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Improving rigor through gender inclusivity in reproductive psychiatric science

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ABSTRACT

Accurately defining the individuals that research involves and generalizes to is critical for rigorous and reproducible science. In reproductive psychiatry, which historically focuses on the impact of the menstrual cycle, pregnancy, and menopause on mental health, this means moving beyond characterizing samples and relevant populations as "women" in favor of language that precisely identifies the physiological characteristics pertinent to the research being conducted and accurately reflects the varied genders represented in those populations. Concrete recommendations are provided for precise use of sex and gender terminology and gender inclusivity throughout the scientific process, including study conceptualization, etiquette in research environments, recruitment, methods, and dissemination. Recommendations are discussed in depth and presented in a checklist format for ease of use by research teams. Suggested items for assessing gender and relevant sex-related physiology in the context of reproductive psychiatry are also provided.

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1. Introduction

Reproductive psychiatric science focuses primarily on the impact of pregnancy, menopause, and the menstrual cycle on mental health. Despite applying to approximately half the population, this work has long been ignored, un- or underfunded, and deemed a niche area. However, a burgeoning number of health scientists are working hard to address this gap [1], accompanied by funding initiatives and sex-related research mandates aimed at improving women's health [2–5]. However,

the term "women" does not include all of the individuals who experience menstruation, pregnancy, or (peri)menopause. Accurately defining the individuals that research involves and generalizes to is critical for rigorous and reproducible science. This commentary advocates for precise use of sex and gender terminology and gender inclusivity throughout the scientific process, including specific recommendations across study conceptualization, recruitment, methods, and dissemination.

We are focusing on scientific work involving recruitment, measurement, or manipulation of reproductive factors typically described as female, including but not limited to research on ovarian steroid hormones and related phenomena (e.g., puberty, menstruation, pregnancy, and menopause) and health conditions or experiences relating to having a vagina, uterus, ovaries, and/or developed breast tissue that may be studied in the context of psychological or psychiatric settings. We are not covering research specifically about gender identity and expression, although this is another critical area similarly deserving of careful and inclusive approaches. Further, we do not focus on clinical practice in this commentary, although we assert that one reason this matters in research is potential downstream effects on clinical care. Others have published

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thorough recommendations on gender inclusive approaches to patient care in contexts of overall health [6,7], obstetrics and gynecology [8], and mental health [9]. Finally, we discuss language throughout; we focus on English, but recognize that further work is warranted applying a gender inclusive lens to other languages, especially languages with grammatical gender.

2. Sex and gender

Sex refers to a large number of biological processes and physical traits, many of which relate to reproduction (e.g. genotype, internal and external anatomy, and hormone levels) [10]. While often conceived of as a binary (female, male), and for many experienced as such, sex is nuanced and diverse. As part of routine medical care, most individuals are assigned either female or male at birth (AFAB or AMAB), usually based on visible gonads consistent with one category. These external features are often presumed to correspond to genotype and eventual sex hormones/development; however, this is not typically directly evaluated. Approximately 2% of individuals are intersex or have differences in sex development (DSD), meaning that they do not fit into male or female categories, whether due to genetics other than XX or XY, alterations in how the body responds to reproductive steroid hormones, or many other possibilities (see Refs. [11,12] for thorough reviews of intersex/DSD). Some forms of intersex/DSD are observable at birth. These infants have historically often received surgery so they can appear to fit more clearly into an assigned binary sex; this practice can harm both the physiological and psychological wellbeing of these individuals and is increasingly disavowed by relevant medical organizations [13]. Other forms of intersex/DSD may not be evident until puberty or later.

In contrast, gender refers to a socially determined construct reflecting a constellation of attitudes, feelings, behavior, and self-expression often defined or influenced by cultural expectations. In Western culture, gender has been and largely remains constructed as a binary (woman/girl versus man/boy). Cisgender individuals have a gender identity/expression and lived experience that aligns with their sex assigned at birth; accordingly, many cisgender people may not learn that sex and gender are different [14]. In contrast, transgender (or trans) individuals have a gender identity that is incongruent with sex assigned at birth; this includes trans people whose gender is binary (transgender woman or man) or nonbinary - gender that falls outside the typical gender binary paradigm (e.g., nonbinary, gender fluid, agender, and many more). See Ref. [15] for comprehensive reviews of sex and gender [16], for glossary of transgender identities and terms, and [17] for a glossary of sex and gender terminology for research). The terms gender diverse and gender expansive can also refer to individuals broadly under transgender and nonbinary umbrellas. Gender inclusivity in the context of research is the practice of accurately and consistently acknowledging and affirming gender identity across all aspects of the research process. Our aim with this commentary is to promote gender-inclusive practices in reproductive psychiatric science, including but is not limited to inclusion in research samples, use of gender-affirming research materials and protocols, and inclusion and consideration in the framing and dissemination of theories and findings.

Accordingly, when applying a gender inclusive lens to female reproductive science, the relevant populations can no longer be considered "women," as this refers to gender rather than sex [17,18]. The label "women" can both include individuals without relevant physiology, such as in some cases trans women, and exclude individuals with relevant biological processes who are nonbinary or trans men. Furthermore, individuals in the transgender spectrum vary in the extent to which they medically transition, if at all, and what that may entail. Medical transition can include hormone suppression, hormone replacement therapy (HRT), and gender affirming surgeries [19]. Some choose not to medically transition. Some may also halt aspects of medical transition; for example, a trans man on HRT might stop temporarily in order to carry a pregnancy [8]. Accordingly, when

considering reproductive science, the relevant population is complex and dependent on the biological process in question.

3. Why gender inclusivity is essential for scientific rigor

Science requires precision to be rigorous and replicable, necessitating a clear and accurate approach across all components of the scientific process. Identifying the complete and specific populations relevant to research questions ensures that study samples fully represent this population and that dissemination efforts generalize appropriately. For example, if menstrual cycle research is framed as an issue affecting girls and women, studies of the cycle may (even inadvertently) recruit a sample of only cisgender women, fail to assess and report adequately on sample gender, and then disseminate findings as relevant to women's health (i.e., gender), despite the fact that sex hormone changes are the core processes under study (i.e., an aspect of sex). These studies thus systematically exclude transgender and nonbinary menstruating individuals, threatening generalizability to the entire population.

Furthermore, disseminating work that frames menstruation, pregnancy, and menopause as concerns specifically for women suggests that these issues are irrelevant for people of other genders. This can have wide-reaching effects, including reifying biases in clinicians and the lay public about who may require relevant health services [20]. As scientists in reproductive psychiatry, we are already fighting an uphill battle to ensure these topics are taken seriously, funded, and included in training for healthcare providers. If evidence-based clinical services are to be gender inclusive, we must start with the very science informing evidence-based practice and associated clinical contexts. While the impact of any specific study may be small, every piece of work framed without gender inclusivity reifies biases that continue to make seeking information, support, and care for reproductive health a confusing and uncomfortable prospect for many gender-diverse/expansive individuals (e.g., a trans man seeking care in a "Women's Mental Health Clinic") [8, 211.

While transgender and nonbinary people are a relatively small proportion of the population, the number of people openly identifying as gender diverse is growing [22]. Further, while gender diverse populations experience greater exposure to a wide range of risk factors for psychopathology (e.g., trauma and psychiatric symptoms, including depression, suicide, substance use [23–26]), little is known about prevalence of reproductive mood disorders (RMDs) in these populations. More data on occurrence of RMDs in gender-diverse populations is needed but cannot be obtained if studies systematically discourage or exclude gender diverse people from participating and/or fail to assess and report gender accurately. Studies are also needed on topics specific to this population, such as effects of gender-affirming hormone care on RMD symptoms.

Finally, all researchers are ethically mandated to minimize potential risks or harm to study participants [27]. Choosing to participate in research is an act of trust in the researcher that must be met with appropriate care and empathy. Gender diverse participants in research deserve respect and understanding. We hope our recommendations move researchers toward these principles and increase safety and comfort for gender diverse individuals in reproductive psychiatry studies.

4. Addressing barriers to gender-inclusive language

4.1. The fight for inclusion

For much of the history of medicine and science, male bodies were considered the default [28], and female or intersex bodies were systematically excluded as practitioners, scientists, and participants in health research. The fight for recognition of these distinct and specific health needs has been long and is far from over, and much of this battle has been fought by women. Many of these hard-won victories have come

in the forms of centers, initiatives, and funding opportunities named with terms like "women's health"; accordingly, the significance of these achievements for many of those involved may be intertwined with these names and the concept of womanhood. As we push for further movement toward inclusivity and reducing gender-based marginalization, we must be clear that <u>our goal is not to erase or negate these prior efforts</u>, but to expand them.

4.2. The trouble with "Female(s)"

An important linguistic challenge when disambiguating between sex and gender is that some words are commonly applied to both in everyday English. For example, while "female" in scientific writing typically refers to sex, there is no specific, commonly used adjective for gender that parallels the word "woman." The word female (which, as we have described above, most closely aligns with sex rather than gender) is therefore often also used to describe gender, e.g., "I identify as female" or "female gender." This reduces the clarity of using the adjective "female" to specifically reference sex ("female reproductive health") because it may be commonly interpreted as additionally or alternatively referencing gender.

The use of "female" as a noun is particularly fraught, given that referencing people as "female(s)" (especially as a parallel term to "man" or "men") can reflect disrespect, objectification, or dehumanization [29, 30]. For many, this serves a flag for potential misogyny. Increasingly, use of female as a noun is also common among *trans*-exclusive radical feminists (who may refer to themselves as "gender critical"), who use it to assert that who use it to assert that a woman is an "adult human female", emphasizing their belief that biological features determine gender [31,32]. Given these intense negative connotations, it is understandable that many object to the use of female(s) as a way to reference sex (versus gender). Therefore, the decision to use the word female in human research should be carefully considered, keeping in mind that "participants", "individuals", or "patients" are often functional replacements.

It is possible that new terminology could be developed and used for the specific purpose of referencing sex characteristics without invoking gender. However, even if it were clear that a word referenced only sex, this may not always solve the problem given that people vary in which sex characteristics are relevant to their bodies, especially for individuals who have undergone medical and/or surgical gender-affirming treatments.

4.3. But It's awkward ...

Given the complexities described above and the lack of a currently understood and unambiguous single term that fits the needs of reproductive psychiatric science, we advocate for using words with as much specificity to the research question as possible, without gendered language unless clearly relevant. For example, a study on post-partum depression might include "pregnant people," or a study on treatment for premenstrual dysphoric disorder might include "ovulating patients." Objections to this straightforward and scientific approach often come down to awkwardness or unfamiliarity with these types of terms. For a guide for selecting specific appropriate, gender inclusive phrasing in pregnancy research (largely generalizable across other areas of reproductive psychiatry), see [20].

While this phrasing may evoke feelings of awkwardness or discomfort as one first encounters and uses it, this inherently diminishes with time and practice. These approaches often require additional words, which can feel cumbersome or even disadvantageous in the context of tight limits on words or space. However, as scientists we frequently sacrifice concision for precision in other ways. If using multiple words feels too aversive or burdensome, sentences can often be restructured or even acronyms could be used if preferred.

In addition to these issues arising from lack of familiarity, a backlash

has emerged in response to efforts toward gender inclusive language, such as "pregnant people". Some say that this practice dehumanizes women by reducing them to biological functions (see Ref. [33] for examples). We and many others (e.g. Refs. [20,34]) argue that terms like pregnant people are not used to force a non-woman identity on anyone—these terms are for *groups of people* that include (often primarily) pregnant women alongside others with different gender identities who are pregnant.

5. Concrete actions toward gender inclusivity across stages of research

Below we discuss steps that can be taken toward gender-inclusive research in reproductive psychiatry. These recommendations are also summarized concisely as part of a Gender Inclusivity Checklist (Appendix A).

5.1. Study conceptualization and design

Given that reproductive psychiatry focuses primarily on biological processes and their impact, framing research through that lens (rather than through gender) is the most scientifically precise and our strong recommendation when possible. A critical starting point is to identify specific relevant biological processes to the research area and scientific question without gendered terms. From there, it becomes easier to determine the relevant population and the likely range of gender identities within that group. Identifying the range of genders of the target population can help ensure that studies represent and generalize to the whole population versus potentially systematically excluding or deterring participants who are not cisgender women.

For example, a researcher studying perinatal depression might be studying pregnant people. This topic is relevant to pregnant AFAB individuals, including cisgender women, nonbinary individuals, and trans men. For most menstrual cycle research, ovulation is the biological process responsible for hormonal flux and menstruation; accordingly, this work focuses on ovulating people. This would include a subset of AFAB people: specifically, those who have ovaries, are post-puberty and pre-menopausal, and who do not take hormones or other medications that inhibit ovulation. Thus, the relevant population includes cisgender women, nonbinary individuals, and trans men who meet the specific biological inclusion criteria.

In contrast, a study on how to increase breast self-examination behaviors as a preventative measure for breast cancer may be relevant to most AFAB individuals, as well as AMAB individuals on estrogenic HRT and thus at similar levels of risk for breast cancer. However, it may not be relevant to AFAB individuals post-mastectomy; for this topic, the relevant population would include a specifically-defined group of at-risk people that includes a mixture of cisgender women, nonbinary individuals (both AFAB and AMAB), trans men, and trans women.

Within reproductive psychiatry, we argue that it is typically inappropriate to intentionally recruit based on gender (e.g., "seeking women for a research study ...") unless experiences specific to gender are an explicit focus of the study. These exceptions likely would involve studying intersections of biological processes and gender. For example, a study on the potential role of gender dysphoria in perinatal mood symptoms for nonbinary and transgender pregnant people might limit inclusion to trans/nonbinary gender identities. It is uncommon that there is a reason to restrict studies to cisgender women—if proposed, this should be examined critically for a clear and compelling rationale as to why broader gender inclusion would not be appropriate. Not having the power to test effects of gender identity on the study outcomes, while a limitation that prevents direct gender comparisons, is not an acceptable reason to restrict inclusion criteria to only a subset of the relevant population.

5.2. Gender inclusive interaction with participants

Understanding terminology, definitions, and frameworks around sex and gender is an essential first toward gender affirmating interactions [35]. This knowledge translates to engagement with participants that communicates their gender is valid and seen, even in the potentially fraught context of discussing sex-related physiological processes. These topics typically cannot be learned effectively in a single training; ongoing supervision and team discussions are needed to address any confusion, issues, or participant feedback. For many teams, it may be ideal to hire a consultant with knowledge and experience around transgender issues to provide training for the entire team, including investigators, as well as review of study methods and materials. Consultants should be paid for their time, especially if working on funded research projects. Research groups should not assume that LGBTQ + team members have this background, nor should they be automatically expected to do this labor unless it is part of their defined role on the team.

Many human reproductive science studies involve obtaining highly personal information from study participants, which can be awkward or a deterrent for any participant. For gender minority participants to feel comfortable, study staff need to be trained on gender-inclusive etiquette from screening through all aspects of participation. This includes matter-of-factly asking about gender and pronouns and knowing how to apologize and correct oneself if necessary. In addition, study personnel should practice using gender-inclusive language if unfamiliar (e.g., the use of singular they as a person's pronoun) before interacting with participants. For a pragmatic and approachable primer on gender-inclusive etiquette, see Ref. [36].

Growth requires creating a lab culture where correction is welcome. Mistakes such as misgendering can cause stress and distress [37] and should be avoided as much as possible. Setting an expectation that if mistakes happen, team members will kindly and briefly correct each other in those moments facilitates learning across the group. Team members should be encouraged to respond to corrections without defensiveness and by thanking the person and continuing forward with correct terms [38]. It is essential to demonstrate this from top down—investigators must clearly welcome corrections, including from staff who are lower ranking within the team, especially given that research assistants are likely more familiar with participant demographics.

One way to convey respect and safety is to ask for permission before asking participants questions about their body parts, medical history, and reproductive health, explaining clearly why this information is needed and reminding people they can decline to answer any questions for any reason. This should be done, in addition to all requisite informed consent processes, immediately before asking potentially sensitive questions. These questions often happen during initial phone screenings to determine study eligibility. This can be an awkward and uncomfortable experience for people of any gender. Obtaining permission includes previewing potential question content, such as "Next, I would like to ask you a series of questions about body parts you may or may not have and your medical history. We understand these questions can be sensitive, and we are asking because this information is necessary to determine whether you are eligible for the current study. Is that ok with you?" If the response is affirmative, this can be followed by the reminder "Remember if you want, you can decline to answer or stop the screening at any time for any reason." If someone declines to answer or expresses discomfort about discussing aspects of their body that are centrally relevant to the research, it may not be possible to continue with screening. That may indicate that this is not an ideal study for that person to participate in-being direct and kind about explaining that, without judgments, annoyance, or further inquiry as to why it is uncomfortable, will increase the likelihood of the person feeling positively about the interaction, even if they are unable to participate.

5.3. Recruitment materials and methods

Recruitment methods and materials in reproductive psychiatric science often specify gender ("seeking women for a study" or "study on women's health"), despite eligibility for most studies in this field actually being determined by the occurrence of biological processes and not gender identity. We recommend using gender-neutral phrasing for studies potentially relevant to multiple genders. This could include using phrases such as "seeking participants for a study about pregnancy" or "study of mental health across the menopause transition" (see Ref. [20] for additional examples).

It is possible if not likely, especially given rising global levels of transphobia [39], that using these non-gendered terms may invoke criticism or derision by some. Our teams have received occasional negative comments on the gender-inclusive aspects of our social media recruitment advertisements. While we argue that ensuring our study materials are open and inviting to the full spectrum of relevant humans is worth the risk of upsetting some transphobic individuals, we understand that some research groups may wish to minimize the need monitor these types of responses and respond to negative feedback. Alternate phrasing, such as "we are studying pregnancy" or listing an eligibility requirement as "you are pregnant," achieves the goal of gender inclusivity while being less likely to attract attention from groups and individuals who may protest or deride gender-inclusive practices.

Many studies use screening forms to determine study eligibility. Questions about gender or that are unclear whether they refer to gender or sex, may screen out individuals who may in fact have the physiological processes or features relevant to the study, especially if skip logic is applied in electronic surveys [8]. A set of gender-inclusive questions designed for reproductive psychiatric science (Sex and Gender for Reproductive Science Form) that can be used as part of the screening process is included in Appendix B. Some individuals may experience these questions as uncomfortable or invasive, so explaining the rationale for collecting this information allows participants to make an informed decision about their comfort providing it. A gender item provides multiple gender options, allowing participants to check all that apply, and an option of "not listed, please specify." We choose to ask this, as well as pronouns, initially to communicate that the following questions about reproductive physiology will be understood as independent of gender and to validate those identities prior to asking potentially more sensitive physiological questions. These are followed by an item asking for assigned/assumed sex at birth and one asking about current reproductive organs—these are typically the appropriate items for determining eligibility and applying skip logic if used. The current physiology item can also be adapted to include other aspects if relevant to the study or to have follow-up questions as needed. For further discussion of best practices in assessing sex and gender, see Refs. [40,41].

In addition to these issues around wording, study advertisements often include non-verbal signifiers of gender or gender expression, such as colors and fonts typically perceived as feminine, and using photographs of traditionally feminine people in advertising. Given how strongly these cues can communicate about gender, using them may limit who may even notice the ad or flier, let alone perceives the research as relevant to themselves and enquires about participation. Nonbinary, transgender, and otherwise gender nonconforming individuals who experience the process being studied may assume the research opportunity is not for them or conclude the study will not be designed for or welcoming to non-cisgender individuals (perhaps correctly), especially given the amount of misgendering many have likely faced in reproductive health care settings. We also suggest considering the impact of the lab name, logo, and website, especially anything visible as part of recruitment or to potential participants.

As menstrual cycle researchers, we have seen these effects on study samples. Few if any participants endorse transgender or nonbinary identities in studies that advertised for women and used images of feminine people in their materials. However, our recent and ongoing studies of menstrual cycle exacerbation of suicidality and other forms of psychopathology use recruitment materials with either gender-neutral phrasing (e.g., people who menstruate) or without mentioning sex or gender (e.g., people experiencing suicidal thoughts) and utilize study images either not of people at all or of people with diverse gender expressions. These result in approximately 10–15% of the sample being gender diverse.

5.4. Study assessments and documentation

Study materials such as consent forms and assessments should be gender inclusive, including, but not limited to, demographic forms that comprehensively assess gender identity [41,42] (see Recruitment section for a description of the SGRS form to assess this, along with aspects of reproductive physiology, provided in Appendix B). Comprehensive assessments are needed even if you do not expect gender diversity in your sample—if you ask, the answers may surprise you! These assessments allow for accurate reporting of sample characteristics, in addition to sending a clear message that participants are expected to have a diverse range of gender identities. It is similarly important not to assume the sex or gender of participants' sexual and romantic partners. People may decline to enroll or drop out if the study seems non-inclusive or as if it were not designed with them in mind. It is entirely reasonable, especially given the degree of minority stress faced by members of the transgender community in daily life, for people not to opt into situations that seem likely to generate more of it.

When at all possible, study records should reflect a person's chosen name, even if different from their legal or given name (sometimes referred to as a "deadname" for gender diverse individuals [43]). The use of deadnames can cause distress and is another form of misgendering. It should be avoided in all person-to-person engagement. If there are situations that absolutely require a legal name (e.g. for research involving medical records where legal names are required to bill for services or for compensation-related tax forms), context should be provided to the participant as to exactly why this is needed and assurances made that only their chosen name will otherwise be used. Steps to ensure this happens include not storing deadnames in the same databases or same areas within a database where study staff look up participant information before contact and limiting staff access to deadnames as much as is feasible (e.g., only having the staff member who processes payments have access). These practices reduce (and ideally eliminate) the potential for potentially hurtful and alienating errors.

5.5. Dissemination

Precisely and accurately describing both the sample and relevant populations is essential for rigorous dissemination of findings. In reproductive psychiatry, when providing background for the study, as well as contextualizing the findings in discussion, it is typically accurate to refer to people who experience the relevant phenomenon (e.g., menstrual cycle, pregnancy, menopause); this is rarely defined by gender. Accordingly, manuscripts should not generalize to women (gender) if the study recruited participants based on sex or a biological process—even if the entire sample happens to identify as "women". In this case, saying "women" in the title, introduction, or discussion is likely inappropriate. While many of the recommendations presented do not apply to scientists conducting translational research with animals, if results from animal studies are discussed as potentially relevant to humans, the same specificity around defining relevant populations is warranted.

When describing a study sample, report on recruitment methods and materials clearly, including whether gendered language was used and whether it was clear that the study was open to people of multiple genders. If a study used terms like "women" in recruitment materials, this should be explicitly disclosed. Even if a study's sample is presumed

to be all women, this may not be the case if this was never explicitly assessed. Be transparent about whether you have the data to describe gender identity comprehensively or if this was assessed at all (many existing datasets may have assumed all participants to be women). If this was not assessed, clearly state this as a limitation in relevant manuscripts. If the study does lack data to generalize to all individuals in the relevant population, such as if the sample is all cisgender or you are using data where that was not (adequately) assessed, those limitations are important and need to be acknowledged directly.

As with recruitment materials described previously, presentations, posters, and other dissemination efforts that involve visual components should be considered for their messaging about gender. Consider whether images of people represent the population in question and are not limited to highly feminine people (or, for that matter, those who are white, thin, without visible disabilities, and conventionally attractive). While scientists often lack control over how their work may be reported on and discussed in general media, efforts should be made to encourage accurate reporting to the extent possible. This includes working with anyone drafting press releases and providing clear information in interviews if allowed to review articles before publication. And while researchers may lack any influence over images used in reporting on their work, they can make requests if interviewed as part of the process.

6. Conclusion

Gender inclusivity is necessary for research in reproductive psychiatry to be rigorous, ethical, and meaningful. While gender inclusive practices may seem confusing or awkward to people new to these concepts, generating science relevant to the full spectrum of humans experiencing reproductive psychiatric conditions requires moving past potential discomfort. Importantly, our discussion here is intended as the start of a much-needed conversation, not to have the final word. We hope to provide initial guidance and practical suggestions, and these will need to evolve alongside our understanding of gender and language. Best practices must include thoughtful and open exploration of these ideas, combined with actions to promote both scientific rigor and inclusivity.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendices A and B. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.cpnec.2023.100194.

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