Stigmatizing Terminology for Outcomes and Processes (STOP) in Alcohol Research: A Meta-epidemiologic Assessment of Language Used in Clinical Trial Publications

Micah Hartwell, PhD, Vanessa Lin, BA, Mackenzee Hester, BS, Nicholas B. Sajjadi, BSc, Kelly Dunn, MD, James Morris, PhD, and Katie Witkiewitz, PhD

Introduction: Stigmatizing language used to describe patients and medical conditions is associated with poorer health outcomes. A recent investigation showed that approximately 80% of medical literature focused on alcohol use disorder (AUD) contained stigmatizing terms related to individuals; however, the quantification of stigmatizing terminology for outcomes and processes (STOP) among AUD research is unknown. Thus, our primary objective was to evaluate publications of clinical trials for their inclusion of STOP.

Methods: We performed a systematic search of PubMed for AUD clinical trials between January 1, 2017 and June 30, 2021. Article screening and data extraction were performed in a masked, duplicate manner by 2 investigators. We searched the full text of included manuscripts for STOP. We reported the frequency and percentage of manuscripts with STOP and individual terms. We evaluated associations between STOP usage and several clinical trial characteristics via logistic regression.

Results: Our search returned 1552 articles, which were then randomized and the first 500 were screened for inclusion. Of 147 included articles, 115 (78.2%) included STOP. The most common STOP were "drop out" (38.78%; 57/147), "relapse" (36.05%; 53/147), and "adherent, nonadherence" (35.37%; 52/147). No significant associations were found between STOP usage and trial characteristics.

Discussion: STOP was found in a majority of AUD clinical trial publications. As AUD is highly stigmatized, steps should be taken to eliminate usage of STOP in literature pertaining to AUD treatments. Many stigmatizing terms can be replaced by person-centered, more clinically accurate terms to further combat AUD stigma.

Key Words: alcohol use disorder, clinical trials, person centered language, stigma

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The use of nonstigmatizing, clinically accurate terminology in the field of addiction medicine is gaining traction in an effort to minimize the negative effects of stigma on patient healthcare outcomes.[1] Stigmatizing language is known to negatively alter providers' perceptions of patients, patients' self-perceptions, and treatment engagement.[2–4] Negative perceptions of patients by providers may impact the quality of care. For example, Kelly et al found that labeling patients as "substance abusers" led to providers pursuing more punitive measures rather than treatments.[2] Stigmatizing language not only impacts provider's perceptions but also impacts patients' self-image,[5] and recovery capital—the collective personal and institutional resources one has to overcome addiction.[5,6] The embedded nature of stigmatizing language in medical culture suggests that reducing the use of stigmatizing language requires intentionality—actively dismantling the presence of stigmatizing language in medical literature, medical terminology, medical education, and patient interactions.[2–4] Recent studies have discussed the importance of using nonstigmatizing terminology and patient-centered language and have offered alternative nomenclature that may facilitate positive culture change in medicine, particularly regarding addiction and psychiatric illness.[1,7]

Person-centered language emphasizes the patient or person above any disease or condition they may have.[8] Many studies have highlighted the high prevalence of stigmatizing, nonperson-centered language (labeling, euphemistic language,

and emotive terminology) in the medical literature from journals of numerous disciplines and specialties,[9–11] including alcohol use disorder (AUD).[7] Alcohol use is a major cause of morbidity and mortality and is annually responsible for 3 million deaths worldwide.[12] When comparing AUD with other mental health conditions, AUD was less likely to be seen as a chronic medical condition and linked to individual-blame as a component of stigma.[13,14] However, it has also been highlighted that the perceived causes of mental health and addiction may have complex stigma effects whereby biomedical attributions may alleviate blame, but may also increase other stigma components such as social distance, and perceived dangerousness or prognostic pessimism.[15,16] As such, all efforts seeking to enhance patient care in AUD are important healthcare objectives that warrant careful consideration concerning language and attributional consequences.

Another potential source of pejorative language in medicine is the use of stigmatizing terminology for outcomes and processes (STOP) used in clinical trial reporting.[17,18] A study by Ashford et al highlighted the lack of discussion surrounding precise terminology used in treatment outcomes of AUD.[3] In clinical trial reporting, many processes and outcomes have been defined with terms that bear a negative connotation,[1,17] such as "failing a test" rather than "testing positive," or "dropping out" of a study rather than "discontinuing participation" or more simply reporting attrition rates. STOP can lead to inaccurate assumptions about the patient receiving care-misidentifying reasons for discontinuity of care or implying that treatment design and clinician opinion supersede a patient's experience.[3] Eliminating the use of STOP in AUD clinical trial reporting may further support the change to nonstigmatizing, more clinically accurate terminology regarding patients with AUD.

The primary objective of the current study was to examine the prevalence of STOP among publications of clinical trials of alcohol use interventions, including AUD and heavy or binge drinking, from January 1, 2017 to June 30, 2021. These dates were selected because they follow the publication of *Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health*[19]-which specifically called for reducing stigma regarding substance use disorders. Findings from this study may reveal areas of medical literature that can be actively improved to further reduce stigma experienced by patients living with AUD.

METHODS

Journal Selection and Publication Randomization and Reduction

We conducted a systematic search via PubMed for publications of clinical trial results for alcohol interventions, from January 1, 2017 to June 30, 2021, with a search strategy adapted from the *Practice Guidelines For The Pharmacological Treatment of Patients with Alcohol Use Disorder*[20] (Supplement 1, http://links.lww.com/JAM/A326). Search returns were extracted from PubMed as a comma-sorted-value file and imported to Stata (StataCorp LLC, College Station, TX) for randomization (Supplement 2, http://links.lww.com/JAM/A327).

Search returns were randomly sorted, and the first 500 articles were selected to screen for inclusion by investigator VL and MHe. Screening was conducted in a masked, duplicated fashion.

Article Eligibility

Publications of primary or secondary results from clinical trials of alcohol use interventions including AUD and heavy or binge drinking were included for this investigation. Binge or heavy drinking studies were included when the publication operationalized and reported these terms. We included trials in any phase assessing feasibility, safety, or efficacy of pharmacologic treatments, devices, behavioral interventions, or other medical treatments. Studies must have been published between January 1, 2017 and June 30, 2021, and be available in English.

Data Extraction

Investigators (VL and Mhe) used a pilot-tested Google Sheet to report assessment of STOP in articles and to extract study characteristics. Before full initiation of extraction, authors VL and MHe extracted data from the first 30 manuscripts and compared results to ensure uniform answers. Data extraction responses were masked until completion, upon which the 2 investigators were unmasked and resolved any discrepancies.

STOP Identification

To explore our primary research question, we systematically searched each article for the presence of the following terms related to trial outcomes which were developed a priori to the study being conducted: "Clean," "Dirty," "Resistant," (as in "treatment-resistant"), "Compliant*" (as in compliant, compliance, or non-), "Adherent*" (as in adherent, adherence, or non-), "Dropout," "Fail" (as in failed, failure: related to treatment or testing), "Relapse," "Wagon," "Recovered." These terms have been shown to carry negative connotations within patient populations[3] or have been identified by experienced alcohol and addiction researchers as having negative bias.[17,21,22] The terms "medication-assisted treatment" or "-therapy," "recurrence," and "recovery" were not included, as Ashford et al found differing associations among patient populations when compared to terms such as "relapse," which was frequently associated with negative connotations.[3] We evaluated the full text of each article for any occurrence of the STOP listed previously using the *Find* feature in Adobe Acrobat Reader DC (Acrobat. adobe.com). Articles containing STOP were coded as "*including STOP*," and the incidence of each term was recorded.

Other Study Characteristics

During extraction, we also identified the type of intervention involved, the institution type of the first author, the study's funding source, the journal's H-index from Scientific Journal Rankings,[23] and whether the study mentioned adherence to the CONsolidated Standards Of Reporting Trials (CONSORT) reporting guidelines.

Data Analysis

From the systematic search, we reported (1) the total number of journals and articles returned from the PubMed search, (2)

the number of studies that were screened, and (3) the number of studies that were included based on the eligibility criteria from each selected journal. To estimate the presence of STOP within our sample, we calculated the frequency and proportion of articles with stigmatizing terminology in the sample. Further, to evaluate the most common STOP within these articles, we calculated frequencies and percentages for each STOP term overall. To evaluate associations between STOP occurrence and study characteristics, we used bivariate and multivariate regression analysis.

This study adhered to the Strengthening the Reporting of Observational Studies in Epidemiology guidelines for reporting and guidance from *Guidelines for reporting meta-epidemiological methodology research*[24]—as our study followed a research-on-research approach. Analyses were performed with a Type 1 error rate set at 0.05 and performed using STATA 16.1 (StataCorp LLC). This study was determined not to be human subjects research by an institutional review board. A protocol for this study, written before starting our study can be found on Open Science Framework (osf.io/sr65f/).

RESULTS

Search Returns and Study Characteristics

Our systematic search returned 1552 articles from 389 journals. Articles were then randomized and 500 were screened for inclusion—from which 147 met inclusion criteria (Fig. 1). Among the 147 included articles, 73 (49.66%) used behavioral interventions, 45 (30.61%) used pharmacologic treatments, 25 (17.01%) used devices, and 4 (2.72%) were grouped as *Other* (Table 1). A majority of studies were grant-funded (117/147; 79.59%). Fifty of the studies (34.01%) mentioned adherence to CONSORT reporting guidelines, and 103 were published in journals that required American Medical Assocation or International Committee of Medical Journal Editors (AMA or ICMJE) reporting guidelines. Study characteristics can be found in Table 1.

Inclusion of STOP

We found that 115 of the 147 (78.2%) articles included 1 or more instances of STOP. Among the 147 articles, we found

Systematic Search:
A search was conducted on 03/7/2021 of PubMed for clinical trials alcohol consumption interventions. A time frame between 01/01/2017 and 06/30/2021 was specified for the search.

Overall Search Returns:
1,552 articles returned

Article Randomization:
After downloading search returns, we used Stata 16.1 to randomized and 500 articles were selected for screening.

Article Eligibility:
To meet inclusion criteria, the article must have a publication of a clinical trial intervention for alcohol use disorder, dependence, and heavy or binge drinking assessing feasibility, safety, or efficacy of a pharmacologic, device, or behavioral intervention.

Articles Retained:
500 articles were screened of which 147 met inclusion criteria. 322 were excluded because they did not include alcohol interventions, 29 articles were not clinical trials, and 2 were not among population of interest.

Data Extraction for Primary Objective:
Primary Objective: The primary objective of this study is to quantify the use of stigmatizing terminology used to describe processes and outcomes in clinical trials for alcohol interventions.

Primary Outcome:
32 of 147 (21.76%) of articles were free of stigmatizing process and outcomes language.
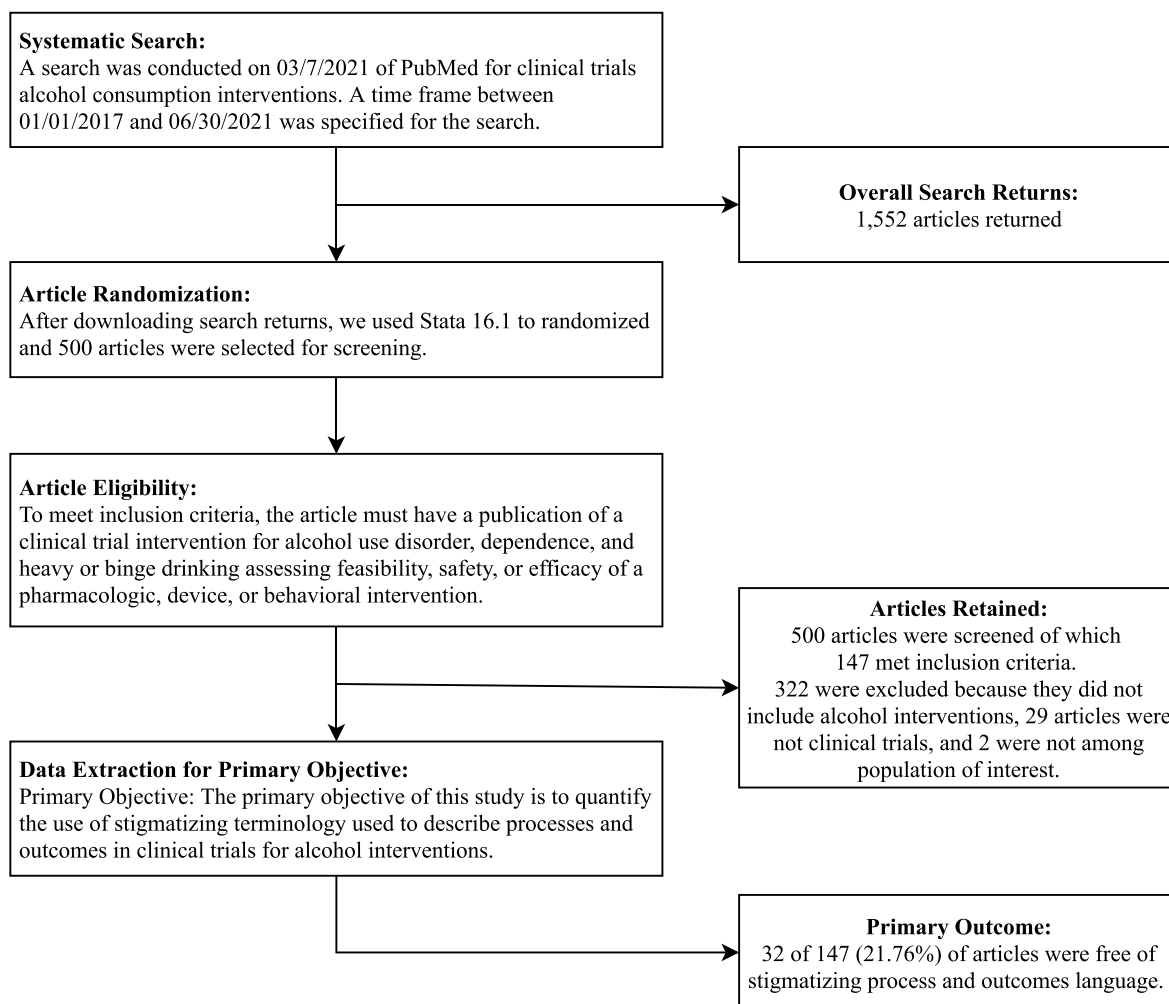
FIGURE 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram.

TABLE 1. Clinical Trial Publication Characteristics and Associations Containing Stigmatizing Terminology for Outcomes and Processes (STOP)

Article Characteristics	Articles With STOP (115) No. (%)	Articles Without STOP (32) No. (%)	Total (147) No. (%)	OR (95% CI)	AOR (95% CI)
Type of intervention					
Behavioral	58 (50.43)	15 (46.88)	73 (49.66)	1 (Ref)	1 (Ref)
Device	18 (15.65)	7 (21.88)	25 (17.01)	1.5 (0.53–4.26)	2.07 (0.67–6.4)
Pharmacologic	35 (30.43)	10 (31.25)	45 (30.61)	1.1 (0.45–2.73)	1.19 (0.43–3.29)
Other	4 (3.48)	0 (0)	4 (2.72)	1 -	1 -
Article funding					
Grant	94 (81.74)	23 (71.88)	117 (79.59)	1 (Ref)	1 (Ref)
Industry	3 (2.61)	1 (3.13)	4 (2.72)	1.36 (0.14–13.71)	1.64 (0.14–18.53)
No funding	2 (1.74)	0 (0)	2 (1.36)	—	—
No Statement	12 (10.43)	5 (15.63)	17 (11.56)	1.7 (0.55–5.32)	1.41 (0.42–4.8)
Public	4 (3.48)	3 (9.38)	7 (4.76)	3.07 (0.64–14.66)	6.83 (0.97–48.05)
Mention of CONSORT					
No	74 (64.35)	23 (71.88)	97 (65.99)	1 (Ref)	1 (Ref)
Yes	41 (35.65)	9 (28.13)	50 (34.01)	0.71 (0.3–1.67)	0.64 (0.24–1.68)
First author employment					
Government	14 (12.17)	4 (12.5)	18 (12.24)	1 (Ref)	1 (Ref)
Private	25 (21.74)	5 (15.63)	30 (20.41)	0.7 (0.16–3.04)	0.69 (0.14–3.29)
Public	74 (64.35)	23 (71.88)	97 (65.99)	1.07 (0.32–3.58)	0.97 (0.27–3.5)
Journal requires AMA/ICMJE guidelines					
Government	32 (27.83)	12 (37.5)	44 (29.93)	1 (Ref)	1 (Ref)
Private	83 (72.17)	20 (62.5)	103 (70.07)	0.64 (0.28–1.46)	0.6 (0.25–1.44)
Journal H-index*					
Mean (SD)	132.42 (64.97)	123.75 (61.58)	130.53 (64.14)	1 (0.99–1)	1 (0.99–1.01)

*H-index from Scientific Journal Rankings (https://www.scimagojr.com/journalrank.php) current as of July 21, 2021.

CI indicates confidence interval; CONSORT, CONsolidated Standards Of Reporting Trials; OR. odds ratio.

214 unique instances of STOP (Fig. 2). The most frequent STOP was "drop out"—related to a person(s) leaving treatment or discontinuing a study—found in 38.78% (57/147) of articles (Fig. 2). This was closely followed by "relapse" found in 36.05% (53/147) of articles and "adherent" (or "adherence" or "non-adherence/adherent") found in 35.37% (52/147) of articles. Further, "compliant" (or "compliance," or "non-") was found in 14.97% (22/147) of publications, and "fail" (or "failed" or "failure") was found in 14.29% (21/147). Instances

of STOP present in articles by journal are presented in Supplement 3, http:// links.lww.com/JAM/A328.

Associations Between STOP and Study Characteristics

We used bivariate and multivariable regressions to determine associations between the incidence of STOP and (1) the type of intervention, (2) funding source, (3) mention of CONSORT, (4) first author employment, (5) journal requirements

Use of stigmatizing terms for outcomes and processes in clinical trial publications
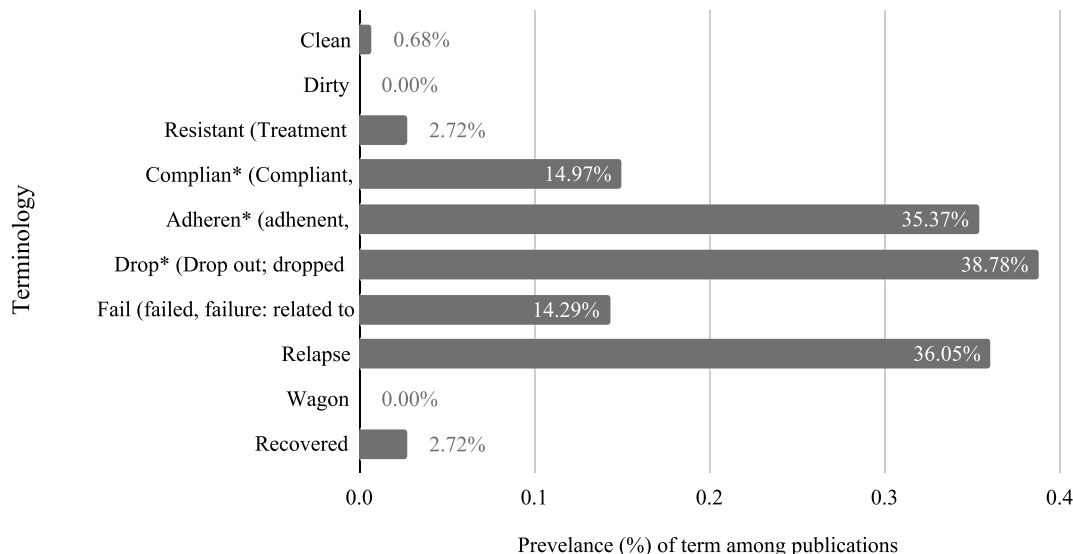
FIGURE 2. Use of STOP in clinical trial publications. STOP indicates stigmatizing terminology for outcomes and processes.

for adhering to AMA/ICMJE guidelines, and (6) journal H-index from Scientific Journal Rankings[23]; however, no statistically significant relationships were found. The multivariable logistic regression model, which included all study characteristics, accounted for 5.4% of the variance among articles including STOP ($X^2_{(10)}$=8.13, $P = 0.62$; Table 1).

DISCUSSION

Our investigation suggests that stigmatizing terminology for outcomes and processes (STOP) among AUD clinical trials is frequent and pervasive—being present in nearly 4 out of 5 studies. This finding highlights the need for improvement regarding clinically accurate, nonstigmatizing language in AUD research reporting. The use of STOP in reports of AUD clinical trials reinforces the stigma surrounding addiction, prevents positive change in medical culture, and may contribute to negative healthcare outcomes.[1,2] To our knowledge, our research is the first to quantify the prevalence of STOP within medical literature; however, as person-centered language and STOP are interrelated, comparisons can be drawn from person-centered language research in AUD and other fields. In previous research from our team, Hartwell et al. found that nearly 80% of medical literature focused on AUD was not adherent to the person-centered language guidelines presented in the American Medical Association's Manual of Style.[7] Similar rates of stigmatizing language have been found in medical literature focused on psoriasis,[9] amputations,[25] and heart failure,[26]—the latter of which prompted the Editor-in-Chief of the *Journal for Patient Centered Care* to assess the stigmatizing language appearing within the journal.[27] Therefore, in the context of these previous studies, our findings further highlight the prevalence of stigmatizing language in medical literature.

The most frequently used STOP in our sample were "drop out," and "relapse." The term "drop out" is synonymous with leaving high school early—therefore often associated with having inadequate education, poorer health, lower wages, higher rates of incarceration, and inability to achieve life goals.[28,29] However, using the term "drop out" to describe individuals who discontinue trial participation is inaccurate and harmful, as participant discontinuation may result from other causes such as lack of access to transportation, changes in housing status, mistrust in the medical community, or stigma surrounding mental health conditions.[30] "Relapse" is a term that associates a binary outcome with a person's engagement in drinking—thereby leading individuals to cross an imaginary line in which all progress is seemingly lost. As Miller points out in a 2015 article, all-or-none progress is antithetical to AUD treatment.[21] To portray this fact, Miller relates using the term "relapse'' to describe a person with diabetes presenting to the emergency room in a glycemic crisis. An individual with diabetes in the aforementioned setting is not told they have "relapsed"—nor should they be told they have "failed" in their treatment. Although clinical trials often rely on criteria to judge treatment effectiveness, reduced alcohol use or cravings may be best reported on a spectrum as opposed to a dichotomous endpoint. Moreover, individuals with AUD often have varying degrees of success, and if unplanned drinking does resume, it may be due to changes in their treatment needs or because treatment needs are not fully being

met. The term "adherence" or "adherent" was also frequently identified and can imply that patients' outcomes are solely dependent on receiving a full course of treatment which is often imprecise and inaccurate[31] It also dichotomizes individuals as adherent or nonadherent which may lead providers to a negative bias towards the latter group[32] even though behavior change is not always dependent on treatment engagement[31] These terms not only carry a stigma for the person receiving treatment but are also reductive—minimizing the importance of a trial participant's experience and diminishing the validity of their experiences. Consequently, the continual use of STOP in medical literature may contribute to its persistence in clinical practice[27,33] and may perpetuate the negative bias of health care providers toward individuals with substance use disorders.

Translation into Clinical Practice and Society

By implicitly endorsing stigmatizing language, authors of clinical trial publications may be potentially undermining efforts to promote person-centered language and alternatives to STOP. Notably, stigmatizing language has real-world implications for both people with AUD in terms of public stigma, selfchange, and treatment-seeking.[14,34,35] Terms such as "relapse'' are strongly associated with disease model conceptualizations of alcohol problems which, whilst important in some recovery contexts, can be harmful in others.[36] Relapse and other disease model conceptualizations can create a false binary in which people are either viewed as having a "problem'' or not. In contrast, models and language promoting more continuum or psychosocially-orientated models of AUD may have important benefits for problem recognition and help-seeking,[37,38] potentially mediated by lower stigma.[35,39,40] As such, clinical trialists should lead by example, ceasing the use of STOP and replacing it with person-centered and nonstigmatizing language. This change may in turn have important collateral benefits for other AUD discourses including public and policy spheres. For instance, significant efforts to implement alcohol brief interventions programs may have been undermined by binary and stigmatizing conceptualizations of AUD.[41] Similarly, underrecognition of the possibility of drinking reduction goals as a valid, self-directed treatment goal has also been associated with the over-application of binary and stigmatizing conceptualizations.[34,35] Notwithstanding the right for people to self-label or use terminology that may be common within certain recovery discourses, prioritizing person-centered language is a key strategy for addressing the persistent and damaging effects of addiction stigma.[42]

Implications for Clinical Trialists

Our findings, in addition to the previously mentioned person-centered language studies, further the need for language reform within the medical research community—especially for those treating stigmatized conditions. The design and implementation of clinical trials guides language within research settings, and it also guides clinical perceptions, patient experiences, and media narratives that report the findings from clinical trials. As such, it is critically important for AUD clinical trialists to consider reporting standards and whether STOP can be avoided in the trial registration, trial documents (including advertisements, consent forms, protocols, etc.), and in the reporting of trial results.

Considering language in trials and refraining from STOP may not only reduce the stigma of AUD but may also enhance precision and increase the rigor and reproducibility of clinical trial designs. For example, the term "relapse," used in more than one-third of trials in the current study, does not have a single agreedupon definition. A recent systematic review identified 25 unique definitions of "relapse" used in the alcohol literature, with definitions ranging from any use of alcohol to admission to treatment for acute services.[43] Thus, using the term "relapse" in clinical trials is not only stigmatizing, but it also lacks precision. Defining clinical trial processes and outcomes by the observed behaviors is far more likely to enhance rigor and reproducibility.

Recommendations

Within addiction treatment, long-term care for AUD is multifaceted and does not often hinge on pass-or-fail criteria. Completing treatment does not necessarily mean there will not be recurrences of symptoms. A novel approach to overcome these potential recurrences may be to consider that a person's treatment needs have changed and are no longer fully being met. Additionally, understanding that, in the process of change and recovery, progress should be expected—but not perfection. Changing the language used to describe the outcomes and processes of clinical trials will likely lead to conceptual changes regarding the addiction and recovery process and vice versa. In turn, this change may lead to reduced stigma and an improved, scientifically-driven understanding of addiction treatment. Given the potentially detrimental effects of STOP on patient outcomes, steps should be taken to eliminate STOP in AUD research. We recommend implementing training on STOP in future research to reduce the harm of STOP and using new terms to describe processes and outcomes of clinical trials. Firstly, "recurrence of use," which describes the non-judgemental return of behaviors or symptoms as used with other disease processes, could replace "relapse" terms, also noting that the word "abuse" is avoided due to its stigmatizing association. Secondly, "concordance with treatment/protocol," emphasizes the shared responsibility of both the person receiving the treatment and the providers or researchers administering the treatment in following mutually agreed-upon treatment plans or protocols. Lastly, "discontinuation" or "trial attrition rate," both of which describe the morally neutral event of a participant who is unable to continue with the study or treatment, could replace "drop out" terms. In a similar fashion to how we screened these articles—using the *Find* feature within the document viewer, we encourage authors to search for STOP and make adjustments to their manuscripts before submission, and we encourage journal editors to become more vigilant in their review, acceptance, and publication of articles in which STOP and nonperson-centered language are included.

Strengths and Limitations

A major strength of our paper is the use of previously published methodology[7,26] adapted to systematically search for STOP within articles, and in this case, publications of clinical trials. Further, to enhance transparency and reproducibility, our protocol is publicly available on OSF.io. The limitations of our study include the subjective nature of the terminology

assessed within articles; however, this risk was mitigated by identifying our list of search terms a priori and using the *Find* feature to systematically search each article. Another limitation is that we may not have included all STOP that pertains to AUD, thereby possibly underestimating the frequency in which it seems in the literature. Future research may expand this examination to include systematic reviews of clinical trials, as they are at the apex of the evidence hierarchy, and among other medical topics.

CONCLUSIONS

The current study identified the inclusion of STOP within nearly 80% of clinical trial publications for alcohol interventions—a finding consistent with the rates of nonperson-centered language found in other studies. Our study demonstrates a pervasive use of stigmatizing language within medical literature for AUD, which may lead to poorer health outcomes, lower problem recognition and treatment engagement, and fewer people seeking treatment options. Thus, we, as medical researchers in the field of addiction, must ensure that we use appropriate medical and technical language that incorporates the nature of patient-centered care when reporting outcomes in clinical trial publications.

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