuqhagamshelwane nayo kwaye kwenziwe udliwanondlebe ngeenjongo zolu phando. Ndikhululekile ngokwabelana ngeenkcukacha zabo kunye neqela lophando.

I agree/Ndiyavuma: ☐ Yes ☐ No

Participants Signature/Tyikitya _____

Appendix B: Information sheet and consent for staff and family members

UNIVERSITY OF CAPE TOWN
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Title: A case study evaluating the effectiveness of ACs in Gugulethu as a strategy for mobilizing and engaging men in HIV treatment.

PRINCIPAL INVESTIGATOR

Name: Petronella Ncube.

Department: Social and Behavioral Sciences .Public Health .University of Cape Town

Address: University of Cape Town. Health science. Observatory.7708

Phone: 0797803520

INFORMATION SHEET

The project is concerned with understanding the effectiveness of different strategies in engaging men living with HIV. This sub-study tries to assess the perceived impact of the ART adherence club in retaining, engaging, and mobilizing men through a qualitative approach which involves everyone as a participant who is part of the club to understand how it facilitates engagement. This means that family members will potentially be participants for this study but will only be allowed to participate with your consent first.

Efforts will be made by the researcher to ensure that you remain anonymous, and all information provided in the interviews kept confidential. All information collected will be carefully stored and locked away. We would appreciate your participation in the interviews.

PROCESS

All interviews will be telephonic with the researcher. They will approximately be an hour. The participants will be asked to be in a quiet room so that there is clear communication between them and the researcher. With your permission, the interview will be recorded and the recording will be safely stored on the researcher's computer. All names will be kept confidential. To protect your identities and data, pseudo names will be used and only the research supervisors apart from the researcher will have access to data Once study is completed, the recording will be kept safe and deleted after 5 years. You will receive a transport voucher to cover expenses incurred by travelling to take part in this study.

RISKS

There are not any physical risks in taking part in this study. If there is any emotional harm induced by the questionnaire, you will be referred to a social worker.

BENEFITS

If you decide to participate in this study, this will assist in the collection of information regarding the perceived effectiveness of ACs in Gugulethu. These findings will help you understand and utilise the full benefits of ACs. The study findings will assist health workers to understand how best to improve your experiences with the adherence club and understand your needs to make your experience at the club better.

WITHDRAWAL

Your participation in this study is voluntary. No penalty or prejudice will be held against you in the Adherence Club should you choose to withdraw. The reason for your withdrawal will not be asked. Any information that has already been shared will not be used without your consent. All information collected in this study will be kept private and confidential; there won't be any identifiable information.

If you have any concerns or issues at any point during the study, you may contact either the UCT Human Research Ethics Committee hrec-enquiries@uct.ac.za or reach the UCT HREC Chairperson on this number 021 650 1236 , my supervisors on; Christopher Colvin. cj.colvin@uct.ac.za and Nonzuzo Mbokazi. nonzuzo.mbokazi@uct.ac.za .

Consent Form

By signing this document

I……have gone through the information sheet and I am aware of what the study entails. I understand that my study participation is voluntary therefore I can freely withdraw anytime. By signing, I am confirming that I have had time to ask questions and I am satisfied with the responses. I give my permission for the data collected during the interview to be utilized for research purposes and academic publication.

I consent to take part in this study.

Participant's signature _____ Date _____

Witness signature _____Date _____

Investigator's signature _____ Date _____

Appendix C: Semi- Interview Schedule

Semi- Interview schedule for patients

1. What has been your experience with the Adherence Club?
2. How well are you managing your health day to day ever since you started coming to the club?
3. What is your attitude towards your treatment?
4. Has coming to the club motivated you to adhere to your pills and encourage your peers to do likewise?
5. What has been the benefits of attending the Adherence Club?
6. How is your relationship like with the people at the club? The facilitator? The club members? The counselor?
7. Is there information that is provided at the club which you find helpful?
8. Does anyone at home know about the club? Do they come collect pills for you?
9. What has been the challenges that you have faced at the club? What can be done differently?

Semi- Interview schedule for facilitators

1. How would you describe your role in the adherence club?
2. What are the benefits of attending the club?
3. Are there any disparities between men and women who attend the club?
4. What are your thoughts around patients who stop coming to the club?
5. What can be improved that is of concern to them?
6. What are the challenges that you face?

Semi- Interview schedule for family members whom the HIV status has been disclosed to

1. Do you know anything about the adherence club and what it does?
2. How do you encourage your family member to attend the club?

3. Have you seen any change ever since they started attending the club?
4. Do you believe the club is beneficial to them?
5. Has the family environment changed in any way to encourage help the, eat well or go to the clinic?

Semi-Interview schedule for community workers

1. How would you describe your role in the club?
2. What impact do you see the club having on the patients that attend?
3. Are there any disparities between men and women in terms of attendance and adherence?
4. What has been their reasons for coming regularly?
5. What reasons do men (those who stop) have that have stopped coming?
6. How are family members attitude towards you and the adherence club?
7. What strategies does the club have in place to reengage them?
8. Are there any recommendations that you think will help foster adherence and retention?

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E: Helene.Visser@capetown.gov.za

2015-05-13

Re: Research Request: Using Information to Align Services and Link and Retain Men in the HIV Cascade (6478) (ID No: 10491)

Dear Mr Colvin,

Your research has been approved (noting that Nyanga CHC is a "combined" site with MDHS and Gugulethu CHC is under MDHS so WCG approval must be obtained for those sites as well.)

Klipfontein Sub District:	**Gugulethu, Masincedane, Vuyani, Nyanga**
Contact People	Mr K Nkoko (Sub District Manager) Tel: (021) 630-1667/ 082 433 1332 Mrs T Nojaholo (Head: PHC & Programmes) Tel: (021) 630-1626/ 084 220 0133

Please note the following:

1. All individual patient information obtained must be kept confidential.
2. Access to the clinics and its patients must be arranged with the relevant Managers such that normal activities are not disrupted.
3. A copy of the final report must be sent to the City Health Head Office, P O Box 2815 Cape Town 8001, within 6 months of its completion and feedback must also be given to the clinics involved.
4. Your project has been given an ID Number (10491). Please use this in any future correspondence with us.
5. No monetary incentives to be paid to clients on the City Health premises.

Thank you for your co-operation and please contact me if you require any further information or assistance.

Yours sincerely

pp DR VISSER

DR G H VISSER
MANAGER: SPECIALISED HEALTH

cc. Mr Nkoko & Mrs Nojaholo
Dr Jennings
Ms Caldwell

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room G50- Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492
Email: hrec-enquiries@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

08 February 2021

HREC REF: 652/2020

Prof C Colvin
Social & Behavioural Sciences
Public Health & Family Medicine-
Email: cj.colvin@uct.ac.za
Student: ncbpet001@myuct.ac.za

Dear Prof Colvin

PROJECT TITLE: CASE STUDY EVALUATING THE EFFECTIVENESS OF ADHERENCE CLUB IN GUGULETHU AS A STRATEGY FOR MOBILIZING AND ENGAGING MEN IN HIV TREATMENT - MASTERS CANDIDATE-MS PETRONELLA NCUBE SUB-STUDY LINKED TO HREC REF: 802/2014

Thank you for your response letter, addressing the issues raised by the Faculty of Health Sciences Human Research Ethics Committee (HREC).

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Please include the name of Prof Blockman as the HREC chairperson in the informed consent form.

This approval is subject to strict adherence to the HREC recommendations regarding research involving human participants during COVID -19, dated 17 March 2020 & 06 July 2020.

Approval is granted for one year until the 28 February 2022.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

The HREC acknowledge that the student: - Ms Petronella Ncube will also be involved in this study.

Please quote the HREC REF 652/2020 in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

Yours sincerely

pp TBriggs

PROFESSOR M BLOCKMAN
CHAIRPERSON, FACULTY OF HEALTH SCIENCES HUMAN RESEARCH ETHICS COMMITTEE
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
NHREC-registration number: REC-210208-007

This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use: Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2006), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI), and Declaration of Helsinki (2013) guidelines. The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals

Updated December 2019

I. About the Recommendations

A. Purpose of the Recommendations

ICMJE developed these recommendations to review best practice and ethical standards in the conduct and reporting of research and other material published in medical journals, and to help authors, editors, and others involved in peer review and biomedical publishing create and distribute accurate, clear, reproducible, unbiased medical journal articles. The recommendations may also provide useful insights into the medical editing and publishing process for the media, patients and their families, and general readers.

B. Who Should Use the Recommendations?

These recommendations are intended primarily for use by authors who might submit their work for publication to ICMJE member journals. Many non-ICMJE journals voluntarily use these recommendations (see www.icmje.org/journals-following-the-icmje-recommendations/). The ICMJE encourages that use but has no authority to monitor or enforce it. In all cases, authors should use these recommendations along with individual journals' instructions to authors. Authors should also consult guidelines for the re-

porting of specific study types (e.g., the CONSORT guidelines for the reporting of randomized trials); see www.equator-network.org.

Journals that follow these recommendations are encouraged to incorporate them into their instructions to authors and to make explicit in those instructions that they follow ICMJE recommendations. Journals that wish to be identified on the ICMJE website as following these recommendations should notify the ICMJE secretariat at www.icmje.org/journals-following-the-icmje-recommendations/journal-listing-request-form/. Journals that in the past have requested such identification but who no longer follow ICMJE recommendations should use the same means to request removal from this list.

The ICMJE encourages wide dissemination of these recommendations and reproduction of this document in its entirety for educational, not-for-profit purposes without regard for copyright, but all uses of the recommendations and document should direct readers to www.icmje.org for the official, most recent version, as the ICMJE updates the recommendations periodically when new issues arise.

C. History of the Recommendations

The ICMJE has produced multiple editions of this document, previously known as the Uniform Requirements for Manuscripts Submitted to Biomedical Journals (URMs). The URM was first published in 1978 as a way of standardizing manuscript format and preparation across journals. Over the years, issues in publishing that went well beyond manuscript preparation arose, resulting in the development of separate statements, up-dates to the document, and its renaming as "Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals" to reflect its broader scope. Previous versions of the document may be found in the "Archives" section of www.icmje.org.

II. Roles and Responsibilities of Authors, Contributors, Reviewers, Editors, Publishers, and Owners

A. Defining the Role of Authors and Contributors

1. Why Authorship Matters

Authorship confers credit and has important academic, social, and financial implications. Authorship also implies responsibility and accountability for published work. The following recommendations are intended to ensure that contributors who have made substantive intellectual contributions to a paper are given credit as authors, but also that contributors credited as authors understand their role in taking responsibility and being accountable for what is published.

Because authorship does not communicate what contributions qualified an individual to be an author, some journals now request and publish information about the contributions of each person named as having participated in a submitted study, at least for original research. Editors are strongly encouraged to develop and implement a contributorship policy. Such policies remove much of the ambiguity surrounding contributions, but leave unresolved the question of the quantity and quality of contribution that qualify an individual for authorship. The ICMJE has thus developed criteria for authorship that can be used by all journals, including those that distinguish authors from other contributors.

2. Who Is an Author?

The ICMJE recommends that authorship be based on the following 4 criteria:

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
2. Drafting the work or revising it critically for important intellectual content; AND
3. Final approval of the version to be published; AND
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

In addition to being accountable for the parts of the work he or she has done, an author should be able to identify which co-authors are responsible for specific other parts of the work. In addition, authors should have confidence in the integrity of the contributions of their co-authors.

All those designated as authors should meet all four criteria for authorship, and all who meet the four criteria should be identified as authors. Those who do not meet all four criteria should be acknowledged—see Section II.A.3 below. These authorship criteria are intended to reserve the status of authorship for those who deserve credit and can take responsibility for the work. The criteria are not intended for use as a means to disqualify colleagues from authorship who otherwise meet authorship criteria by denying them the opportunity to meet criterion #s 2 or 3. Therefore, all individuals who meet the first criterion should have the opportunity to participate in the review, drafting, and final approval of the manuscript.

The individuals who conduct the work are responsible for identifying who meets these criteria and ideally should do so when planning the work, making modifications as appropriate as the work progresses. We encourage collaboration and co-authorship with colleagues in the locations where the research is conducted. It is the collective responsibility of the authors, not the journal to which the work is submitted, to determine that all people named as authors meet all four criteria; it is not the role of journal editors to determine who qualifies or does not qualify for authorship or to arbitrate authorship conflicts. If agreement cannot be reached about who qualifies for authorship, the institution(s) where the work was performed, not the journal editor, should be asked to investigate. The criteria used to determine the order in which authors are listed on the byline may vary, and are to be decided collectively by the

author group and not by editors. If authors request removal or addition of an author after manuscript submission or publication, journal editors should seek an explanation and signed statement of agreement for the requested change from all listed authors and from the author to be removed or added.

The corresponding author is the one individual who takes primary responsibility for communication with the journal during the manuscript submission, peer review, and publication process. The corresponding author typically ensures that all the journal's administrative requirements, such as providing details of authorship, ethics committee approval, clinical trial registration documentation, and disclosures of relationships and activities, are properly completed and reported, although these duties may be delegated to one or more coauthors. The corresponding author should be available throughout the submission and peer-review process to respond to editorial queries in a timely way, and should be available after publication to respond to critiques of the work and cooperate with any requests from the journal for data or additional information should questions about the paper arise after publication. Although the corresponding author has primary responsibility for correspondence with the journal, the ICMJE recommends that editors send copies of all correspondence to all listed authors.

When a large multi-author group has conducted the work, the group ideally should decide who will be an author before the work is started and confirm who is an author before submitting the manuscript for publication. All members of the group named as authors should meet all four criteria for authorship, including approval of the final manuscript, and they should be able to take public responsibility for the work and should have full confidence in the accuracy and integrity of the work of other group authors. They will also be expected as individuals to complete disclosure forms.

Some large multi-author groups designate authorship by a group name, with or without the names of individuals. When submitting a manuscript authored by a group, the corresponding author should specify the group name if one exists, and clearly identify the group members who can take credit and responsibility for the work as authors. The byline of the article identifies who is directly responsible for the manuscript, and MEDLINE lists as authors whichever names appear on the byline. If the byline includes a group name, MEDLINE will list the names of individual group members who are authors or who are collaborators, sometimes called non-author contributors, if there is a note associated with the byline clearly stating that the individual names are elsewhere in the paper and whether those names are authors or collaborators.

3. Non-Author Contributors

Contributors who meet fewer than all 4 of the above criteria for authorship should not be listed as authors, but they should be acknowledged. Examples of activities that alone (without other contributions) do not qualify a contributor for authorship are acquisition of funding; general supervision of a research group or general administrative support; and writing assistance, technical editing, language editing, and proofreading. Those whose contributions do not justify authorship may be acknowledged individually or together as a group under a single heading (e.g., "Clinical Investigators" or "Participating Investigators"), and their contributions should be specified (e.g., "served as scientific advisors," "critically reviewed the study proposal," "collected data," "provided and cared for study patients", "participated in writing or technical editing of the manuscript").

Because acknowledgment may imply endorsement by acknowledged individuals of a study's data and conclusions, editors are advised to require that the corresponding author obtain written permission to be acknowledged from all acknowledged individuals.

B. Disclosure of Financial and Non-Financial Relationships and Activities, and Conflicts of Interest

Public trust in the scientific process and the credibility of published articles depend in part on how transparently an author's relationships and activities, directly or topically related to a work, are handled during the planning, implementation, writing, peer review, editing, and publication of scientific work.

The potential for conflict of interest and bias exists when professional judgment concerning a primary interest (such as patients' welfare or the validity of research) may be influenced by a secondary interest (such as financial gain). Perceptions of conflict of interest are as important as actual conflicts of interest.

Individuals may disagree on whether an author's relationships or activities represent conflicts. Although the presence of a relationship or activity does not always indicate a problematic influence on a paper's content, perceptions of conflict may erode trust in science as much as actual conflicts of interest. Ultimately, readers must be able to make their own judgments regarding whether an author's relationships and activities are pertinent to a paper's content. These judgments require transparent disclosures. An author's complete disclosure demonstrates a commitment to transparency and helps to maintain trust in the scientific process.

Financial relationships (such as employment, consultancies, stock ownership or options, honoraria, patents, and paid expert testimony) are the most easily identifiable, the ones most often judged to represent potential conflicts of interest and thus the most likely to undermine the credibility of the journal, the authors, and science itself. Other interests may also represent or be perceived as conflicts, such as personal relationships or rivalries, academic competition, and intellectual beliefs.

Authors should avoid entering in to agreements with study sponsors, both for-profit and nonprofit, that interfere

with authors' access to all of the study's data or that interfere with their ability to analyze and interpret the data and to prepare and publish manuscripts independently when and where they choose. Policies that dictate where authors may publish their work violate this principle of academic freedom. Authors may be required to provide the journal with the agreements in confidence.

Purposeful failure report those relationships or activities specified on the journal's disclosure form is a form of misconduct, as is discussed in Section III.B.

1. Participants

All participants in the peer-review and publication process—not only authors but also peer reviewers, editors, and editorial board members of journals—must consider and disclose their relationships and activities when fulfilling their roles in the process of article review and publication.

a. Authors

When authors submit a manuscript of any type or format they are responsible for disclosing all relationships and activities that might bias or be seen to bias their work. The ICMJE has developed a Disclosure Form to facilitate and standardize authors' disclosures. ICMJE member journals require that authors use this form, and ICMJE encourages other journals to adopt it.

b. Peer Reviewers

Reviewers should be asked at the time they are asked to critique a manuscript if they have relationships or activities that could complicate their review. Reviewers must disclose to editors any relationships or activities that could bias their opinions of the manuscript, and should recuse themselves from reviewing specific manuscripts if the potential for bias exists. Reviewers must not use knowledge of the work they're reviewing before its publication to further their own interests.

c. Editors and Journal Staff

Editors who make final decisions about manuscripts should recuse themselves from editorial decisions if they have relationships or activities that pose potential conflicts related to articles under consideration. Other editorial staff members who participate in editorial decisions must provide editors with a current description of their relationships and activities (as they might relate to editorial judgments) and recuse themselves from any decisions in which an interest that poses a potential conflict exists. Editorial staff must not use information gained through working with manuscripts for private gain. Editors should regularly publish their own disclosure statements and those of their journal staff. Guest editors should follow these same procedures.

Journals should take extra precautions and have a stated policy for evaluation of manuscripts submitted by individuals involved in editorial decisions. Further guidance is available from COPE (https://publicationethics.org/files/A_Short_Guide_to_Ethical_Editing.pdf) and WAME (http://wame.org/conflict-of-interest-in-peer-reviewed-medical-journals).

2. Reporting Relationships and Activities

Articles should be published with statements or supporting documents, such as the ICMJE Disclosure Form, declaring:

– Authors' relationships and activities; and

– Sources of support for the work, including sponsor names along with explanations of the role of those sources if any in study design; collection, analysis, and interpretation of data; writing of the report; any restrictions regarding the submission of the report for publication; or a statement declaring that the supporting source had no such involvement or restrictions regarding publication; and

– Whether the authors had access to the study data, with an explanation of the nature and extent of access, including whether access is ongoing.

To support the above statements, editors may request that authors of a study sponsored by a funder with a proprietary or financial interest in the outcome sign a statement, such as "I had full access to all of the data in this study and I take complete responsibility for the integrity of the data and the accuracy of the data analysis."

C. Responsibilities in the Submission and Peer-Review Process

1. Authors

Authors should abide by all principles of authorship and declaration of relationships and activities detailed in section IIA and B of this document.

a. Predatory or Pseudo-Journals

A growing number of entities are advertising themselves as "scholarly medical journals" yet do not function as such. These journals ("predatory"or "pseudo-journals") accept and publish almost all submissions and charge article processing (or publication) fees, often informing authors about this after a paper's acceptance for publication. They often claim to perform peer review but do not and may purposefully use names similar to well established journals. They may state that they are members of ICMJE but are not (see www.icmje.org for current members of the ICMJE) and that they follow the recommendations of organizations such as the ICMJE, COPE and WAME. Researchers must be aware of the existence of such entities and avoid submitting research to them for publication. Authors have a responsibility to evaluate the integrity, history, practices and reputation of the journals to which they submit manuscripts. Guidance from various organizations is available to help identify the characteristics of rep-

utable peer-reviewed journals (www.wame.org/identifying-predatory-or-pseudo-journals and www.wame.org/about/principles-of-transparency-and-best-practice). Seeking the assistance of scientific mentors, senior colleagues and others with many years of scholarly publishing experience may also be helpful.

Authors should avoid citing articles in predatory or pseudo-journals.

2. Journals

a. Confidentiality

Manuscripts submitted to journals are privileged communications that are authors' private, confidential property, and authors may be harmed by premature disclosure of any or all of a manuscript's details.

Editors therefore must not share information about manuscripts, including whether they have been received and are under review, their content and status in the review process, criticism by reviewers, and their ultimate fate, to anyone other than the authors and reviewers. Requests from third parties to use manuscripts and reviews for legal proceedings should be politely refused, and editors should do their best not to provide such confidential material should it be subpoenaed.

Editors must also make clear that reviewers should keep manuscripts, associated material, and the information they contain strictly confidential. Reviewers and editorial staff members must not publicly discuss the authors' work, and reviewers must not appropriate authors' ideas before the manuscript is published. Reviewers must not retain the manuscript for their personal use and should destroy paper copies of manuscripts and delete electronic copies after submitting their reviews.

When a manuscript is rejected, it is best practice for journals to delete copies of it from their editorial systems unless retention is required by local regulations. Journals that retain copies of rejected manuscripts should disclose this practice in their Information for Authors.

When a manuscript is published, journals should keep copies of the original submission, reviews, revisions, and correspondence for at least three years and possibly in perpetuity, depending on local regulations, to help answer future questions about the work should they arise.

Editors should not publish or publicize peer reviewers' comments without permission of the reviewer and author. If journal policy is to blind authors to reviewer identity and comments are not signed, that identity must not be revealed to the author or anyone else without the reviewers' expressed written permission.

Confidentiality may have to be breached if dishonesty or fraud is alleged, but editors should notify authors or reviewers if they intend to do so and confidentiality must otherwise be honored.

b. Timeliness

Editors should do all they can to ensure timely processing of manuscripts with the resources available to them. If editors intend to publish a manuscript, they should attempt to do so in a timely manner and any planned delays should be negotiated with the authors. If a journal has no intention of proceeding with a manuscript, editors should endeavor to reject the manuscript as soon as possible to allow authors to submit to a different journal.

c. Peer Review

Peer review is the critical assessment of manuscripts submitted to journals by experts who are usually not part of the editorial staff. Because unbiased, independent, critical assessment is an intrinsic part of all scholarly work, including scientific research, peer review is an important extension of the scientific process.

The actual value of peer review is widely debated, but the process facilitates a fair hearing for a manuscript among members of the scientific community. More practically, it helps editors decide which manuscripts are suitable for their journals. Peer review often helps authors and editors improve the quality of reporting.

It is the responsibility of the journal to ensure that systems are in place for selection of appropriate reviewers. It is the responsibility of the editor to ensure that reviewers have access to all materials that may be relevant to the evaluation of the manuscript, including supplementary material for e-only publication, and to ensure that reviewer comments are properly assessed and interpreted in the context of their declared relationships and activities.

A peer-reviewed journal is under no obligation to send submitted manuscripts for review, and under no obligation to follow reviewer recommendations, favorable or negative. The editor of a journal is ultimately responsible for the selection of all its content, and editorial decisions may be informed by issues unrelated to the quality of a manuscript, such as suitability for the journal. An editor can reject any article at any time before publication, including after acceptance if concerns arise about the integrity of the work.

Journals may differ in the number and kinds of manuscripts they send for review, the number and types of reviewers they seek for each manuscript, whether the review process is open or blinded, and other aspects of the review process. For this reason and as a service to authors, journals should publish a description of their peer-review process.

Journals should notify reviewers of the ultimate decision to accept or reject a paper, and should acknowledge the contribution of peer reviewers to their journal. Editors are encouraged to share reviewers' comments with co-reviewers of the same paper, so reviewers can learn from each other in the review process.

As part of peer review, editors are encouraged to review research protocols, plans for statistical analysis if separate from the protocol, and/or contracts associated with project-specific studies. Editors should encourage authors

to make such documents publicly available at the time of or after publication, before accepting such studies for publication. Some journals may require public posting of these documents as a condition of acceptance for publication.

Journal requirements for independent data analysis and for public data availability are in flux at the time of this revision, reflecting evolving views of the importance of data availability for pre- and post-publication peer review. Some journal editors currently request a statistical analysis of trial data by an independent biostatistician before accepting studies for publication. Others ask authors to say whether the study data are available to third parties to view and/or use/reanalyze, while still others encourage or require authors to share their data with others for review or reanalysis. Each journal should establish and publish their specific requirements for data analysis and post in a place that potential authors can easily access.

Some people believe that true scientific peer review begins only on the date a paper is published. In that spirit, medical journals should have a mechanism for readers to submit comments, questions, or criticisms about published articles, and authors have a responsibility to respond appropriately and cooperate with any requests from the journal for data or additional information should questions about the paper arise after publication (see Section III).

ICMJE believes investigators have a duty to maintain the primary data and analytic procedures underpinning the published results for at least 10 years. The ICMJE encourages the preservation of these data in a data repository to ensure their longer-term availability.

d. Integrity

Editorial decisions should be based on the relevance of a manuscript to the journal and on the manuscript's originality, quality, and contribution to evidence about important questions. Those decisions should not be influenced by commercial interests, personal relationships or agendas, or findings that are negative or that credibly challenge accepted wisdom. In addition, authors should submit for publication or otherwise make publicly available, and editors should not exclude from consideration for publication, studies with findings that are not statistically significant or that have inconclusive findings. Such studies may provide evidence that, combined with that from other studies through meta-analysis, might still help answer important questions, and a public record of such negative or inconclusive findings may prevent unwarranted replication of effort or otherwise be valuable for other researchers considering similar work.

Journals should clearly state their appeals process and should have a system for responding to appeals and complaints.

e. Diversity and Inclusion

To improve academic culture, editors should seek to engage a broad and diverse array of authors, reviewers, editorial staff, editorial board members, and readers.

f. Journal Metrics

The journal impact factor is widely misused as a proxy for research and journal quality and as a measure of the importance of specific research projects or the merits of individual researchers, including their suitability for hiring, promotion, tenure, prizes, or research funding. ICMJE recommends that journals reduce the emphasis on impact factor as a single measure, but rather provide a range of article and journal metrics relevant to their readers and authors.

3. Peer Reviewers

Manuscripts submitted to journals are privileged communications that are authors' private, confidential property, and authors may be harmed by premature disclosure of any or all of a manuscript's details.

Reviewers therefore should keep manuscripts and the information they contain strictly confidential. Reviewers must not publicly discuss authors' work and must not appropriate authors' ideas before the manuscript is published. Reviewers must not retain the manuscript for their personal use and should destroy copies of manuscripts after submitting their reviews.

Reviewers who seek assistance from a trainee or colleague in the performance of a review should acknowledge these individuals' contributions in the written comments submitted to the editor. These individuals must maintain the confidentiality of the manuscript as outlined above.

Reviewers are expected to respond promptly to requests to review and to submit reviews within the time agreed. Reviewers' comments should be constructive, honest, and polite.

Reviewers should declare their relationships and activities that might bias their evaluation of a manuscript and recuse themselves from the peer-review process if a conflict exists.

D. Journal Owners and Editorial Freedom

1. Journal Owners

Owners and editors of medical journals share a common purpose, but they have different responsibilities, and sometimes those differences lead to conflicts.

It is the responsibility of medical journal owners to appoint and dismiss editors. Owners should provide editors at the time of their appointment with a contract that clearly states their rights and duties, authority, the general terms of their appointment, and mechanisms for resolving conflict. The editor's performance may be assessed using mutually agreed-upon measures, including but not necessarily limited to readership, manuscript submissions and handling times, and various journal metrics.

Owners should only dismiss editors for substantial reasons, such as scientific misconduct, disagreement with the long-term editorial direction of the journal, inadequate performance by agreed-upon performance metrics, or inappropriate behavior that is incompatible with a position of trust.

Appointments and dismissals should be based on evaluations by a panel of independent experts, rather than by a small number of executives of the owning organization. This is especially necessary in the case of dismissals because of the high value society places on freedom of speech within science and because it is often the responsibility of editors to challenge the status quo in ways that may conflict with the interests of the journal's owners.

A medical journal should explicitly state its governance and relationship to a journal owner (e.g., a sponsoring society).

2. Editorial Freedom

The ICMJE adopts the World Association of Medical Editors' definition of editorial freedom (http://wame.org/editorial-independence), which holds that editors-in-chief have full authority over the entire editorial content of their journal and the timing of publication of that content. Journal owners should not interfere in the evaluation, selection, scheduling, or editing of individual articles either directly or by creating an environment that strongly influences decisions. Editors should base editorial decisions on the validity of the work and its importance to the journal's readers, not on the commercial implications for the journal, and editors should be free to express critical but responsible views about all aspects of medicine without fear of retribution, even if these views conflict with the commercial goals of the publisher.

Editors-in-chief should also have the final say in decisions about which advertisements or sponsored content, including supplements, the journal will and will not carry, and they should have final say in use of the journal brand and in overall policy regarding commercial use of journal content.

Journals are encouraged to establish an independent and diverse editorial advisory board to help the editor establish and maintain editorial policy. To support editorial decisions and potentially controversial expressions of opinion, owners should ensure that appropriate insurance is obtained in the event of legal action against the editors, and should ensure that legal advice is available when necessary. If legal problems arise, the editor should inform their legal adviser and their owner and/or publisher as soon as possible. Editors should defend the confidentiality of authors and peer-reviewers (names and reviewer comments) in accordance with ICMJE policy (see Section II C.2.a). Editors should take all reasonable steps to check the facts in journal commentary, including that in news sections and social media postings, and should ensure that staff working for the journal adhere to best journalistic practices including contemporaneous note-taking and seeking a response from all parties when possible before publication. Such practices in support of truth and public interest may be particularly relevant in defense against legal allegations of libel.

To secure editorial freedom in practice, the editor should have direct access to the highest level of ownership, not to a delegated manager or administrative officer.

Editors and editors' organizations are obliged to support the concept of editorial freedom and to draw major transgressions of such freedom to the attention of the international medical, academic, and lay communities.

E. Protection of Research Participants

All investigators should ensure that the planning conduct and reporting of human research are in accordance with the Helsinki Declaration as revised in 2013 (www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/). All authors should seek approval to conduct research from an independent local, regional, or national review body (e.g., ethics committee, institutional review board). If doubt exists whether the research was conducted in accordance with the Helsinki Declaration, the authors must explain the rationale for their approach and demonstrate that the local, regional, or national review body explicitly approved the doubtful aspects of the study. Approval by a responsible review body does not preclude editors from forming their own judgment whether the conduct of the research was appropriate.

Patients have a right to privacy that should not be violated without informed consent. Identifying information, including names, initials, or hospital numbers, should not be published in written descriptions, photographs, or pedigrees unless the information is essential for scientific purposes and the patient (or parent or guardian) gives written informed consent for publication. Informed consent for this purpose requires that an identifiable patient be shown the manuscript to be published. Authors should disclose to these patients whether any potential identifiable material might be available via the Internet as well as in print after publication. Patient consent should be written and archived with the journal, the authors, or both, as dictated by local regulations or laws. Applicable laws vary from locale to locale, and journals should establish their own policies with legal guidance. Since a journal that archives the consent will be aware of patient identity, some journals may decide that patient confidentiality is better guarded by having the author archive the consent and instead providing the journal with a written statement that attests that they have received and archived written patient consent.

Nonessential identifying details should be omitted. Informed consent should be obtained if there is any doubt that anonymity can be maintained. For example, masking the eye region in photographs of patients is inadequate

protection of anonymity. If identifying characteristics are de-identified, authors should provide assurance, and editors should so note, that such changes do not distort scientific meaning.

The requirement for informed consent should be included in the journal's instructions for authors. When informed consent has been obtained, it should be indicated in the published article.

When reporting experiments on animals, authors should indicate whether institutional and national standards for the care and use of laboratory animals were followed. Further guidance on animal research ethics is available from the International Association of Veterinary Editors' Consensus Author Guidelines on Animal Ethics and Welfare (http://www.veteditors.org/consensus-author-guidelines-on-animal-ethics-and-welfare-for-editors).

III. Publishing and Editorial Issues Related to Publication in Medical Journals

A. Corrections, Retractions, Republications, and Version Control

Honest errors are a part of science and publishing and require publication of a correction when they are detected. Corrections are needed for errors of fact. Matters of debate are best handled as letters to the editor, as print or electronic correspondence, or as posts in a journal-sponsored online forum. Updates of previous publications (e.g., an updated systematic review or clinical guideline) are considered a new publication rather than a version of a previously published article.

If a correction is needed, journals should follow these minimum standards:

- The journal should publish a correction notice as soon as possible detailing changes from and citing the original publication; the correction should be on an electronic or numbered print page that is included in an electronic or a print Table of Contents to ensure proper indexing.
- The journal should also post a new article version with details of the changes from the original version and the date(s) on which the changes were made.
- The journal should archive all prior versions of the article. This archive can be either directly accessible to readers or can be made available to the reader on request.
- Previous electronic versions should prominently note that there are more recent versions of the article.
- The citation should be to the most recent version.

Pervasive errors can result from a coding problem or a miscalculation and may result in extensive inaccuracies throughout an article. If such errors do not change the direction or significance of the results, interpretations, and conclusions of the article, a correction should be published that follows the minimum standards noted above.

Errors serious enough to invalidate a paper's results and conclusions may require retraction. However, retraction with republication (also referred to as "replacement") can be considered in cases where honest error (e.g., a misclassification or miscalculation) leads to a major change in the direction or significance of the results, interpretations, and conclusions. If the error is judged to be unintentional, the underlying science appears valid, and the changed version of the paper survives further review and editorial scrutiny, then retraction with republication of the changed paper, with an explanation, allows full correction of the scientific literature. In such cases, it is helpful to show the extent of the changes in supplementary material or in an appendix, for complete transparency.

B. Scientific Misconduct, Expressions of Concern, and Retraction

Scientific misconduct in research and non-research publications includes but is not necessarily limited to data fabrication; data falsification, including deceptive manipulation of images; purposeful failure to disclose relationships and activities; and plagiarism. Some people consider failure to publish the results of clinical trials and other human studies a form of scientific misconduct. While each of these practices is problematic, they are not equivalent. Each situation requires individual assessment by relevant stakeholders. When scientific misconduct is alleged, or concerns are otherwise raised about the conduct or integrity of work described in submitted or published papers, the editor should initiate appropriate procedures detailed by such committees as the Committee on Publication Ethics (COPE) (publicationethics.org/resources/flowcharts), consider informing the institutions and funders, and may choose to publish an expression of concern pending the outcomes of those procedures. If the procedures involve an investigation at the authors' institution, the editor should seek to discover the outcome of that investigation; notify readers of the outcome if appropriate; and if the investigation proves scientific misconduct, publish a retraction of the article. There may be circumstances in which no misconduct is proven, but an exchange of letters to the editor could be published to highlight matters of debate to readers.

Expressions of concern and retractions should not simply be a letter to the editor. Rather, they should be prominently labelled, appear on an electronic or numbered print page that is included in an electronic or a print Table of Contents to ensure proper indexing, and include in their heading the title of the original article. Online, the retraction and original article should be linked in both directions and the retracted article should be clearly labelled as retracted in all its forms (abstract, full text, PDF). Ideally, the authors of the retraction should be the same as those of the article, but if they are unwilling or unable the editor may under certain circumstances accept retractions by other responsible persons, or the editor may be the sole author of the retraction or expression of concern. The text of the retraction should explain why the article is being retracted and include a complete citation reference to that article.

Retracted articles should remain in the public domain and be clearly labelled as retracted.

The validity of previous work by the author of a fraudulent paper cannot be assumed. Editors may ask the author's institution to assure them of the validity of other work published in their journals, or they may retract it. If this is not done, editors may choose to publish an announcement expressing concern that the validity of previously published work is uncertain.

The integrity of research may also be compromised by inappropriate methodology that could lead to retraction.

See COPE flowcharts for further guidance on retractions and expressions of concern. See Section IV.g.i. for guidance about avoiding referencing retracted articles.

C. Copyright

Journals should make clear the type of copyright under which work will be published, and if the journal retains copyright, should detail the journal's position on the transfer of copyright for all types of content, including audio, video, protocols, and data sets. Medical journals may ask authors to transfer copyright to the journal. Some journals require transfer of a publication license. Some journals do not require transfer of copyright and rely on such vehicles as Creative Commons licenses. The copyright status of articles in a given journal can vary: Some content cannot be copyrighted (e.g., articles written by employees of some governments in the course of their work). Editors may waive copyright on other content, and some content may be protected under other agreements.

D. Overlapping Publications

1. Duplicate Submission

Authors should not submit the same manuscript, in the same or different languages, simultaneously to more than one journal. The rationale for this standard is the potential for disagreement when two (or more) journals claim the right to publish a manuscript that has been submitted simultaneously to more than one journal, and the possibility that two or more journals will unknowingly and unnecessarily undertake the work of peer review, edit the same manuscript, and publish the same article.

2. Duplicate and Prior Publication

Duplicate publication is publication of a paper that overlaps substantially with one already published, without clear, visible reference to the previous publication. Prior publication may include release of information in the public domain.

Readers of medical journals deserve to be able to trust that what they are reading is original unless there is a clear statement that the author and editor are intentionally republishing an article (which might be considered for historic or landmark papers, for example). The bases of this position are international copyright laws, ethical conduct, and cost-effective use of resources. Duplicate publication of original research is particularly problematic because it can result in inadvertent double-counting of data or inappropriate weighting of the results of a single study, which distorts the available evidence.

When authors submit a manuscript reporting work that has already been reported in large part in a published article or is contained in or closely related to another paper that has been submitted or accepted for publication elsewhere, the letter of submission should clearly say so and the authors should provide copies of the related material to help the editor decide how to handle the submission. See also Section IV.B.

This recommendation does not prevent a journal from considering a complete report that follows publication of a preliminary report, such as a letter to the editor, a preprint, or an abstract or poster displayed at a scientific meeting. It also does not prevent journals from considering a paper that has been presented at a scientific meeting but was not published in full, or that is being considered for publication in proceedings or similar format. Press reports of scheduled meetings are not usually regarded as breaches of this rule, but they may be if additional data tables or figures enrich such reports. Authors should also consider how dissemination of their findings outside of scientific presentations at meetings may diminish the priority journal editors assign to their work.

Authors who choose to post their work on a preprint server should choose one that clearly identifies preprints as not peer-reviewed work and includes disclosures of authors' relationships and activities. It is the author's responsibility to inform a journal if the work has been previously posted on a preprint server. In addition, it is the author's (and not the journal editors') responsibility to ensure that preprints are amended to point readers to subsequent versions, including the final published article.

In the event of a public health emergency (as defined by public health officials), information with immediate implications for public health should be disseminated without concern that this will preclude subsequent consideration for publication in a journal. We encourage editors to give priority to authors who have made crucial data publicly available (e.g., in a gene bank) without delay.

Sharing with public media, government agencies, or manufacturers the scientific information described in a paper or a letter to the editor that has been accepted but not yet published violates the policies of many journals. Such reporting may be warranted when the paper or letter describes major therapeutic advances; reportable diseases; or public health hazards, such as serious adverse effects of drugs, vaccines, other biological products, medical devices. This reporting, whether in print or online, should not jeopardize publication, but should be discussed with and agreed upon by the editor in advance when possible.

The ICMJE will not consider as prior publication the posting of trial results in any registry that meets the criteria noted in Section III.L. if results are limited to a brief (500

word) structured abstract or tables (to include participants enrolled, key outcomes, and adverse events). The ICMJE encourages authors to include a statement with the registration that indicates that the results have not yet been published in a peer-reviewed journal, and to update the results registry with the full journal citation when the results are published.

Editors of different journals may together decide to simultaneously or jointly publish an article if they believe that doing so would be in the best interest of public health. However, the National Library of Medicine (NLM) indexes all such simultaneously published joint publications separately, so editors should include a statement making the simultaneous publication clear to readers.

Authors who attempt duplicate publication without such notification should expect at least prompt rejection of the submitted manuscript. If the editor was not aware of the violations and the article has already been published, then the article might warrant retraction with or without the author's explanation or approval.

See COPE flowcharts for further guidance on handling duplicate publication.

3. Acceptable Secondary Publication

Secondary publication of material published in other journals or online may be justifiable and beneficial, especially when intended to disseminate important information to the widest possible audience (e.g., guidelines produced by government agencies and professional organizations in the same or a different language). Secondary publication for various other reasons may also be justifiable provided the following conditions are met:

1. The authors have received approval from the editors of both journals (the editor concerned with secondary publication must have access to the primary version).

2. The priority of the primary publication is respected by a publication interval negotiated by both editors with the authors.

3. The paper for secondary publication is intended for a different group of readers; an abbreviated version could be sufficient.

4. The secondary version faithfully reflects the authors, data, and interpretations of the primary version.

5. The secondary version informs readers, peers, and documenting agencies that the paper has been published in whole or in part elsewhere—for example, with a note that might read, "This article is based on a study first reported in the [journal title, with full reference]"—and the secondary version cites the primary reference.

6. The title of the secondary publication should indicate that it is a secondary publication (complete or abridged republication or translation) of a primary publication. Of note, the NLM does not consider translations to be "republications" and does not cite or index them when the original article was published in a journal that is indexed in MEDLINE.

When the same journal simultaneously publishes an article in multiple languages, the MEDLINE citation will note the multiple languages (e.g., Angelo M. Journal networking in nursing: a challenge to be shared. Rev Esc Enferm USP. 2011 Dec 45[6]:1281-2,1279-80,1283-4. Article in English, Portuguese, and Spanish. No abstract available. PMID 22241182).

4. Manuscripts Based on the Same Database

If editors receive manuscripts from separate research groups or from the same group analyzing the same data set (e.g., from a public database, or systematic reviews or meta-analyses of the same evidence), the manuscripts should be considered independently because they may differ in their analytic methods, conclusions, or both. If the data interpretation and conclusions are similar, it may be reasonable although not mandatory for editors to give preference to the manuscript submitted first. Editors might consider publishing more than one manuscript that overlap in this way because different analytical approaches may be complementary and equally valid, but manuscripts based upon the same dataset should add substantially to each other to warrant consideration for publication as separate papers, with appropriate citation of previous publications from the same dataset to allow for transparency.

Secondary analyses of clinical trial data should cite any primary publication, clearly state that it contains secondary analyses/results, and use the same identifying trial registration number as the primary trial and unique, persistent dataset identifier.

Sometimes for large trials it is planned from the beginning to produce numerous separate publications regarding separate research questions but using the same original participant sample. In this case authors may use the original single trial registration number, if all the outcome parameters were defined in the original registration. If the authors registered several substudies as separate entries in, for example, clinicaltrials.gov, then the unique trial identifier should be given for the study in question, The main issue is transparency, so no matter what model is used it should be obvious for the reader.

E. Correspondence

Medical journals should provide readers with a mechanism for submitting comments, questions, or criticisms about published articles, usually but not necessarily always through a correspondence section or online forum. The authors of articles discussed in correspondence or an online forum have a responsibility to respond to substantial criticisms of their work using those same mechanisms and should be asked by editors to respond. Authors of correspondence should be asked to declare any competing relationships or activities.

Correspondence may be edited for length, grammatical correctness, and journal style. Alternatively, editors may choose to make available to readers unedited correspondence, for example, via an online commenting system. Such commenting is not indexed in Medline unless it is subsequently published on a numbered electronic or print page. However the journal handles correspondence, it should make known its practice. In all instances, editors must make an effort to screen discourteous, inaccurate, or libellous comments.

Responsible debate, critique, and disagreement are important features of science, and journal editors should encourage such discourse ideally within their own journals about the material they have published. Editors, however, have the prerogative to reject correspondence that is irrelevant, uninteresting, or lacking cogency, but they also have a responsibility to allow a range of opinions to be expressed and to promote debate.

In the interests of fairness and to keep correspondence within manageable proportions, journals may want to set time limits for responding to published material and for debate on a given topic.

F. Fees

Journals should be transparent about their types of revenue streams. Any fees or charges that are required for manuscript processing and/or publishing materials in the journal shall be clearly stated in a place that is easy for potential authors to find prior to submitting their manuscripts for review or explained to authors before they begin preparing their manuscript for submission (http://publicationethics.org/files/u7140/Principles_of_Transparency_and_Best_Practice_in_Scholarly_Publishing.pdf).

G. Supplements, Theme Issues, and Special Series

Supplements are collections of papers that deal with related issues or topics, are published as a separate issue of the journal or as part of a regular issue, and may be funded by sources other than the journal's publisher. Because funding sources can bias the content of supplements through the choice of topics and viewpoints, journals should adopt the following principles, which also apply to theme issues or special series that have external funding and/or guest editors:

1. The journal editor must be given and must take full responsibility for the policies, practices, and content of supplements, including complete control of the decision to select authors, peer reviewers, and content for the supplement. Editing by the funding organization should not be permitted.

2. The journal editor has the right to appoint one or more external editors of the supplement and must take responsibility for the work of those editors.

3. The journal editor must retain the authority to send supplement manuscripts for external peer review and to reject manuscripts submitted for the supplement with or without external review. These conditions should be made known to authors and any external editors of the supplement before beginning editorial work on it.

4. The source of the idea for the supplement, sources of funding for the supplement's research and publication, and products of the funding source related to content considered in the supplement should be clearly stated in the introductory material.

5. Advertising in supplements should follow the same policies as those of the primary journal.

6. Journal editors must enable readers to distinguish readily between ordinary editorial pages and supplement pages.

7. Journal and supplement editors must not accept personal favors or direct remuneration from sponsors of supplements.

8. Secondary publication in supplements (republication of papers published elsewhere) should be clearly identified by the citation of the original paper and by the title.

9. The same principles of authorship and disclosure of relationships and activities discussed elsewhere in this document should be applied to supplements.

H. Sponsorship or Partnership

Various entities may seek interactions with journals or editors in the form of sponsorships, partnerships, meetings, or other types of activities. To preserve editorial independence, these interactions should be governed by the same principles outlined above for Supplements, Theme Issues, and Special Series (Section III.G).

I. Electronic Publishing

Most medical journals are now published in electronic as well as print versions, and some are published only in electronic form. Principles of print and electronic publishing are identical, and the recommendations of this document apply equally to both. However, electronic publishing provides opportunities for versioning and raises issues about link stability and content preservation that are addressed here.

Recommendations for corrections and versioning are detailed in Section III.A.

Electronic publishing allows linking to sites and resources beyond journals over which journal editors have no editorial control. For this reason, and because links to external sites could be perceived as implying endorsement of those sites, journals should be cautious about external linking. When a journal does link to an external site, it should state that it does not endorse or take responsibility or liability for any content, advertising, products, or other materials on the linked sites, and does not take responsibility for the sites' availability.

Permanent preservation of journal articles on a journal's website, or in an independent archive or a credible repository, is essential for the historical record. Removing an article from a journal's website in its entirety is almost never justified as copies of the article may have been downloaded even if its online posting was brief. Such archives

should be freely accessible or accessible to archive members. Deposition in multiple archives is encouraged. However, if necessary for legal reasons (e.g., libel action), the URL for the removed article must contain a detailed reason for the removal, and the article must be retained in the journal's internal archive.

Permanent preservation of a journal's total content is the responsibility of the journal publisher, who in the event of journal termination should be certain the journal files are transferred to a responsible third party who can make the content available.

Journal websites should post the date that nonarticle web pages, such as those listing journal staff, editorial board members, and instructions for authors, were last updated.

J. Advertising

Most medical journals carry advertising, which generates income for their publishers, but journals should not be dominated by advertisements, and advertising must not be allowed to influence editorial decisions.

Journals should have formal, explicit, written policies for advertising in both print and electronic versions. Best practice prohibits selling advertisements intended to be juxtaposed with editorial content on the same product. Advertisements should be clearly identifiable as advertisements. Editors should have full and final authority for approving print and online advertisements and for enforcing advertising policy.

Journals should not carry advertisements for products proven to be seriously harmful to health. Editors should ensure that existing regulatory or industry standards for advertisements specific to their country are enforced, or develop their own standards. The interests of organizations or agencies should not control classified and other nondisplay advertising, except where required by law. Editors should consider all criticisms of advertisements for publication.

K. Journals and the Media

Journals' interactions with media should balance competing priorities. The general public has a legitimate interest in all journal content and is entitled to important information within a reasonable amount of time, and editors have a responsibility to facilitate that. However media reports of scientific research before it has been peer-reviewed and fully vetted may lead to dissemination of inaccurate or premature conclusions, and doctors in practice need to have research reports available in full detail before they can advise patients about the reports' conclusions.

An embargo system has been established in some countries and by some journals to assist this balance, and to prevent publication of stories in the general media before publication of the original research in the journal. For the media, the embargo creates a "level playing field," which most reporters and writers appreciate since it minimizes the pressure on them to publish stories before competitors when they have not had time to prepare carefully. Consistency in the timing of public release of biomedical information is also important in minimizing economic chaos, since some articles contain information that has potential to influence financial markets. The ICMJE acknowledges criticisms of embargo systems as being self-serving of journals' interests and an impediment to rapid dissemination of scientific information, but believe the benefits of the systems outweigh their harms.

The following principles apply equally to print and electronic publishing and may be useful to editors as they seek to establish policies on interactions with the media:

- Editors can foster the orderly transmission of medical information from researchers, through peer-reviewed journals, to the public. This can be accomplished by an agreement with authors that they will not publicize their work while their manuscript is under consideration or awaiting publication and an agreement with the media that they will not release stories before publication of the original research in the journal, in return for which the journal will cooperate with them in preparing accurate stories by issuing, for example, a press release.
- Editors need to keep in mind that an embargo system works on the honor system—no formal enforcement or policing mechanism exists. The decision of a significant number of media outlets or biomedical journals not to respect the embargo system would lead to its rapid dissolution.
- Notwithstanding authors' belief in their work, very little medical research has such clear and urgently important clinical implications for the public's health that the news must be released before full publication in a journal. When such exceptional circumstances occur, the appropriate authorities responsible for public health should decide whether to disseminate information to physicians and the media in advance and should be responsible for this decision. If the author and the appropriate authorities wish to have a manuscript considered by a particular journal, the editor should be consulted before any public release. If editors acknowledge the need for immediate release, they should waive their policies limiting prepublication publicity.
- Policies designed to limit prepublication publicity should not apply to accounts in the media of presentations at scientific meetings or to the abstracts from these meetings (see Duplicate Publication). Researchers who present their work at a scientific meeting should feel free to discuss their presentations with reporters but should be discouraged from offering more detail about their study than was presented in the talk, or should consider how giving such detail might diminish the priority journal editors assign to their work (see Duplicate Publication).
- When an article is close to being published, editors or journal staff should help the media prepare accurate reports by providing news releases, answering questions, supplying advance copies of the article, or referring reporters to appropriate experts. This assistance should be con-

tingent on the media's cooperation in timing the release of a story to coincide with publication of the article.

L. Clinical Trials

i. Registration

The ICMJE's clinical trial registration policy is detailed in a series of editorials (see Updates and Editorials [www.icmje.org/news-and-editorials/] and FAQs [www.icmje.org/about-icmje/faqs/]).

Briefly, the ICMJE requires, and recommends that all medical journal editors require, registration of clinical trials in a public trials registry at or before the time of first patient enrollment as a condition of consideration for publication. Editors requesting inclusion of their journal on the ICMJE website list of publications that follow ICMJE guidance [icmje.org/journals.html] should recognize that the listing implies enforcement by the journal of ICMJE's trial registration policy.

ICMJE uses the date trial registration materials were first submitted to a registry as the date of registration. When there is a substantial delay between the submission of registration materials and their posting at the trial registry, editors may inquire about the circumstances that led to the delay.

The ICMJE defines a clinical trial as any research project that prospectively assigns people or a group of people to an intervention, with or without concurrent comparison or control groups, to study the relationship between a health-related intervention and a health outcome. Health-related interventions are those used to modify a biomedical or health-related outcome; examples include drugs, surgical procedures, devices, behavioral treatments, educational programs, dietary interventions, quality improvement interventions, and process-of-care changes. Health outcomes are any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events. The ICMJE does not define the timing of first participant enrollment, but best practice dictates registration by the time of first participant consent.

The ICMJE accepts publicly accessible registration in any registry that is a primary register of the WHO International Clinical Trials Registry Platform (ICTRP) (www.who.int/ictrp/network/primary/en/index.html) that includes the minimum acceptable 24-item trial registration dataset or in ClinicalTrials.gov, which is a data provider to the WHO ICTRP. The ICMJE endorses these registries because they meet several criteria. They are accessible to the public at no charge, open to all prospective registrants, managed by a not-for-profit organization, have a mechanism to ensure the validity of the registration data, and are electronically searchable. An acceptable registry must include the minimum 24-item trial registration dataset (http://prsinfo.clinicaltrials.gov/trainTrainer/WHO-ICMJE-ClinTrialsgov-Cross-Ref.pdf or www.who.int/ictrp/network/trds/en/index.html) at the time of registration and before enrollment of the first participant. The ICMJE considers inadequate trial registrations missing any of the 24 data fields, those that have fields that contain uninformative information, or registrations that are not made publicly accessible such as phase I trials submitted to the EU-CTR and trials of devices for which the information is placed in a "lock box." In order to comply with ICMJE policy, investigators registering trials of devices at ClinicalTrials.gov must "opt out" of the lock box by electing public posting prior to device approval. Approval to conduct a study from an independent local, regional, or national review body (e.g., ethics committee, institutional review board) does not fulfill the ICMJE requirement for prospective clinical trial registration. Although not a required item, the ICMJE encourages authors to include a statement that indicates that the results have not yet been published in a peer-reviewed journal, and to update the registration with the full journal citation when the results are published.

The purpose of clinical trial registration is to prevent selective publication and selective reporting of research outcomes, to prevent unnecessary duplication of research effort, to help patients and the public know what trials are planned or ongoing into which they might want to enroll, and to help give ethics review boards considering approval of new studies a view of similar work and data relevant to the research they are considering. Retrospective registration, for example at the time of manuscript submission, meets none of these purposes. Those purposes apply also to research with alternative designs, for example observational studies. For that reason, the ICMJE encourages registration of research with non-trial designs, but because the exposure or intervention in non-trial research is not dictated by the researchers, the ICMJE does not require it.

Secondary data analyses of primary (parent) clinical trials should not be registered as separate clinical trials, but instead should reference the trial registration number of the primary trial.

The ICMJE expects authors to ensure that they have met the requirements of their funding and regulatory agencies regarding aggregate clinical trial results reporting in clinical trial registries. It is the authors', and not the journal editors', responsibility to explain any discrepancies between results reported in registries and journal publications. The ICMJE will not consider as prior publication the posting of trial results in any registry that meets the above criteria if results are limited to a brief (500 word) structured abstract or tables (to include trial participants enrolled, baseline characteristics, primary and secondary outcomes, and adverse events).

The ICMJE recommends that journals publish the trial registration number at the end of the abstract. The ICMJE also recommends that, whenever a registration number is available, authors list this number the first time they use a trial acronym to refer either to the trial they are reporting or to other trials that they mention in the manuscript.

Editors may consider whether the circumstances involved in a failure to appropriately register a clinical trial were likely to have been intended to or resulted in biased reporting. Because of the importance of prospective trial registration, if an exception to this policy is made, trials must be registered and the authors should indicate in the publication when registration was completed and why it was delayed. Editors should publish a statement indicating why an exception was allowed. The ICMJE emphasizes that such exceptions should be rare, and that authors failing to prospectively register a trial risk its inadmissibililty to our journals.

ii. Data Sharing

The ICMJE's data sharing statement policy is detailed in an editorial (see Updates and Editorials [www.icmje.org/update.html]).

1. As of 1 July 2018 manuscripts submitted to ICMJE journals that report the results of clinical trials must contain a data sharing statement as described below.

2. Clinical trials that begin enrolling participants on or after 1 January 2019 must include a data sharing plan in the trial's registration. The ICMJE's policy regarding trial registration is explained at www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html. If the data sharing plan changes after registration this should be reflected in the statement submitted and published with the manuscript, and updated in the registry record.

Data sharing statements must indicate the following: whether individual deidentified participant data (including data dictionaries) will be shared ("undecided" is not an acceptable answer); what data in particular will be shared; whether additional, related documents will be available (e.g., study protocol, statistical analysis plan, etc.); when the data will become available and for how long; by what access criteria data will be shared (including with whom, for what types of analyses, and by what mechanism). Illustrative examples of data sharing statements that would meet these requirements are provided in the **Table**.

Authors of secondary analyses using shared data must attest that their use was in accordance with the terms (if any) agreed to upon their receipt. They must also reference the source of the data using its unique, persistent identifier to provide appropriate credit to those who generated it and allow searching for the studies it has supported. Authors of secondary analyses must explain completely how theirs differ from previous analyses. In addition, those who generate and then share clinical trial data sets deserve substantial credit for their efforts. Those using data collected by others should seek collaboration with those who collected the data. As collaboration will not always be possible, practical, or desired, the efforts of those who generated the data must be recognized.

IV. Manuscript Preparation and Submission

A. Preparing a Manuscript for Submission to a Medical Journal

1. General Principles

The text of articles reporting original research is usually divided into Introduction, Methods, Results, and Discussion sections. This so-called "IMRAD" structure is not an arbitrary publication format but a reflection of the process of scientific discovery. Articles often need subheadings within these sections to further organize their content. Other types of articles, such as meta-analyses, may require different formats, while case reports, narrative reviews, and editorials may have less structured or unstructured formats.

Electronic formats have created opportunities for adding details or sections, layering information, cross-linking, or extracting portions of articles in electronic versions. Supplementary electronic-only material should be submitted and sent for peer review simultaneously with the primary manuscript.

2. Reporting Guidelines

Reporting guidelines have been developed for different study designs; examples include CONSORT (www.consort-statement.org) for randomized trials, STROBE for observational studies (http://strobe-statement.org/), PRISMA for systematic reviews and meta-analyses (http://prisma-statement.org/), and STARD for studies of diagnostic accuracy (http://www.equator-network.org/reporting-guidelines/stard/). Journals are encouraged to ask authors to follow these guidelines because they help authors describe the study in enough detail for it to be evaluated by editors, reviewers, readers, and other researchers evaluating the medical literature. Authors of review manuscripts are encouraged to describe the methods used for locating, selecting, extracting, and synthesizing data; this is mandatory for systematic reviews. Good sources for reporting guidelines are the EQUATOR Network (www.equator-network.org/home/) and the NLM's Research Reporting Guidelines and Initiatives (www.nlm.nih.gov/services/research_report_guide.html).

3. Manuscript Sections

The following are general requirements for reporting within sections of all study designs and manuscript formats.

a. Title Page

General information about an article and its authors is presented on a manuscript title page and usually includes the article title, author information, any disclaimers, sources of support, word count, and sometimes the number of tables and figures.

Article title. The title provides a distilled description of the complete article and should include information that, along with the abstract, will make electronic retrieval of the article sensitive and specific. Reporting

Table. **Examples of Data Sharing Statements That Fulfill These ICMJE Requirements***

	Example 1	Example 2	Example 3	Example 4
Will individual participant data be available (including data dictionaries)?	Yes	Yes	Yes	No
What data in particular will be shared?	All of the individual participant data collected during the trial, after deidentification.	Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices).	Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices).	Not available
What other documents will be available?	Study Protocol, Statistical Analysis Plan, Informed Consent Form, Clinical Study Report, Analytic Code	Study Protocol, Statistical Analysis Plan, Analytic Code	Study Protocol	Not available
When will data be available (start and end dates)?	Immediately following publication. No end date.	Beginning 3 months and ending 5 years following article publication.	Beginning 9 months and ending 36 months following article publication.	Not applicable
With whom?	Anyone who wishes to access the data.	Researchers who provide a methodologically sound proposal.	Investigators whose proposed use of the data has been approved by an independent review committee (learned intermediary) identified for this purpose.	Not applicable
For what types of analyses?	Any purpose.	To achieve aims in the approved proposal.	For individual participant data meta-analysis.	Not applicable
By what mechanism will data be made available?	Data are available indefinitely at (*Link to be included).*	Proposals should be directed to xxx@yyy. To gain access, data requestors will need to sign a data access agreement. Data are available for 5 years at a third party website (*Link to be included).*	Proposals may be submitted up to 36 months following article publication. After 36 months the data will be available in our University's data warehouse but without investigator support other than deposited metadata. Information regarding submitting proposals and accessing data may be found at (*Link to be provided*).	Not applicable

* These examples are meant to illustrate a range of, but not all, data sharing options.

guidelines recommend and some journals require that information about the study design be a part of the title (particularly important for randomized trials and systematic reviews and meta-analyses). Some journals require a short title, usually no more than 40 characters (including letters and spaces) on the title page or as a separate entry in an electronic submission system. Electronic submission systems may restrict the number of characters in the title.

Author information. Each author's highest academic degrees should be listed, although some journals do not publish these. The name of the department(s) and institution(s) or organizations where the work should be attributed should be specified. Most electronic submission systems require that authors provide full contact information, including land mail and e-mail addresses, but the title page should list the corresponding authors' telephone and fax numbers and e-mail address. ICMJE encourages the listing of authors' Open Researcher and Contributor Identification (ORCID).

Disclaimers. An example of a disclaimer is an author's statement that the views expressed in the submitted article are his or her own and not an official position of the institution or funder.

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The guiding principle of the Methods section should be clarity about how and why a study was done in a particular way. The Methods section should aim to be sufficiently detailed such that others with access to the data would be able to reproduce the results. In general, the section should include only information that was available at the time the plan or protocol for the study was being written; all information obtained during the study belongs in the Results section. If an organization was paid or otherwise contracted to help conduct the research (examples include data collection and management), then this should be detailed in the methods.

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Clearly describe the selection of observational or experimental participants (healthy individuals or patients, including controls), including eligibility and exclusion criteria and a description of the source population. Because the relevance of such variables as age, sex, or ethnicity is not always known at the time of study design, researchers should aim for inclusion of representative populations into all study types and at a minimum provide descriptive data for these and other relevant demographic variables.

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Describe statistical methods with enough detail to enable a knowledgeable reader with access to the original data to judge its appropriateness for the study and to verify the reported results. When possible, quantify findings and present them with appropriate indicators of measurement error or uncertainty (such as confidence intervals). Avoid relying solely on statistical hypothesis testing, such as *P* values, which fail to convey important information about effect size and precision of estimates. References for the design of the study and statistical methods should be to standard works when possible (with pages stated). Define statistical terms, abbreviations, and most symbols. Specify the statistical software package(s) and versions used. Distinguish prespecified from exploratory analyses, including subgroup analyses.

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Present your results in logical sequence in the text, tables, and figures, giving the main or most important findings first. Do not repeat all the data in the tables or figures in the text; emphasize or summarize only the most important observations. Provide data on all primary and secondary outcomes identified in the Methods section. Extra or supplementary materials and technical details can be placed in an appendix where they will be accessible but will not interrupt the flow of the text, or they can be published solely in the electronic version of the journal.

Give numeric results not only as derivatives (e.g., percentages) but also as the absolute numbers from which the derivatives were calculated. Restrict tables and figures to those needed to explain the argument of the paper and to assess supporting data. Use graphs as an alternative to tables with many entries; do not duplicate data in graphs and tables. Avoid nontechnical uses of technical terms in statistics, such as "random" (which implies a randomizing device), "normal," "significant," "correlations," and "sample."

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