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Andrea Seach

I. Abstract

As social media use connects more people virtually, that increased connection creates opportunities for researchers to expand their reach for clinical trials. Despite these opportunities, social media is not widely used by clinical researchers. Some researchers have begun using it to enhance recruitment, accelerate community consultations, increase follow up retention, and promote dissemination of results. However, because these techniques are new, their effects on cost and efficiency have not been well studied. Researchers were hopeful that the broad reach of social media could improve clinical trial efficiency and lower costs. Early studies suggest that using social media to recruit participants and to disseminate results is less efficient than expected. Moreover, the lack of regulations on social media use gives rise to certain ethical concerns, such as privacy and coercion. Although there are no legal or regulatory requirements for social media use, researchers can look to the well-established Belmont principles of respect for persons, beneficence, and justice for how to best incorporate social media into clinical trials while still maintaining ethics. IRBs are used to uphold these principles, but without mandatory regulations, researchers apply the principles inconsistently. Thus, not all uses of social media in clinical trials are justified, and researchers should contemplate the ethical risks and proposed benefits. However, federal regulations specific to social media are necessary because specific regulations would promote effective and safe use of social media in clinical trials.

II. Introduction

Many industries are rapidly adapting to society's growing social media use, and clinical trials should aim to incorporate social media in an effective and ethical manner. With over 430,000 active clinical trials in the world today, updated regulations are urgently needed.[1] Clinical trials have given us treatment options that were unfathomable fifty years ago.[2] For example, clinical research has cut the age-adjusted death rate for coronary artery disease in half.[3] Likewise, a randomized trial involving 600,000 participants led to the first polio vaccine.[4] Clinical trials are studies involving human subjects that test the safety and efficacy of new treatment methods, such as medications, vaccines, and therapies.[5] Clinical trials are the highest standard of research because they are implemented through rigorous study protocols that outline the specific treatment and testing to measure safety and efficacy in a standard manner by separating participants into different treatment groups.[6] The designs of clinical trials constrain participants to distinct subject groups to ensure the new treatment works on the intended population.[7] Researchers consider randomized clinical trials to be the gold standard for demonstrating efficacy.[8]

However, clinical trials are costly, and these important medical advances are only possible with the participation of research subject volunteers.[9] For example, it takes nearly a decade and $1 billion to bring one drug to market.[10] Thus, placing ever more importance on proper design and participant selection will reduce unnecessary costs of extended duration and wasted time and effort on trials with ineffective design. Effectively designed clinical trials include the following three participant-related considerations: recruitment, protocol adherence, and retention.[11] Clinical trial recruitment is a costly endeavor that will be explored more below. [12] Participants must follow the study protocol to ensure reliable results.[13] Furthermore, participants must remain in the study for the duration of the trial so that the researchers have a complete data set.[14] However, an estimated 18% of enrolled and randomized participants drop out and do not complete the study, which is a costly problem for many researchers that can delay clinical trial progression.[15]

Additionally, clinical trial participation in the United States is low: less than 10% of all patients enroll in clinical trials.[16] Slow enrollment is also a costly problem that can lead to premature termination of the study, which occurs in 12% of trials.[17] Moreover, clinical trials must involve a diverse selection of participants in order to expose how the tested treatment will affect specific populations.[18] However, African Americans and Hispanics only make up 5% and 1% of clinical trial participants respectively, resulting in a lack of minority representation.[19]

Researchers have looked to radio advertisements, flyers, and direct contact to solve low enrollment and low engagement.[20] However, with our growing presence online, researchers are turning to social media as a potential, cost-effective solution.[21] Researchers are aware of the potential risks and the lack of guidance on using social media for recruitment and engagement,[22] but social media has the potential to reach diverse patients and increase compliance with study protocols. This article will review and analyze that balance of potential benefits and ethical risks involved with using social media in clinical trials and will discuss how to use existing regulations to mitigate the risks.

a. A Brief History of the Rise of Social Media and the Shift to Electronic Health

Though many people believe that the spike in internet use in the United States began in the 90s, internet use didn't fully bloom until recently. Currently, 93% of Americans access the internet, compared to only 55% in the early 2000's, before the social media boom.[23] People of all ages access the internet—75% of people aged 65 and older access the internet and 99% of people aged 18-29 years old report internet usage.[24]

As internet use has increased, social media use has followed. In 2005, only 5% of American adults had at least one social media account, compared to 72% today.[25] However, the popularity of social media differs between age groups. For example, only 45% of Americans aged 65 and over have a social media account, but 84% of 18–29-year-olds have a social media account.[26] Moreover, the popularity of each site differs among each age group. Instagram is most popular with the younger age group, while Facebook is more popular for those aged 30 and over.[27]

As we shift to socializing online, many industries are taking advantage of the change as well, such as the medical field. The medical field was early to embrace the digital world. For example,

though only 10% of hospitals in 2008 had adopted electronic health records (EHR), by 2015, 80% of hospitals had done so.[28] This change has led to many improvements in patient care, such as decreasing diagnostic and medical errors, increasing communication among interdisciplinary teams, and increasing access to care.[29] However, there are continual concerns for breach of privacy with EHRs.[30] Therefore, we have extensive regulations governing the use of EHR.[31] For example, the Health Insurance Portability and Accountability Act (HIPAA) set national standards for protection of health information that predated many EHRs, but has since been adapted to apply to EHRs.[32] The goal of HIPAA is "to improve the ... efficiency and effectiveness of the health information system through the establishment of standards and requirements for the electronic transmission of certain health information," and in enacting HIPAA, Congress "recognized the importance of protecting the privacy of health information in the midst of the rapid evolution of health information systems."[33] The Health Information Technology for Economic and Clinical Health (HITECH) Act gives the United States Department of Health and Human Services the power to improve healthcare through information technology, for example, by recommending policies and standards to improve electronic access to healthcare information.[34] Additionally, the 21st Century Cures Act governs the flow of health information and patient accessibility.[35] The large success of EHR could be attributed to the extensive regulations that guided implementation and use.

Another growing use of the internet in the healthcare field is telehealth. Telehealth is a cost-effective method of healthcare delivery, especially in remote or underserved areas.[36] The Oregon Health and Science University saw 1,100 telehealth visits in 2019, but because of the COVID-19 pandemic, centers across the country have been experiencing as much as a 154% increase in telehealth visits.[37] Because of this rapid increase in demand for telehealth visits, legislators eased some of the regulations surrounding telehealth, for example, removing the requirement for HIPAA compliant videos.[38] However, these relaxed regulations have had negative consequences such as removing the HIPAA requirement has led to 30% of providers reporting a data breach.[39] Lawmakers have thus not been able to keep up with the rapidly changing landscape of telehealth, which leaves patient privacy vulnerable.

Moreover, while social media initially began as a method to connect friends and family, hospitals have also adapted it to educate the public.[40] Many hospitals and physicians have professional social media accounts to educate on matters affecting their community.[41] They see social media as a way to overcome physical barriers and reach more of the public in remote or medically underserved areas.[42] Therefore, it is only logical that clinical trials also take advantage of the growing popularity of social media, and researchers have already adopted several uses for social media.

III. Uses

Given the high cost of clinical trials and the challenges associated with finding participants, social media may offer new options to improve efficacy. Social media has been used to virtually reach subjects for recruitment, community consultation, retention and follow up, and disseminating results.

a. Recruitment

Researchers have used social media to enhance recruitment methods. Low clinical trial enrollment and lack of participant diversity is problematic because it leads to premature termination or unplanned extension of the clinical trial, both of which are costly to researchers.[43] Clinical trials are designed to specific powers, and thus, each trial requires a threshold limit of participants in order to obtain clinically significant results.[44] Therefore, slow or inadequate enrollment will lead to a sample size that is too small to detect a difference between the study treatment group and the comparison.[45] Thus, it is important for researchers to plan efficient and cost-effective recruitment methods.

Recruitment can also be complicated by extensive inclusion and exclusion criteria. For every study, participants must be assessed by eligibility criteria to ensure they meet the needs of the trial.[46] Researchers want to include patients with specific conditions to ensure clinically significant results, but sometimes the eligibility criteria are too strict, making it difficult to find participants.[47] For example, researchers for a study on irritable bowel syndrome budgeted $5,000 and four months for recruitment; however, slow enrollment stretched recruitment to 26 months and ballooned the cost to $75,056.[48]

Traditional methods of recruitment include television, radio, and print advertisements; in-person, physician recruitment; and word of mouth.[49] A study by Kakumanu and others found that physician recruitment was the most successful, but that it also consumed half of the recruitment budget.[50] However, relying on physicians for recruitment has its limitations.[51] Many physicians report difficulty enrolling clinical trial subjects in person because of time constraints during patient visits, difficulty identifying eligible patients, and staffing constraints.[52] Having a high cost but low efficacy, paid media recruitment methods were found to be the least cost-effective because this method only recruited 2% of the overall subjects.[53] Moreover, because an overwhelming majority of trial participants are white, the traditional means of recruitment are failing to recruit from minorities populations, which is necessary for obtaining trial results that benefit our entire population.[54] Therefore, it is important to identify a cost-effective, wide-reaching recruitment tool.

Social media has the potential to reach a variety of potential subjects. Many social media platforms have diverse users, which could help to mitigate the low enrollment of minorities.[55] For example, Twitter has a high proportion of African American users compared to other social media sites.[56] Moreover, since a major source of enrollment is from community-based physician recruitment, social media can bring awareness to harder-to-reach rural populations.[57] Social media ads offer the ability to tailor the ad's message to different populations.[58] Examining different recruitment techniques for a diabetes trial, Salvy and others found that participants were most likely to click on the social media ad when the ad mentioned altruism or compensation.[59] Therefore, social media is useful for recruiting participants from more diverse populations.

However, there is conflicting information regarding the cost-effectiveness of using social media for recruitment. Researchers were initially enthusiastic that social media would be a cost-effective alternative to participant recruitment. The intention was that the advertisement about the clinical trial would spread quickly and researchers would exert little active recruitment and

simply wait to receive inquiries from interested parties.[60] However, despite early hopes, few researchers report successful, cost-effective use of social media for recruitment.[61] Many researchers experience a high volume of inquiries from ineligible patients, and therefore, social media yields few enrolled patients, which drives up the cost of recruitment.[62] Therefore, because of the high response from mostly ineligible patients, social media may be more useful to certain studies that do not have strict inclusion criteria. Though social media can reach participants that physician recruitment cannot, for any particular study it is unclear if social media recruitment is cost-effective. Before engaging social media as a recruitment tool, researchers should take into consideration the effectiveness of social media for their intended study, especially constrictiveness of the inclusion criteria.

b. Exception from Informed Consent

Researchers have also used social media to expedite the community consultation process. The Code of Federal Regulations (C.F.R.) Title 21, § 50.20 requires that, to protect research participants, informed consent must be obtained before anyone can participate in research.[63] According to 21 C.F.R. § 50.25, the informed consent process must present the participant with the necessary information to make an informed decision about participation, such as:

> (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
> (2) A description of any reasonably foreseeable risks or discomforts to the subject.
> (3) A description of any benefits to the subject or to others which may reasonably be expected from the research.[64]

Informed consent is designed to be a process more than a signature on a form and can take significant time to complete. Therefore, in certain emergency settings, informed consent is not possible. In order to allow research to progress in these emergent conditions, researchers can circumvent informed consent and obtain approval for Exception from Informed Consent (EFIC) from the Food and Drug Administration (FDA).[65] Under the C.F.R., EFIC is appropriate when "human subjects are in a life-threatening situation, available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence. . . is necessary to determine the safety and effectiveness of particular interventions."[66]

Moreover, for an exception to be approved, informed consent must not be possible because of the following reasons:

> (i) subjects will not be able to give their informed consent as a result of their medical condition; (ii) The intervention under investigation must be administered before consent from the subjects' legally authorized representatives is feasible; and (iii) There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the clinical investigation.[67]

Researchers must further protect the rights and welfare of participants through community consultations and public disclosures. A community consultation requires consulting with

representatives of the communities where the study will be conducted and from populations in which the patients will be included in the study.[68] Public disclosure requires disclosure to the communities where the study will be conducted and from the population that will be included, prior to initiation of the study, of plans for the study and its risks and expected benefits.[69]

Because of the stringent rules on EFIC approvals, the FDA has only approved approximately 40 EFIC trials in areas such as "cardiac arrest, hemorrhagic shock, traumatic brain injury, status epilepticus, ischemic stroke, respiratory failure, and acute coronary syndrome."[70] Though researchers can meet the requirements of community consultations and public disclosures through public meetings, telephone surveys, and print advertisements, the FDA has little guidance on how extensive the disclosures should be.[71] Therefore, because the FDA has no restriction on using social media, social media could be used as an alternative to the direct contact methods previously used during the EFIC approval process.

A large deterrent for conducting EFIC trials is the cost and time of the community consultations and public disclosures that are required for approval.[72] Even researchers experienced in EFIC trials can take more than eight months to complete the disclosure requirements.[73] As of 2018, a majority of researchers were still using random digit dialing telephone surveys as a primary method for their community consultation, which consumes the valuable time and effort of research staff.[74] Typically, these campaigns can cost $60,000.[75] However, the rapid spread of information through social media provides a promising solution. In the recruitment for one study, a Facebook advertisement for a community consult campaign was able to reach 332,081 people over 8 weeks as opposed to the months this process can take using conventional methods.[76] Thus, using social media reduces the time commitment and cost of community consult campaigns by decreasing the required staffing effort.[77]

Community consults and public disclosures should aim to reach the same target populations that would be enrolled in the clinical trial.[78] However, a review of data reported to the FDA on trials using conventional methods for EFIC approval found that African Americans were underrepresented in the random sampling, making up only 16.7% of those surveyed but 29.3% of those enrolled in the trial.[79] Therefore, researchers need a better method to target minority groups, and social media shows promise in this area, even though this topic hasn't been specifically evaluated. Moreover, data review suggests that social media EFIC campaigns are better at targeting rural populations.[80] For example, though Facebook ads were viewed mostly by people in large to medium-sized cities, the ads also reached sparsely populated areas within 150 miles.[81] Therefore, social media is an encouraging option for expanding reach in community consults and public disclosures for EFIC trials.

c. Subject Retention & Engagement

Another use of social media in clinical trials is to retain subjects for follow up. Subject retention is important for complete clinical trial results to have adequate statistical power.[82] If patients drop out or are lost to follow up, researchers will not be able to reach the required sample size for clinically significant results.[83] Some researchers respond to losses in data by excluding the missing results or using imputation to estimate results.[84] However, the FDA recommends mitigating participant drop out by improving trial design rather than adjusting for missing data

after the fact.[85] This is likely because high attrition can cause results bias, which is when the results of the study are influenced by the patient population that dropped out of the study; for example, if less symptomatic patients drop out, the results are less likely to reflect actual treatment efficacy.[86]

For certain studies, assessing a participant's progress may require multiple follow up visits over several years, and it may be difficult for the researchers to maintain contact with certain populations because those populations may not have permanent telephone numbers or addresses, which are the standard contact methods for follow up visits.[87] For example, substance abuse treatments are known to have unstable housing and as a result, poor attrition with only 56% of studies obtaining their necessary retention rates.[88] Some researchers have found success in reducing attrition with compensation for follow up visits.[89] However, this is most prevalent when the compensation is significant.[90] Others can retain a small group of participants through database searches; however, these are mostly only effective when researchers only need to obtain survival status.[91] Therefore, researchers need a more flexible method to maintain contact and sustain participant engagement.

The popularity of social media makes it a promising tool to maintain contact with study participants. However, if researchers intend to use social media to contact patients, it must be included in the informed consent; therefore, using social media for retention requires some forethought.[92] Many people are on Facebook, checking in daily.[93] Therefore, researchers could use Facebook to contact participants who are lost to follow up. Some researchers have had success with this method by capturing more follow up visits than they would have otherwise.[94] Therefore, social media can be an effective tool to contact participants and reduce attrition.

Moreover, using social media after enrollment offers participants emotional support to continue with treatment.[95] A social media group for participants can foster communication, support, and encouragement among members.[96] These groups can even encourage others to participate in research.[97] However, social media groups have significant privacy concerns, especially groups not run by study investigators.[98] Researchers are unable to restrict participants from creating unauthorized social media groups or otherwise communicating freely about the trial.[99] This could result in participants sharing information regarding what treatment they are taking; this unauthorized sharing would be dangerous because it could cause "unblinding."[100] Blinding is important because it eliminates bias by preventing researchers from knowing which treatment the participant is undergoing.[101] Furthermore, participants may be sharing medical advice that will negatively impact protocol adherence, confidential clinical trial information, or misinformation on adverse events.[102] Thus, regulating and restricting information during the trial is crucial. Nonetheless, social media could be a successful tool for subject retention and engagement if used properly.

d. Disseminating Results

Additionally, science communicators have used social media to assist in disseminating study results. Sharing the results of clinical trials allows medical providers and patients to implement the results into their treatment methods.[103] Traditional methods of disseminating results include conferences and journal articles.[104] While thousands of professionals can attend conferences each

year and thousands of articles are published each year, these methods do not reach all interested parties.[105] These traditional methods can take up to 17 years for new treatments to reach widespread clinical practice.[106] The most impactful way to update professionals and the public on new treatment methods is to amend evidence based clinical guidelines.[107] Therefore, quicker dissemination is vital.

Medical groups have been using social media to educate the public on new results.[108] They use Twitter as a method of having an open discussion about the results.[109] For example, researchers created a Twitter campaign with a unique hashtag to raise awareness about dementia.[110] They found "2,376,853 unique users who had seen or interacted with the hashtag."[111] They also found that tweets regarding dementia had nearly doubled since the start of the campaign.[112] Therefore, researchers believe they have demonstrated that social media can reach more interested parties than traditional methods.

However, this widespread dissemination is not without risks. When the information is given to the general public, research results can be misinterpreted.[113] Also, journal articles are peer-reviewed to ensure accuracy; however, social media does not have this guarantee.[114] Moreover, research presented at conferences is aimed at an audience that can distinguish nuances in results that would escape a lay audience. Thus, researchers should be cautious about how the information is posed online, but social media could be a useful tool to disseminate results.

IV. Current Laws, Rules, and Regulations

Despite the various uses of social media in clinical trials, legislators have yet to codify the role of social media in clinical research.[115] Though existing legislation regarding patient privacy and protection are still applicable, researchers are left to interpret how these statutes apply. Created by National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, the Belmont Report is the most on-point guideline that covers clinical research. But the Belmont Report has never been adopted by Congress and is, therefore, not mandatory. The Belmont Report lays out three main principles: beneficence, justice, and respect for persons.[116] Many of its principles have been codified in 21 C.F.R. § 56. This regulation gives institutional review boards (IRBs) the power to ensure protection of human subjects in research by minimizing unnecessary risks.[117] IRBs are independent groups that must review all human subject research as mandated by 21 C.F.R. § 56.109 and have "the authority to approve, require modifications in, or disapprove all research activities."[118]

While neither the Belmont Report nor 21 C.R.F. § 56 specifically mention social media, the same principles must apply to social media use in clinical trials. The Belmont principles are codified into the Code of Federal Regulations, and the Code requires IRBs to uphold these regulations for all research. For example, respect for persons is intended to mean that each person is able to make an autonomous decision about participating in a clinical trial.[119] Therefore, when recruiting participants on social media, researchers must maintain the autonomous component of recruitment and ensure advertisements aren't misleading or coercive.[120] Furthermore, beneficence is achieved by maximizing benefits and minimizing harm.[121] Because social media use increases a risk to the user's privacy, researchers must

balance maximum benefit and minimum harm when using social media in clinical trials.[122] Lastly, justice is accomplished by distributing benefits and risks evenly.[123] This is especially relevant considering the current lack of diversity in clinical trials. Social media could potentially enhance justice in clinical trials by recruiting more diverse participants.

Moreover, existing statutes about patient data privacy can be applied in the context of social media use for clinical trials.[124] For example, HIPAA prohibits disclosing any protected health information, such as names, dates, and other information, that could identify a patient without consent.[125] Therefore, posting any protected information, whether intentionally or unintentionally, would constitute a violation.[126] Privacy violations on social media are increasingly common. In 2018, 56% of compromised data records resulted from social media disclosures.[127] For example, a court found that surgeons breached HIPAA policy by posting to Instagram pictures of patients on the operating table.[128] A HIPAA violation can cost upwards of $50,000 if the violation was of willful neglect.[129] Therefore, if researchers use social media to interact with clinical trial patients, this information must be included in the informed consent. Then, the patient will have given their authorization, and communicating in this manner will not be a HIPAA violation.

Though there are a few guidelines specifically on social media use in clinical trials, most of these guidelines are lacking. Because the guidelines are released by independent agencies rather than guided by legislation, the guidelines are non-binding and, therefore, have no statutory authority.[130] For example, the NIH provides loose guidance on social media use for clinical trials.[131] These guidelines include thinking about privacy information before posting, considering the portability and speed at which the information may spread, and sharing any contact information that would bring interested parties into an encrypted environment.[132] Likewise, the Office for Human Research Protections within the Health and Human Services department mandates that IRBs review and approve any information that participants will be exposed to.[133] However, federally available guidance ends there, and it fails to address many of the uses discussed in the sections above.

As a result, each individual IRB is responsible for determining what social media use is appropriate for clinical trials. While all IRBs are enabled by the same federal regulations, each IRB has its own discretion on social media use. For example, the University of Arizona IRB requires researchers to seek approval for any information posted to social media.[134] The University of Arizona also strictly prohibits researchers from engaging in any personal communications with potential trial subjects on social media.[135] Therefore, direct recruitment via social media is completely forbidden at the University of Arizona. However, Advarra, a centralized IRB that can be utilized by unaffiliated researchers across the country, allows the use of social media to contact participants through an approved social media plan.[136] Therefore, the allowable uses of social media for clinical trials depend entirely on the specific IRB reviewing the study, and the differences highlighted here show the variation in how IRBs interpret existing guidelines. As a whole, the current government regulations regarding social media use in clinical trials are insufficient to provide proper guidance to researchers.

V. Discussion

Though researchers can use social media in diverse ways for clinical trials, but it is more difficult to balance the potential benefits and risks in a way that maintains the three common principles of respect, beneficence, and justice.

Table 1: How Different Social Media Uses Interact with the Belmont Principles

	Benefits	Concerns
Recruitment	• Wide reaching to promote justice • Passive recruitment promotes respect for persons	• Risk of privacy affects principle of beneficence • Not cost-effective
Retention	• Decreases attrition rates	• Risk of privacy affects principle of beneficence
EFIC	• Cost-effective • reduces time to IRB approval • wide reaching to promote justice	• Risk of privacy affects principle of beneficence
Disseminating Result	• wide reaching	• Risk of misinterpretation or lack of transparency implicates beneficence • Not an efficient option

a. Benefits

Many believe that using social media in clinical trials will promote efficiency, decrease the overall length of the trial, and reduce costs. However, some uses of social media provide more promising benefits than others.

i. Cost of Trials

While many researchers believe social media will reduce the cost of recruitment by passively and quickly spreading the word about an upcoming trial, the reality many researchers experience is much different.[137] Many of the inquiries from social media have come from ineligible participants that ultimately could not participate in the trial.[138] Salvy found that in-person recruitment by physicians was more likely to attract eligible participants (69% eligible) compared to social media recruitment (46% eligible).[139] Therefore, due to the lower enrollment, recruiting through social media was more costly per enrolled participant ($334) compared to in-person recruitment ($290).[140] However, success can vary greatly across different trial types.[141] Darmawan and others performed a literature review of 33 studies that reported using social media for recruitment.[142] Thirty-one of those studies used Facebook.[143] Also, 21 studies only used one social media site.[144] However, only 7 of 20 studies reporting recruiting a majority of the subjects through social media.[145] Moreover, only 4 of 19 studies reported lower recruitment costs for social media.[146] Therefore, social media is unlikely to solve the problem of costly patient recruitment efforts.

However, a more promising cost-effective use of social media in clinical trials is using social media for community consultation and public disclosures required for EFIC trials. A review by Harvin and others assessed EFIC methods between different trials.[147] Earlier trials that did not utilize social media took from one to two months longer to complete.[148] The review also noted a decreased amount of personnel effort to complete the disclosure requirements when social media was used, which led to a decreased overall cost.[149] Traditional EFIC methods cost $39 per person reached, which can amount to hundreds of thousands of dollars, but social media EFIC campaigns cost only $3 per person.[150] Another evaluation found the total cost of a community consultation campaign to be only $3,000 when social media was used, a significant decrease from the typical $60,000.[151] Thus, while social media for recruitment is less promising, social media use for community consults and public disclosure in EFIC trials is more efficient and cost-effective than traditional consult and disclosure methods.

ii. Efficiency

Many researchers are hopeful that the speed and reach of social media will increase efficiency in clinical trials. However, some uses are more efficient than others. As discussed, social media for recruitment was less efficient than traditional physician recruitment because it engaged more ineligible participants. However, social media for community consultations in EFIC trials were more efficient because they significantly reduced the time to complete such campaigns.

Researchers also believed that using social media to disseminate results would be a more efficient option than publications and conferences. However, the efficiency of social media was overestimated here as well. While social media does reach millions of viewers, the information that is retained has minimal effects. Narayanaswami and others analyzed the effectiveness of different dissemination methods for complementary and alternative medicine (CAM) in multiple sclerosis. They found a significant increase in awareness of CAM guidelines among physicians after traditional means of dissemination.[152] However, they found no significant increase in awareness after novel dissemination on social media.[153] Thus, while information is widespread

on social media, disseminating information on social media does not seem to promote retention of that information.

Though social media has questionable utility for information retention, social media does show promising effects for subject retention. Researchers used Facebook to decrease attrition in a longitudinal study with a multiyear follow-up.[154] These researchers created a study-specific Facebook page for participants to join.[155] The researchers were able to reduce attrition by 16% when using Facebook to contact participants that would otherwise have been lost to follow-up.[156] Therefore, using social media along with traditional methods of retention can reduce attrition rates and improve study results.

b. Ethical Concerns

The three primary ethical principles from the Belmont Report developed out of necessity from deplorable acts that happened to research subjects in recent history.[157] However, the report has not been updated since its creation in 1979, and other regulations are lacking on the topic of social media use in clinical trials. Therefore, researchers should learn from lessons of the past to shape the ethics surrounding social media use in clinical trials.

i. Respect

The notorious Tuskegee Syphilis Study led to the demand for the principle of respect for persons.[158] The study began in 1932 by the United States Public Health Services to "observe the natural history of untreated syphilis" in African American males.[159] Participants did not give consent and were only told they were receiving treatment for "bad blood".[160] The researchers intentionally did not give the participants any legitimate treatment, even after penicillin became available and was widely used to treat syphilis.[161] The study did not end until 1972 when information about the study was published in the New York Times, creating a public outrage; however, by this time, "128 patients had died of syphilis or its complications, 40 of their wives had been infected, and 19 of their children had acquired congenital syphilis."[162] This tragedy highlighted the need to respect research participants, including the need for autonomous consent and transparent information regarding the study risks and benefits.

Researchers should consider autonomy when recruiting participants via social media. If done ethically, passive advertisements on social media could decrease any coercive effects. The passive advertisement removes direct involvement of the research team and makes coercion less likely to occur.[163] However, researchers must ensure that the information presented is accurate and not misleading, which can be difficult to do when the social media platform limits the size of a post. The FDA has recommended several guidelines to minimize coercion in clinical trial advertisements.[164] Foremost, the advertisement must not emphasize compensation nor mention free treatment.[165] Payment that incentivizes to participation is considered coercive, especially for vulnerable populations.[166]

Moreover, the advertisements should state that the treatment is new and should not promise benefits.[167] Participants should have realistic expectations about the research before they enroll. Because benefits cannot be guaranteed, beneficial treatment should not motivate participation.

This should not only be a consideration in advertisements but also in social media groups for participants. By posting in these groups about the benefits they have experienced, participants would misrepresent the study's overall benefits and influence other participants to enroll. However, it is more difficult to restrict participant's communications about the research study. Misrepresentation should also be a concern when conducting community consultations for EFIC trials through social media. The individuals surveyed during consultations should have transparent information regarding the risks and potential benefits of the research. Moderating risks or highlighting benefits could influence autonomous consent and violate the respect for persons principle.

Maintaining transparency in information also promotes trust in research, which will only help to further researchers' goals.[168] Therefore, in order to maintain respect for persons when using social media in clinical trials, researchers should ensure they are disseminating transparent information regarding the risks and benefits of the research without using overt incentives.

ii. Beneficence

When using social media in clinical trials, researchers should also maintain beneficence. The need for beneficence—minimizing risks to increase benefits—can be illustrated by the Kennedy Krieger Institute lead paint study. In this study, researchers knowingly exposed children to lead paint so that the government could find a more cost-effective solution to dealing with the effects of lead paint.[169] Low-income families with children were allowed to live in contaminated houses in exchange for their participation.[170] However, participants later sued the researchers claiming they were not properly informed of the risks of lead paint and that the researchers unnecessarily increased risks to participants.[171] Ultimately, the researchers were held liable because they exposed the children to greater than minimal risk with no therapeutic benefit.[172] Therefore, the researchers did not uphold the principle of beneficence during this study.

Use of social media in clinical trials could create an increased risk to privacy. For example, in 2019, Facebook experienced a data breach that made 530 million users' personal information such as phone number, email, and location publicly available.[173] Researchers should consider potential data breaches when setting up social media groups for clinical trial retention. This could place participants in a risky position that they otherwise may not have been in if they created an account for trial purposes only. Because of the history of data breaches on social media, leaked data can derive simply from collecting surveys for EFIC trials over social media. Therefore, privacy is a risk that must be weighed when considering the use of social media in clinical trials.

Even though most social media users post information voluntarily, most intend the information to be for social networking purposes and not for medical research.[174] Likewise, most social media users are not aware of how to adjust privacy settings.[175] Therefore, researchers should not take advantage of unsavvy users and should take care when actively contacting and recruiting individual participants through social media. Some IRBs, such as the one at the University of Arizona, expressly prohibit recruiting participants in this way because of the privacy concerns. However, other IRBs are open to researchers recruiting in disease support groups.[176] Nonetheless, researchers should approach the situation with sensitivity because users do not

share their disease information for the purpose of research. Moreover, researchers should not reach out to participants via social media for follow up purposes unless participants had previously given informed consent. It would be a violation of the participant's privacy to engage in unsolicited communication through social media without their consent.

Disseminating research results through social media is also risky. With limited character space, it can be difficult to thoroughly explain results. Also, researchers must cater the tone to the general public, in contrast to catering the tone to the professionals who read the published articles. Catering to the public creates a great risk that information could be misinterpreted. Additionally, published articles are typically peer reviewed, but disseminating research result on social media contains no such scrutiny. Therefore, there is a great risk that "junk science" could be distributed and given more weight than deserved.

Thus, in order to uphold the principle of beneficence and minimize risks, researchers should limit their use of social media for active recruitment, safeguard participant information, and aim to spread only reputable information.

iii. Justice

To ensure justice in clinical trials, researchers must distribute the benefits and burdens equally among the population. History has many examples of the harms of research participation being distributed disproportionately to vulnerable populations. For example, African American men were the target of the Tuskegee syphilis study that denied them treatment, low-income families were the target of the Kennedy Krieger Institute lead study that knowingly exposed children to lead paint, and studies that targeted prisoners. Prisoners were often a target for research pre-Belmont Report because they were captive, vulnerable, and had no choice.[177] In the 1940s, prisoners were purposely infected with malaria in order to test experimental treatments, most of which had brutal side effects.[178] Researchers didn't see the need to obtain consent or minimize risks because a prisoner's life was viewed as disposable.[179] Therefore, prisoners were the victims of distributive injustice in clinical research.

Research can also fail to proportionally distribute benefits. For example, minorities are continually underrepresented in clinical trials. This could be due to access barriers, mistrust in research due to the historical mistreatment of vulnerable populations, or failure by current recruitment efforts to notify minorities and minority participants of their research options.[180]

Improving the distribution of benefits is particularly challenging, but regulations are now in place to protect vulnerable populations. The Code of Federal Regulations restricts research in pregnant women, neonates, children, and prisoners unless specific conditions are met to ensure these populations are not being targeted due to their vulnerability.[181] For example, research on prisoners is prohibited unless (1) the research studies "the possible causes, effects, and processes of incarceration and of criminal behavior;" (2) the research is "on conditions particularly affecting prisoners as a class," research on practices that "have the intent and reasonable probability of improving the health or well-being of the subject;" or (3) "the study presents no more than minimal risk."[182] Therefore, there has been significant progress to promote justice in clinical trials.

There has been significant progress to promote justice in clinical trials, but the reach of social media could further this goal. 72% of Americans use social media, amounting to 72% of Americans.[183] Different demographics use different platforms more than others; for example, African Americans use Twitter more than other platforms, younger aged Americans use Instagram, and older Americans primarily utilize Facebook.[184] Many believe that using social media for clinical trials will exclude older adults. Researchers should be cognizant of this because only 45% of Americans over 65 have a social media account.[185] Even so, social media also can reach participants in rural, medically underserved areas. With the exception of alternative methods to reach older adults, using social media can enhance distributive justice in clinical trials by reaching racial minorities and participants further from medical centers.

c. Lack of Regulations

As previously noted, there are no specific federal regulations on the use of social media in clinical trials. Instead, clinical research is governed by the same guidelines and regulations that had been in existence for decades before the explosive growth of social media. Therefore, each individual IRB is responsible for determining what type of social media use fits appropriately with their governing principles. However, this can lead to vast differences in what is acceptable at each research institution. For example, social media recruitment is not allowable at the University of Arizona, but it is at Advarra. This is quite the contradiction because Advarra is a central IRB that researchers at the University of Arizona can defer to due to their alliance agreement.[186] Moreover, this variation makes multi-institutional trials that do not utilize a central IRB more complicated because each institution may require approval from different governing IRBs. There would be no consistency in the governing of the same trial at each different institution. The standards for research should be consistent among every institution because every IRB has the same goal of upholding respect, beneficence, and justice.

Moreover, some researchers and IRB's have been hesitant to engage in social media use because of the lack of regulations.[187] They fear that because there is no clear guidance, they could inadvertently breach privacy or HIPAA laws. Physicians request clearer guidance on social media use because they are generally unfamiliar with how to interpret the existing regulations to apply to social media.[188] Therefore, updated regulatory guidance on using social media in clinical trials would not only help to uphold the Belmont principles, but better guidance could also increase its effective use by researchers who have previously been wary of using social media.

d. Recommendations

The examples of atrocities committed in clinical research in our history highlight the need for updated guidelines. Looking back 100 years from now and viewing our use of social media in clinical research, we do not want our progeny to see violations of the principles in the Belmont Report. This future can be avoided by, at a minimum, the FDA creating specific guidelines for acceptable use of social media use in clinical trials. Even better would be if these guidelines were then codified in the Code of Federal Regulations to provide IRBs with a mandatory rule. However, one of the most crucial points to examine is recruiting through social media.

Researchers must be careful that actively recruiting participants through social media does not take advantage of vulnerable populations or create a coercive environment. Therefore, regulating recruitment should be the first point of issue for the FDA in drafting guidelines.

Existing evaluations do not support passive recruitment through social media as a method to reduce costs or improve efficiency. Therefore, social media likely should only be used to supplement existing recruitment methods. Furthermore, current research does not show that social media is an effective method for disseminating study results because the risk of misinformation is high. However, current research does show promise for using social media in EFIC community consults and participant retention.

Because lack of guidance has dissuaded researchers from adopting social media in clinical trials, the use of social media in clinical trials has not been well explored. Therefore, further studies and guidelines are needed to determine which uses of social media are best.

VI. Conclusion

Many researchers are eager to use social media in clinical trials because of the perceived benefit of increasing efficiency and decreasing costs. However, there are valid ethical concerns of maintaining respect for persons, beneficence, and justice. Moreover, many of these anticipated benefits have yet to be substantiated. The use of social media is still in the early stages and has not been studied rigorously, so the best uses are still yet to be determined. Moreover, there are no specific regulations regarding the use of social media. Instead, each IRB determines what is acceptable use by interpreting the existing regulations surrounding clinical trials in general. Therefore, IRBs are responsible for balancing each of the risks and benefits of social media use. This leads to inconsistencies in clinical trial management across the country; research ethics should not differ based on location. Therefore, it is increasingly important to codify regulations to control the impact of social media use on the principles of respect, beneficence, and justice.

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