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Cite this as: *BMJ* 2024;387:q2227
http://dx.doi.org/10.1136/bmj.q2227

BMJ INVESTIGATION

Dispute arises over World Professional Association for Transgender Health's involvement in WHO's trans health guideline

WHO says that it adheres to standard protocol for its transgender health guideline, but the process has been criticised for lacking transparency and an association with WPATH—an organisation under fire for meddling with its own guideline development. Jennifer Block reports

Jennifer Block *freelance journalist*

When the World Health Organization (WHO) announced the roster last December for its first guideline panel "on the health of trans and gender diverse people," it seemed heavily weighted towards the "gender affirming" approach, which promotes patient led access to hormonal and surgical treatments.[1 2] The endeavour quickly became mired in controversy, including a mass letter to WHO from more than 100 clinicians. Signatories charged that most of the panel's 21 members favoured the affirming approach, reporting affiliations with organisations including Global Action for Trans Equality (GATE) and the World Professional Association for Transgender Health (WPATH). There was also concern over the degree to which the panel's recommendations would be evidence based.

WHO seemed to address some of those criticisms: it published an FAQ document in January, postponed a February meeting to interpret evidence and issue recommendations, and in June announced that it was adding six new members.[2 3]

That same month, however, documents emerged showing that two members of WHO's guideline committee, in their capacity as executives of WPATH, had attempted to interfere with an independent evidence review commissioned by that organisation for its 2022 guidelines—and that the US government appeared to have influenced WPATH's guidelines. Despite these revelations, the two members remain on WHO's committee.

Based on rights or evidence?

A WHO guideline begins with a multidisciplinary panel charged with generating the research synthesis questions in need of answers, explains Paul Garner, professor emeritus at the Liverpool School of Tropical Medicine, UK, who has worked for 30 years in evidence based guideline development with Cochrane and WHO. Those questions determine which evidence reviews it chooses to commission, which will then inform the recommendations. "So, if a guideline development group lacks ideological diversity, it's likely to bias the recommendations," says Garner.

This was the chief concern raised in a January letter signed by more than 100 clinicians from 17 countries. WHO's guideline group "does not reflect the breadth of professional perspectives," it read. "A panel tasked with developing this guideline requires the expertise of members who have experience with patients who have transitioned as well as patients who have detransitioned."

There were also concerns about WHO's stated goal[2] of providing guidance on "interventions aimed at increasing access and utilization" of health services, among them "provision of gender affirming care, including hormones," without first demonstrating strong evidence that those interventions are beneficial.

Letters to WHO from the Society for Evidence Based Gender Medicine (SEGM), which has itself commissioned several forthcoming relevant systematic reviews,[4-7] and the Clinical Advisory Network on Sex and Gender (CAN-SG), a network of mainly UK and Irish clinicians, raised the question of whether WHO would be evaluating the benefits and harms of hormonal treatments for gender incongruence—or if instead it "has taken a policy position on this without critically appraising the evidence," as a letter from CAN-SG put it.[8]

Although WHO began work on the guideline in 2022, its public statements have been light on detail about its scope and process. The agency initially announced that it would follow standard WHO guideline development protocol, but the lack of specifics on a highly contentious topic drew heightened scrutiny. It wasn't until January this year that it clarified that the guideline would apply only to adults.

WHO extended the deadline for public feedback but maintained that it was focused on provision of health services and advocating the legal recognition of self-identified gender.[9] "The guideline will reflect the principles of human rights, gender equality, universality and equity," it wrote in January, but it provided no details or references regarding the "evidence synthesis" that it said was initiated in 2023.[10]

Hannah Ryan, a specialty registrar in clinical pharmacology at the Royal Liverpool University Hospital, is a Cochrane author with experience in guideline development and a member of CAN-SG. Ryan understood from WHO's statement that it saw the expanded provision of gender treatments as a matter of human rights, rendering the evidence base secondary. "While we welcome the commitment to upholding human rights," she tells *The BMJ*, "liberalised access to healthcare interventions that

might in fact have harmful effects is not actually in support of anyone's human rights."

SEGM wrote an 11 page letter in February calling for a more transparent process to ensure that "proper evidence reviews have been commissioned to address key questions." After the June revelations regarding WPATH's executives, both SEGM and CAN-SG wrote to express ongoing concerns that, as SEGM put it, the "strong overlap" between the WHO guideline group and WPATH "will have direct negative implications for the credibility of WHO's own process." WHO didn't respond directly to either group.

Reviews "completed and submitted" but not approved

WPATH's updated Standards of Care Version 8 (SOC8) guidelines—widely cited in support of gender affirming medical interventions for all ages—were published in late 2022 and were promoted as having "followed the most rigorous protocol in the world . . . a long and painstaking scientific review process."[11] In June this year, however, documents from two US lawsuits over the provision of treatment for gender dysphoria showed that WPATH had attempted to institute an "approval process" over manuscripts emanating from the independent systematic reviews it commissioned.[12]

The SOC8 update began in 2018, when WPATH commissioned systematic reviews from a team at Johns Hopkins University, Baltimore. Over the next few years that team "completed and submitted a number of reviews to the WPATH SOC8 Chairs and Chapters," said a March 2023 email exclusively obtained by *The BMJ* through a public records request. But the process didn't go smoothly, and just two manuscripts were published: one on the impact of hormones on mental health and another on prolactin levels in trans women taking oestrogen.[13 14] "We had hoped to publish more of those reviews but for a few reasons have not done so," wrote Karen Robinson, Johns Hopkins research lead, in the email.

In a separate exchange three years earlier with Christine Chang, a director at the US Agency for Healthcare Research and Quality, Robinson had referred to submitting "reports of reviews (dozens!)" to WPATH, but she added that "we have been having issues with this sponsor trying to restrict our ability to publish."

Johns Hopkins is one of nine centres contracted with the Agency for Healthcare Research and Quality to conduct systematic reviews on a wide variety of topics, and the agency was considering having one done on treating gender dysphoria in children and adolescents. Exactly how many systematic review manuscripts Johns Hopkins drafted remains unknown, and neither Robinson nor anyone from the university responded to *The BMJ*'s email requests for comment.

Robinson emailed Chang about problems with WPATH just days after receiving a letter from several members of its executive committee outlining new "policy and procedures," which instructed the Hopkins team to submit manuscripts to WPATH for an approval process that involved a vote by the SOC8 chair and co-chairs, as well as WPATH's board. Only then would the Johns Hopkins researchers be given a "green light to be published."

WPATH sent an update to Robinson and all SOC8 coauthors in October 2020 stating, "It is paramount that any publication based on the WPATH SOC8 data is thoroughly scrutinized and reviewed to ensure that publication does not negatively affect the provision of transgender healthcare in the broadest sense."

The approval process was to be overseen by the organisation's president elect at the time, Walter Bouman, a specialist in trans health at the University of Nottingham, UK. Gail Knudson, a physician at the University of British Columbia and former WPATH president, had also signed the letters to Robinson. Bouman and Knudson were appointed to WHO's guideline development group for transgender health and remain members. Neither responded to *The BMJ*'s request for comment.

Documents turned over to the courts also reveal that, as the SOC8 guidelines were nearing publication in summer 2022, WPATH was under external pressure from high up in the US Department of Health and Human Services to make a last minute change.[15] Specifically, Rachel Levine, assistant secretary for health, asked authors to remove minimum age recommendations[16] for gender related hormones and surgeries. Bouman met with Levine and staff in late July. At first, WPATH declined to remove the age minimums because this would subvert its "consensus based" methodology, offering instead to downgrade those recommendations into weaker "suggestions." But when the American Academy of Pediatrics threatened to denounce SOC8 if this change wasn't made, WPATH removed the ages entirely.[17]

Earlier that year Levine had referred to WPATH on National Public Radio as setting the "evidence based standard of care for the evaluation and treatment of trans individuals." The health agency and the academy declined to comment when approached by *The BMJ*.

The presence of WPATH executives on WHO's guideline development group is especially troubling to watchdogs such as Zhenya Abbruzzese, cofounder of SEGM. "If WHO continues to ignore the evidence that two of its guideline development group members led a recent effort to suppress evidence related to treatments in this area," she says, "it may harm WHO's reputation in other areas of medicine, where its clinical guidance is sorely needed."

WHO responds

When *The BMJ* began querying WHO in July the organisation defended the makeup of its guideline group as well as its process. It was "aware of allegations and media reports regarding WPATH" but "does not comment on legal issues involving external organisations." WHO conducts "careful reviews on conflicts of interest," it said, and "GDG [guideline development group] members act in their own expert capacity." Regarding evidence reviews for hormonal treatments, WHO said only that "members participate in consensus based decision making that uses internationally recognised methods to appraise relevant bodies of evidence."

In late August it provided more detail, telling *The BMJ* that "systematic reviews have been commissioned" to evaluate the risks and benefits of hormone treatment for gender incongruence in adults. This left the critics scratching their heads as to why this hadn't been made explicit, particularly given all the calls for more transparency. "Multiple inquiries from the concerned clinicians and researchers worldwide have been met with silence," says Abbruzzese.

WHO subsequently provided a list of nine systematic reviews and other research protocols to *The BMJ*. Seven are registered with the Prospero database and one with the Open Science Framework. WHO said that it couldn't locate a public link for the final commission, titled "Systematic reviews on the burden and health impact of stigma/discrimination and violence against trans and gender diverse people."[18-25] The registration details indicate that reviews were started as early as January 2023 and that some commenced months

earlier than their public registration in July 2024. None appear to have been completed or published yet.

Of those nine reviews, one will evaluate hormonal treatment specifically. Ryan and Abbruzzese take issue with the lack of attention to harms. Ryan says, "They plan to look for adverse events including misuse of hormones, suicidal behaviours, and mortality, but don't specify that they will examine the evidence for adverse effects attributable to hormone treatment, reproductive health, regret, or detransition." Abbruzzese adds, "There is nothing in the protocol about evaluating any of the potential harms such as cardiovascular and metabolic disease, osteoporosis, and hormone sensitive malignancies. This is highly unusual given the known risks of these medications."

Ryan also expresses concern that the systematic reviews "fail to examine the impacts" of legal recognition of self-identified gender—which WHO has defined as a health measure—"on any group other than trans and gender diverse people." Abbruzzese concurs, saying that "research must examine the potential harm on females who will lose the safety of single sex spaces to potentially fully genitally intact and testosterone empowered biological males. The impact on women's safety and values and preferences must be a key part of the research."

A positive recommendation by WHO has widespread health policy implications, says Garner. Once one of these has been made for a specific drug, for example, it's likely to be submitted for inclusion on WHO's essential medicines list. Garner says that a recommendation in a technical guideline tends to carry weight with WHO's Expert Committee that evaluates essential medicine applications, and it's "likely" to be approved. "Once it goes on the essential medicines list, that obliges governments to supply the drug," he says.

Gordon Guyatt, distinguished professor in the Department of Health Research Methods, Evidence, and Impact at McMaster University in Ontario, isn't bothered by this. "I think most people would say that adults thinking of transitioning should be allowed to make the decision, and the medical care to help them transition should be made available to them," he says. While there may be only low quality evidence of benefit, adds Guyatt, "it seems to me a very value and preference sensitive decision."

Juan Franco, a family physician and editor of *BMJ Evidence-Based Medicine*, agrees, as long as "the guideline clearly clarifies that patients have an understanding that the evidence is uncertain, and safeguards are in place to follow up and monitor for adverse events."

"An untenable position"

Robinson of Johns Hopkins pushed back on WPATH's demands, apparently many times. She wrote to WPATH, "We have the right to publish and any [Johns Hopkins University] publications arising out of the work conducted as part of this contract are not subject to approval by WPATH nor subject to any policy of WPATH. I feel like I have made these statements several times in email and phone conversations, beginning when the contract was being negotiated in 2018."

The hesitation among some WPATH SOC8 authors was that independent appraisals of the evidence would undermine legal efforts to protect affirming interventions from legislative restriction in minors. In a form that appears to have been part of WPATH's SOC8 publication process and is now legal evidence, a chapter author wrote, "Our concerns, echoed by the social justice lawyers we spoke with, is that evidence based review reveals little or no evidence and puts us in an untenable position in terms of affecting policy or winning lawsuits." Several WPATH SOC8 authors were serving as expert witnesses in lawsuits brought by the American Civil Liberties Union and other plaintiffs. Another commented that any language in the guidelines undermining medical necessity—such as "insufficient evidence" or "limited data"—would empower the people calling treatments experimental and arguing for limiting them to clinical trials.

In August 2020 Robinson conveyed to Chang at the Agency for Healthcare Research and Quality that "we found little to no evidence about children and adolescents." WHO came to a similar conclusion this year, calling the evidence "limited and variable."[3] Laura Edwards-Leeper, who cowrote the chapter on adolescents, explains to *The BMJ*, "We were told by WPATH leadership that Johns Hopkins couldn't do a review for the child or adolescent chapters because there weren't enough studies to review, so we just needed to write the guidelines based on expert consensus, essentially." The chapter on adolescents says that the "emerging evidence base indicates a general improvement in the lives of transgender adolescents" who receive medical treatment, but it doesn't cite a systematic review.

Carl Heneghan, director of the University of Oxford's Centre for Evidence-Based Medicine, says, "There's no such thing as 'not enough evidence to do a systematic review,' because what you do is set out a question and try to find all the available evidence." If a review finds only low certainty evidence, he says, the recommendation should be to "pursue treatment in the context of a research study addressing the uncertainties"—otherwise, patients will continue to have limited evidence to inform their decisions.

Franco of *BMJ Evidence-Based Medicine* says, "I think we all agree that we need more evidence in children. And we need to help the parents of children with diverse identities understand the need for research and how it will be helpful for them."

After the dispute between Johns Hopkins and WPATH just one review was published,[13] and it contains the wording WPATH demanded in its email to Robinson—language implying editorial independence: "The authors of this manuscript are responsible for its content. Statements in the manuscript do not necessarily reflect the official views of or imply endorsement by WPATH." Led by Kellan Baker, who received a PhD from Johns Hopkins in 2021, it found the strength of the evidence "low" in determining the effect of hormonal treatment on anxiety, depression, and quality of life, but it nevertheless concluded that such treatment "promotes the health and wellbeing of transgender people." Baker didn't respond to a request for comment.

WPATH stood by its guidelines, commenting that "WPATH could not and did not prohibit the [Johns Hopkins] evidence based review team from publishing." Others have come to WPATH's defence, among them Robinson's colleague Ian Saldanha, associate director of the Johns Hopkins Evidence-Based Practice Center. He cowrote a recently filed "friend of the court" brief that calls the SOC8 development process "rigorous" and "methodologically sound" and states, "While in theory it might be ideal for every aspect of a clinical practice guideline to be directly supported by a systematic review, in practice this is extraordinarily rare if not impossible."[26]

Heneghan says that a guideline written without a systematic review "invalidates the guideline as far as I'm concerned," as without a rigorous appraisal of the evidence "it comes down to opinion and dogma."

Mary Butler, co-director of the University of Minnesota's Evidence-Based Practice Center, signed the legal brief—which was sent to her by attorneys fully drafted—but tells *The BMJ* that she

wasn't familiar with the reported interference in WPATH's guideline development. She believed that the brief's intent was to promote "the ability of evidence based processes to support healthcare."

Guyatt says, "All guidelines should be based on systematic reviews of the relevant evidence." Furthermore, he says, "well conducted science that benefits the general community" should be available to all, so "it's mysterious why Johns Hopkins didn't publish" all the reviews it conducted, and it's "problematic" that WPATH would "attempt to block publication."

"Best practice would be to publish," Franco concurs. Even if the reviews were disseminated on preprint servers, says Heneghan, "there are no excuses in this modern era for not making your data or your particular systematic review available."

Competing interests: I have read and understood the BMJ Group policy on declaration of interests and have no relevant interests to declare.

Provenance: Commissioned; externally peer reviewed.

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