May 9, 2024

From: Paul Terdal, Health Consumer Advocate
To: Karen Winkel, Rules Coordinator, Division of Financial Regulation
Brooke Hall, Senior Health Care Policy Analyst
Lisa Emerson, Senior Policy Advisor
Re: Draft Rules for HB2002, Gender Affirming Treatment

Dear Ms. Winkel, Ms. Hall, and Ms. Emerson,

Thank you again for the opportunity to provide public comment on the draft administrative rules for HB2002, on Gender Affirming Treatment. I have appreciated the opportunity to participate in the rule-making process as an "interested observer."

This memo is to reiterate the points that I made in public comment in the last Rules Advisory Committee meeting regarding the proposed definition of "standard of care" and the need to include rules regarding coverage of detransition services.

The Division should NOT attempt to define an "accepted standard of care"

HB2002 requires carriers to provide coverage of "gender-affirming treatment that is" … "[p]rescribed in accordance with accepted standards of care."

By defining WPATH SOC 8 as the "standard of care" for the purposes of HB2002, you aren't merely identifying a list of services that carriers must cover – you are also prescribing the medical decision-making criteria that licensed health care professionals working for carriers must follow when reviewing prescriptions to confirm that they meet the "standard of care" for medical necessity.

Further, you are pressuring all licensed health care professionals in Oregon who seek insurance reimbursement for their services to make decisions in accordance with the recommendations in WPATH 8 – or risk being excluded from reimbursement.

This is unwise, exceeds your statutory rulemaking authority, and – especially over time – may harm patients. It may also expose both licensed health care professionals – and the Division itself – to considerable legal liability as the true "standard of care" evolves in ways that may contradict WPATH 8.

Meaning of "standard of care"

The "Standard of Care" in the practice of medicine is defined in ORS 677.265:

> ORS 677.265 (1)(c) * * * In determining whether to discipline a licensee for a standard of care violation, the Oregon Medical Board shall determine whether the licensee used that degree of care, skill and diligence that is used by ordinarily careful

> physicians in the same or similar circumstances in the community of the physician or a similar community.

The standard of care in medicine is something that evolves continuously and organically over time – it is not something that is written down in rules. Physicians are expected to stay current in their fields – such as by reading the latest journal articles, and by participating in continuing medical education. (OAR 847-008-0070 Continuing Medical Competency (Education)).

Sometimes the standard of care can change quickly – such as if a major, high-quality study finds a new technique to be markedly superior, or an existing technique to be less effective or more dangerous than previously believed. In some cases, medical devices or pharmaceuticals are recalled or withdrawn from the market based on clinical research or adverse event reports.

Physicians are expected to monitor these changes continuously, and adapt their practices as needed to ensure patient safety and good patient outcomes.

The standard of care is NOT something that should be defined in detail an administrative rule.

For reference, I have attached an article, "The Elusive Standard of Care" from the Journal of the American Academy of Psychiatry and the Law.[1]

The Division Has No Legal Authority over the Standard of Care

Oregon law (ORS 677.265) clearly gives the Oregon Medical Board – and NOT the Division of Financial Regulation – the authority to make determinations about the "standard of care."

There is nothing in the legislative record for HB2002 to suggest that the Legislature intended to transfer this authority over the practice of medicine to the Division of Financial Regulation.

The Division and the RAC Lack the Expertise to define the Standard of Care

None of the Division staff working on the HB2002 rules are licensed to practice medicine in the State of Oregon.

In one meeting, a Division policy analyst told the RAC that she wasn't even very familiar with he contents of the WPATH 8 document and was relying o the RAC members to explain it.

None of the RAC members are licensed to practice medicine in the State of Oregon, either. The RAC consists primarily of lobbyists, lawyers, regulatory specialists, and consumer adovcates without medical training. One RAC member (Amy Penkin, Clinical Program Manager, Transgender Health Program, OHSU) is a Licensed Clinical Social Worker – and is authorized to provide counseling or psychotherapy [ORS 675.510] – but not any of the types of medical or surgical procedures described in WPATH 8.

There is no one involved in this rule-making process with the expertise, licensure, or other qualification to evaluate or advise on the clinical evidence supporting WPATH 8, or the merits of the 260 pages of recommendations contained within it.

[1] Cooke BK, Worsham E, Reisfield GM. The Elusive Standard of Care. J Am Acad Psychiatry Law. 2017 Sep;45(3):358-364. PMID: 28939735. https://pubmed.ncbi.nlm.nih.gov/28939735/

In the April meeting, one RAC member suggested that if there were future developments in clinical evidence, then the RAC could reconvene to consider the evidence and make decisions about whether to amend the rule. Since nobody on the RAC – or in the Division - has any qualifications of any kind to evaluate such clinical evidence, that would be wholly inappropriate.

WPATH 8 is Not Broadly Accepted as the Standard of Care

Even if the Division were to define a "standard of care," WPATH 8 is not a good choice.

A recent systematic review of "Clinical guidelines for children and adolescents experiencing gender dysphoria or incongruence"[2] by the University of York, in coordination with the The Independent Review of Gender Identity Services for Children and Young People (The Cass Review)[3] commissioned by the National Health Service England, raised serious concerns about the validity and integrity of WPATH 8.

For instance, the Cass Review concluded that "WPATH 8 overstates the strength of the evidence in making these recommendations."

The Cass Review also found a pattern of "circular support" for claims of evidence:

> "WPATH 8 cited many of the other national and regional guidelines to support some of its recommendations, despite these guidelines having been considerably influenced by WPATH 7. The links between the various guidelines are demonstrated in the graphics in the guideline appraisal paper (Hewitt et al., Guidelines 1: Appraisal)."
>
> "… The circularity of this approach may explain why there has been an apparent consensus on key areas of practice despite the evidence being poor."

Coverage for Medical Procedures Associated with a Gender Detransition

During the legislative process, DCBS Director Andrew Stolfi sent a letter to Speaker Dan Rayfield regarding coverage for medical procedures associated with a gender detransition:

> Given this definition, we believe that detransition procedures would be included in the definition of "gender affirming treatment" under HB 2002. To illustrate, an individual who previously received gender affirming treatment and who is now seeking to reverse the effect of that treatment would be seeking treatment for an incongruence between their gender identity (namely, their appearance) and their sex assigned at birth. This conclusion is supported by HB 2002's explicit inclusion of

[2] Taylor J, Hall R, Heathcote C, et al. Arch Dis Child Epub 09 April 2024. doi:10.1136/ archdischild-2023-326499. https://doi.org/10.1136/archdischild-2023-326499

[3] Hilary Cass, "Cass Review: Independent Review of Gender Identity Services for Children and Young People," NHS England, April 2024. https://cass.independent-review.uk/wp-content/uploads/2024/04/CassReview_Final.pdf

> "revisions to prior forms of gender affirming treatment" in the same section's list of prohibited exclusions.
>
> Finally, HB 2002 specifically requires the department to adopt rules implementing the bill. If a question remains on this issue after HB 2002 becomes law we would be glad to address that as part of such rulemaking.

In my role as a Consumer Representative, I have been contacted by health consumers seeking help with detransition – who have been told by carriers that coverage is not available. There are key issues to address, including which diagnostic codes should be applied for detransitioning (e.g., is this an "other gender identity disorder F64.8"? Is this consistent with the ICD definition of F64.8?)

Detransitioners are facing considerable social stigma, bullying, and harassment – and report feelings of isolation from the LGBTQ community, the medical community, and the public at large. It is very important for the Division to work directly with detransitioners to get their input. There is no one currently on the RAC who can effectively represent the interests of detransitioners.

I am surprised – and concerned – that there has been no progress on this issue during the rules development process so far, even though I and others have raised the issue several times.

The legislature had been considering a possible amendment to explicitly require coverage of detransition services – and chose not to proceed after receiving this letter from Director Stolfi.

If for some reason the Division feels that coverage of detransition services is so obvious and clear that there is no need for rule-making, please discuss that with the Insurance Advisory Committee, the RAC, the carriers, and the detransitioners to ensure that this conclusion is broadly accepted.

Sincerely,

/s

Paul Terdal

Attachments:

- 358.full.pdf: Cooke BK, Worsham E, Reisfield GM. The Elusive Standard of Care. J Am Acad Psychiatry Law. 2017 Sep;45(3):358-364. PMID: 28939735.
- archdischild-2023-326499.full.pdf: Taylor J, Hall R, Heathcote C, et al. "Clinical guidelines for children and adolescents experiencing gender dysphoria or incongruence: a systematic review of guideline quality (part 1)," Arch Dis Child Epub 09 April 2024. doi:10.1136/archdischild-2023-326499
- Rayfield_ltr_signed.pdf: letter that DCBS Director Andrew Stolfi sent to Speaker Dan Rayfield on April 20, 2023, regarding coverage for medical procedures associated with a gender detransition

The Elusive Standard of Care

Brian K. Cooke, MD, Elizabeth Worsham, MD, and Gary M. Reisfield, MD

In medical negligence cases, the forensic expert must explain to a trier of fact what a defendant physician should have done, or not done, in a specific set of circumstances and whether the physician's conduct constitutes a breach of duty. The parameters of the duty are delineated by the standard of care. Many facets of the standard of care have been well explored in the literature, but gaps remain in a complete understanding of this concept. We examine the standard of care, its origins, and who determines the prevailing standard, beginning with an overview of the historical roots of the standard of care and, using case law, tracing its evolution from the 19th century through the early 21st century. We then analyze the locality rule and consider local, state, and national standards of care. The locality rule requires a defendant physician to provide the same degree of skill and care that is required of a physician practicing in the same or similar community. This rule remains alive in some jurisdictions in the United States. Last, we address the relationship between the standard of care and clinical practice guidelines.

J Am Acad Psychiatry Law 45:358–64, 2017

A medical negligence case is the result of a clinical situation that has had an adverse outcome. The task of the forensic expert is to determine what actions a defendant physician should have taken and whether a breach of duty has occurred, in accordance with the parameters set forth by the standard of care. Thus, the forensic expert must both define the standard of care and opine whether it has been properly applied.[1]

Scholars have examined the standard of care and provided guidance for those involved in these forensic cases. For example, Recupero and Harms[2] studied whether psychiatrists treating outpatients agree about the standard of care for requesting records from a patient's past clinician. Rogers *et al.*[3] provided commentary on the differences between legal and clinical standards of care and offered suggestions on incorporating medicolegal aspects of standard of care in psychiatry residency curricula. Simon[4] wrote an editorial on standard-of-care testimony for *The Journal*.

Experiences with clinicians and a personal review of expert witness testimony suggest that a complete understanding of the standard of care is still elusive. What is a "standard of care"? From whence does it arise? Who determines the prevailing standard? Our aim is to examine these questions, beginning with an overview of the historical roots of the standard of care and using case law to trace its evolution from the 19th century through the 20th and early 21st centuries. We analyze the locality rule and consider local, state, and national standards of care. Finally, we address the relationship between the standard of care and concepts with which it is often conflated, such as best practices, expert opinions, and the now-pervasive clinical practice guidelines.

The Genesis of the Standard of Care

Through most of the first half of the 19th century, there was little scientific foundation for the practice of medicine. It was based largely on a received ancient wisdom, and bore practically no resemblance to the medicine of today.[5] Early American physicians, like their European counterparts, attempted to establish professional authority based on education, licensing, and membership in professional societies, but there was little legitimate basis for their claims.[6] This disjunction was brought into stark relief during Andrew Jackson's administration, which was marked by egalitarian, antielitist sentiments. Under Jackson, all state medical licensing laws were repealed, replaced by a "marketplace professionalism" in which anyone, trained or not, was free to offer their services in an unregulated marketplace.[5]

This situation began to change around the mid-19th century, as traditional medicine began to reas-

Dr. Cooke is Clinical Associate Professor of Psychiatry and Dr. Reisfield is Clinical Associate Professor of Psychiatry, University of Florida College of Medicine, Gainesville, FL. Dr. Worsham is Staff Psychiatrist, Department of Veterans Affairs and Courtesy Assistant Faculty with UFHealth Jacksonville, Department of Psychiatry, Jacksonville, FL. Address correspondence to: Brian K. Cooke, MD, Springhill Health Center, 8491 NW 39th Avenue, Gainesville, FL 32606. E-mail: cooke@ufl.edu.

Disclosure of financial or other potential conflicts of interest: None.

sert its authority. The American Medical Association (AMA), founded in 1847, worked for reforms in medical education, standardization of medical practice, and reinstitution of licensing laws.[5] As well, medical authority began to be asserted on the basis of the legitimacy of practice and scientific breakthroughs in, for example, ether anesthesia (1846), introduction of antisepsis by Lister (1867), and immunology, including the development of vaccines (cholera, 1879; anthrax, 1881; and rabies, 1882). Medical doctors were the primary emissaries of these advances, and their growing competence began to bestow legitimate authority upon them.[7]

Through the first third of the 19th century, medical malpractice lawsuits were extremely rare.[8] These actions, originally derived from English jurisprudence, were comprised chiefly of common law writ proceedings. The middle third of the century, dubbed by Spiegel and Kavaler[8] as America's first medical malpractice crisis, coincided with this era of marketplace professionalism. During this period of unlicensed, unregulated practice, in which medical doctors ("regulars") openly competed both with members of their own profession and with their "irregular" counterparts (e.g., homeopaths, hydropaths, and botanists, among others), medical care was sometimes regarded by the courts as comprising a contract between individuals and malpractice as a breach of contract. Gradually, during the final third of the century, tort emerged as an independent branch of the law and, with it, the concept of medical negligence evolved as a genuine tort doctrine, conditioned on a policy determination that a standard of care had been breached.[9]

White[9] argued that the writ system collapsed of its own weight, devolving into an unwieldy classification system, chiefly because of the growing diversity of American law. Little academic attention has been paid to the reasons for the shift from contract to tort.[10] Certainly, both medical and legal factors were responsible. Mohr[5] asserted that the change was brought about, in large part, by the medical profession's efforts to achieve professional status and to distinguish medical care from ordinary commercial transactions. Medicine argued that contracts assumed equal footing between parties, and the increasing complexity of medicine created asymmetries in knowledge, risk evaluation, and bargaining power that made contract law unsuitable to the evolving nature of the physician–patient relationship.[5] As well, Atiyah[10] argued that medical misadventures, comprising unforeseen and accidental events, could not reasonably be accommodated by contract law.

In any event, the result was that, by the end of the 19th century, medical malpractice was firmly rooted in the principles of tort law. Whereas contract actions are evaluated based on agreed-upon outcomes, tort actions are evaluated by the integrity of processes.[11] The integrity of processes, in turn, are adjudged by the adherence to standards. To be liable for breaching standards of care, accepted standards must first be established.[11] Thus, the adoption of tort law required the establishment of standards by which medical care could be evaluated, standards that the AMA played a role in developing.[5] Although physicians would be protected from claims based on failure to achieve contracted outcomes, it left them vulnerable to whatever deficiencies in adherence to standards of care plaintiffs could demonstrate.[11] The medical establishment was willing to pay this price for its professional status.

The Locality Rule

As malpractice law evolved, courts began comparing a physician's practice to those of similarly situated professionals in their community. The applicable standard of care in medical malpractice lawsuits varies somewhat among jurisdictions in the United States. Expert witnesses should understand whether a locality rule applies in the jurisdiction of the case in which they have been retained. Black's Law Dictionary defines the locality rule as "a term in medical jurisprudence where the physicians of an area must maintain standards of practice."[12] The locality rule requires defendant physicians to provide the same degree of skill and care that is required of other physicians practicing in the same or similar community. It places a geographical dimension on the professional standard of care in medical negligence litigation.[13] The strictest form of the locality rule would require expert witnesses to practice in the same or a similar community of the case in which they are offering opinions.[14]

Once widely adopted in the United States, the locality rule was originally designed to protect rural physicians from having to uphold the same standard of care as that provided in the academic health science centers and modern clinics of the city.[15] It was believed that rural practitioners lacked the equipment of the urban health centers and did not benefit from the latest advances in science and practice that emanated from medical research conducted at urban

hospitals. There is controversy, however, because some critics have called extant locality rules "archaic, anachronistic, and in fact, insulting to modern medicine" (Ref. 13, p 324–5).

Landmark Cases

The origin of the locality rule is often attributed to *Small v. Howard*,[16] an 1880 opinion of the Supreme Judicial Court of Massachusetts that endured until overruled by the same court in 1968. This case is cited as the first appellate decision requiring the use of a locality rule. In *Small*, Dr. Howard was sued by a patient in Massachusetts for alleged "malpractice in dressing and caring for a wound upon the [patient's] wrist" (Ref. 13, p 322). Dr. Howard was a general practitioner in a country town with a population of 2,500. He was consulted by the plaintiff, Mr. Small, to treat a severe wound, a serious injury caused by glass, that required a considerable degree of surgical skill. The wrist wound "extended to the bone, severing all the arteries and tendons" (Ref. 13, p 328). In *Small*, the plaintiff proposed, and the trial court refused, an instruction suggesting "that the skill required of the defendant was merely the average skill of all practitioners, educated and uneducated, permanent and occasional, regulars and interlopers alike" (Ref. 13, p 329). The Supreme Judicial Court of Massachusetts rejected this form of instruction and offered the following, which is often credited as the origin of the locality rule:

> The defendant . . . being the practitioner in a small village . . . was bound to possess that skill only which physicians and surgeons of ordinary ability and skill, practi[c]ing in similar localities, with opportunities for no larger experience, ordinarily possess; and he was not bound to possess that high degree of art and skill possessed by eminent surgeons practi[c]ing in large cities, and making a specialty of the practice of surgery [Ref. 13, p 329].

In *Brune V. Belinkoff*,[17] the Supreme Judicial Court of Massachusetts overturned their prior ruling in *Small*. *Brune* was a malpractice case of Ms. Theresa Brune who sought to recover from the defendant because of alleged negligence in administering a spinal anesthetic. Ms. Brune delivered a baby in 1958 at St. Luke's Hospital in New Bedford, Massachusetts. During the delivery, Dr. Belinkoff, a specialist in anesthesiology practicing in New Bedford, administered a spinal anesthetic to the plaintiff containing 8 mg of pontocaine in 1 cc of a 10% solution of glucose. When Ms. Brune attempted to get out of bed 11 hours later, she slipped and fell on the floor. She subsequently complained of numbness and weakness in her left leg, which appeared to have persisted to the time of trial.

Eight physicians provided testimony, much of which was related to the plaintiff's condition. There was ample evidence that her condition resulted from an excessive dosage of pontocaine. Others testified that it was an appropriate dose and a customary dose for New Bedford vaginal deliveries.[17]

The Supreme Judicial Court of Massachusetts offered:

> A general medical practitioner is to be held to the standard of care and skill of the average qualified practitioner, and a medical specialist is to be held to the standard of care and skill of the average practitioner of the specialty, taking into account with respect to either the general practitioner or the specialist the advances in the profession and the medical resources available to him [Ref. 17, p 798].

Thus, a specialist should be held to the standard of care and skill of the average member of the profession practicing the specialty, taking into account the advances in the profession.

The last case we review redefined the standard of care but was heard in a different jurisdiction than the previously two described cases. In *Hall v. Hilbun*,[18] Terry Hall was admitted to the hospital in Mississippi in May 1978 complaining of abdominal pain. Dr. Hilbun, a general surgeon, was consulted and performed surgery for a small bowel obstruction. Mr. Hall had provided adequate consent, and surgery was performed with apparent success. However, Mr. Hall later died in the hospital of respiratory failure.

Two areas of fault suggested were Dr. Hilbun's failure to make inquiry regarding his patient's postoperative course before retiring on the night of May 20 and his alleged failure to give appropriate postoperative instructions to the hospital nursing staff. The plaintiff called Dr. S. O. Hoerr, a retired surgeon from Cleveland, Ohio, as an expert witness. Through that testimony, the plaintiff sought to establish that there is a national standard of surgical practice and surgical care of patients in the United States to which all surgeons, including Dr. Hilbun, are obligated to adhere. Dr. Hoerr conceded that he did not know for a fact the standard of professional skill, including surgical skills and postoperative care, practiced by general surgeons in Pascagoula, Mississippi, but that he did know what the standard should have been. The Mississippi Supreme Court provided the following:

> [G]iven the circumstances of each patient, each physician has a duty to use his or her knowledge and therewith treat through maximum reasonable medical recovery, each patient, with such reasonable diligence, skill, competence and prudence as are practiced by minimally competent physicians in the same specialty or general field of practice throughout the United States, who have available to them the same general facilities, services, equipment and options [Ref. 18, p 873].

Emergence of Professional Standards

The locality rule was established before the standardization of medical training and certification, which, critics argue, obviated the need for a locality rule. The Liaison Committee on Medical Education (LCME) is recognized by the U.S. Department of Education as the reliable authority for the accreditation of medical education programs leading to a Doctor of Medicine degree.[19] The LCME was founded at a 1942 meeting of the Association of American Medical Colleges and the AMA.[20] The accreditation of allopathic medical schools in the United States is granted by the LCME through compliance with national standards. The locality rule is now difficult to justify, as medical education has become more standardized, and modern technology provides rural physicians with the same access to information for patient care as is available to urban ones.

The Accreditation Council for Graduate Medical Education (ACGME) was founded in 1981 and accredits all U.S. clinical residency and fellowship programs.[21] The ACGME accredits organizations that provide continuing medical education that has a national focus. Medical board certification examinations, administered by the member boards of the American Board of Medical Specialties since its founding in 1933, are national in scope. Although medical school training, medical licensing requirements, and board certification requirements are based on national standards, some states continue to rely on local practice standards to determine the applicable standard of care in medical malpractice lawsuits.

Toward a National Standard of Care

Although *Brune* overturned *Small* and there is an established national basis to the training and certification of medical education, the locality rule remains alive in the United States. Lewis and colleagues[22] delineated which states had established different standards of care. At the time of that publication in 2007, 21 states maintained a version of the locality rule, in which physicians are judged by the standard of care in their locality; 29 states followed a national standard. Of the 21 states that followed a version of the locality rule, 3 followed a statewide standard, 2 the same-community standard, 11 the same- or similar-community standard, and 5 the similar-community standard for general practitioners and a national standard for specialists. These counts were updated in 2014 (M. H. Lewis, personal communication, July 6, 2015); 45 states are now believed to follow a national standard, whereas only 5 states (Arizona, Arkansas, Idaho, New York, and Pennsylvania), still follow a version of the locality rule. Notably, medical schools operate in all states that adhere to the locality rule except Idaho.

A national standard of care presupposes that rural physicians will have the same training, and exercise the same level of judgment and diligence, as urban practitioners. It does not require that rural physicians have the same available medical facilities. For example, if the community does not have facilities for emergency surgery, physicians cannot be found negligent for failing to perform this surgery within the amount of time that might constitute the standard in a well-equipped urban hospital. Because there would still be differences in available resources, physicians practicing under a national standard would need to alert patients to the lack of necessary facilities or resources, should they exist. Advances in modern medicine and the ease of access to those advances regardless of practice location give further support for the eradication of the last vestiges of the locality rule in United States.

Clinical Practice Guidelines

In the 1970s and 1980s, the literature regarding health care costs, common practices, and outcomes surged.[23–26] Research demonstrated that medicine was practiced differently depending on location. For example, patients in Miami spent twice as much time in the hospital and intensive care units as similar patients in Minneapolis.[26,27] In addition, costs for comparable populations differed markedly across the United States. Gawande[24] reported that, in 2006, the average Medicare enrollee in McAllen, Texas, received approximately $15,000 per year in medical services, twice as much as comparable patients in the nearby and sociodemographically similar El Paso. Such disparities represent, in part, local differences in medical culture, including the degree to which communities practice defensively, especially if the science is unclear.

Because of these marked health care delivery inconsistencies, the United States Congress heeded the call for improvements in 1989 by creating the Agency for Healthcare Quality and Research, now called the Agency for Healthcare Research and Quality (AHRQ).[28] This agency was charged with creating specialty-specific clinical practice guidelines to align the fragmented practice of medicine in America. The AHRQ defined practice guidelines as "systematically developed statements [to] assist health care practitioners and patients to make decisions about appropriate health care for specific clinical circumstances."[29]

Professional medical societies, state governments, liability insurers, and health insurance companies followed suit and created their own guidelines. The AHRQ hoped that practice guidelines would result in a more uniform practice of medicine. In addition, the guidelines would provide a host of other benefits, including effective dissemination of research findings into clinical practice, promotion of patient safety, and reduction in the rising cost of health care.[30,31] With regard to health care costs, the goal was to reduce the practice of both defensive and offensive medicine. The latter refers to reducing the frequency of unnecessary interventions performed by physicians purely for financial gain. In establishing these guidelines, the intent was not to establish the standard of care. In fact, each American Psychiatric Association (APA) practice guideline clearly defines the proper use of the guide. For example, the APA Practice Guidelines for the Psychiatric Evaluation of Adults states:

> The American Psychiatric Association Practice Guidelines are not intended to serve or be construed as a "standard of medical care." Judgments concerning clinical care depend on the clinical circumstances and data available for an individual patient and are subject to change as scientific knowledge and technology advance and practice patterns evolve [Ref. 32, p 799].

Nonetheless, many states hoped that, through the creation of these guidelines, adherent practitioners could be shielded from frivolous litigation, eventually reducing the practice of defensive medicine.[26] Most notably, Maine promised in the 1990s that strict adherence to practice guidelines would shield practitioners as an affirmative defense to medical malpractice. However, this one-way street would not allow plaintiffs to use nonadherence to the guidelines as evidence in a malpractice case. Despite similar programs and intents in Florida, Minnesota, and Vermont, none of the state programs was successful, nor did they control costs. Furthermore, Florida and Minnesota failed to issue practice guidelines.[30]

As of April 2017, there were 8,228 individual guideline summaries for all medical specialties according to the AHRQ.[33] Of those, there were 229 individual guideline summaries for psychiatry and psychology. With this surfeit of guidelines, it is easy to conclude that, at best, many provide redundant information and, at worst, they provide conflicting information, thus undermining their primary intent. These guidelines have at least four significant pitfalls that limit their usefulness in unifying the practice of medicine and providing a concise summary of appropriate medical care for a specific clinical circumstance. More have been explicated by Recupero.[28]

First, many guidelines quickly become outdated because of new research and practices. After approximately six years, only half of all practice guidelines on the AHRQ website were valid.[34] Replacing a guideline costs an average of $350,000. The rapid expiration of guidelines requires large expenditures of time and money that can hamper effective dissemination of concise recommendations.

Second, many of the guidelines conflict with each other, even when created contemporaneously. Saddichha and Chaturvedi[35] highlighted how some preeminent psychiatric institutions' guidelines differ from one another. For example, in the management of schizophrenia, the duration of treatment and recommended psychosocial interventions differed significantly. These clashes confuse patients and may cause clinicians to ignore the weight of the recommendations.

Third, many of the guidelines lacked the requisite scientific evidence to support their recommendations. One study found that 90 percent of guidelines failed to describe formal methods of how guideline authors reconcile scientific evidence with expert opinion, and more than 25 percent of guidelines failed to cite any references.[36] Furthermore, some guidelines note that relevant older literature was explicitly excluded from the guidelines for practical purposes, to streamline literature review. For example, the authors of the APA's Major Depressive Disorder practice guideline acknowledged that the recommendations emphasize newer treatments, minimizing helpful information regarding tricyclic antidepressants and monoamine oxidase inhibitors.[37] To mitigate these omissions, the authors encouraged readers to consult older versions of the practice guidelines. However, these older versions are not available on the website.

Finally, guidelines established by private health insurance companies, liability insurers, and the pharmaceutical industry, groups without fiduciary responsibilities to patients, may be biased. Guidelines created by these entities should be considered with skepticism because of inherent conflicts. Nor are guidelines that are issued by professional medical societies immune from bias, as many authors have significant relationships with industry. Choudhry and colleagues[38] discovered that only seven percent of guideline authors believed that their own relationship with the pharmaceutical industry influenced their recommendations. Yet, of that same group of authors, 19 percent believed that their coauthors' recommendations were influenced by pharmaceutical relationships.

Notwithstanding these many pitfalls, the question remains of whether physicians adhere to their specialty's practice guidelines with the goal of unifying and improving the practice of medicine. Even with free online access to over 8,200 individual guidelines, the behavior of physicians has not measurably changed.[30] More than half of the physicians surveyed did not know that guidelines existed online. Even those aware of the guidelines objected to following them for various reasons, including an aversion to practicing "cookbook" medicine, the wish to adhere to non–evidence-based recommendations, and the perception that guidelines represented a threat to their practice autonomy.[39]

Even though the creation of practice guidelines was not intended to set the standard of care, artful attorneys have found that these widely published standards, despite their many pitfalls, could be persuasive to juries in malpractice litigation, especially those guidelines created by professional medical societies. The Federal Rules of Evidence[40] and landmark cases of *Reilly v. Pinkus*[41] and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*[42] paved the way for entering medical treatises as evidence. Plaintiff attorneys attempt to use CPGs as a "sword," or as inculpatory evidence. Defense attorneys attempt to use CPGs as a "shield," or as exculpatory evidence.[43] Although malpractice cases rarely make it to trial,[44] the cases that do may involve use of CPGs as evidence on either side of the courtroom.

Hyams and colleagues[43] assessed how often and how successfully CPGs were used as evidence in malpractice cases. In a computerized search of U.S. courts from 1980 through 1994, there were 37 instances in which CPGs were used as either a shield or sword, whether successful or not. CPGs were used successfully in 28 cases, 22 times by plaintiffs, and 6 times by the defense. Generally, when CPGs were used successfully, the guidelines originated from strong, evidence-based sources, such as the APA, American College of Obstetrics and Gynecology, American Heart Association, AMA, American Academy of Pediatrics, and the American Society of Anesthesiologists. However, nine times the guidelines were used unsuccessfully: seven times by plaintiffs and twice by the defense. In those instances, the guidelines originated principally from liability carriers or federal institutions, not professional medical societies, likely contributing to their failure to persuade. It should be noted that these outcomes hinged on the verdict at trial and CPGs were just one part of the larger body of evidence. In addition, because of the age of that study, the findings may be limited; it is unclear if this pattern of CPG use in the courtroom persists today.

Discussion

This historical review of the development of the standard of care reminds mental health experts that despite case law and the national standards of medical training and certification, the locality rule remains alive in some jurisdictions of the United States. The distinction between a generalist and a specialist still prevails. For example, a family medicine practitioner in the rural southern United States will not be expected to possess the same knowledge of viruses as an infectious disease specialist at an academic institution in a major city in the southeast.

When retained in medical malpractice cases, the expert must remember that the standard of care may vary among jurisdictions in the United States. Practice guidelines, although intended to unify and improve the practice of medicine, often fail to provide sufficient clarity because of age, conflicting recommendations, various levels of evidential support, and underutilization by practitioners. In many cases, the standard of care is determined *de novo* and is a moving target. This is one reason why static documents, guidelines, and algorithms are not quite coextensive with the requirements of the legal system. Furthermore, learned medical treatises do not constitute evidence *per se*. Rather, they are elements of the experts' opinions that may be introduced into evidence at trial.

Expert witnesses must carefully consider whether to use CPGs in reports or testimony, for example in personal-injury cases. Newer technologies and data analytics, including standards built into the elec-

tronic health record, may also shape the modern standard of care. Future research should examine the current use of practice guidelines and emerging technologies as evidence in malpractice cases.

References

1. Jerold L: The role of the expert witness. Surg Clin North Am 87:889–901, 2007
2. Recupero PR, Harms SE: Outpatient psychiatrists' practices for requesting prior treatment records. J Am Acad Psychiatry Law 43:444–50, 2015
3. Rogers JE, Neumann CL, Myers WC: Commentary: bringing order to chaos: how psychiatrists know the standard of care. J Am Acad Psychiatry Law 43:451–5, 2015
4. Simon RI: Editorial: Standard-of-care testimony: best practices or reasonable care? J Am Acad Psychiatry Law 33:8–11, 2005
5. Mohr JC: American medical malpractice litigation in historical perspective. JAMA 283:1731–7, 2000
6. Mehlman MJ: Professional power and the standard of care in medicine. Ariz St L J 44:1166–235, 2012
7. Starr P: The Social Transformation of American Medicine. New York: Basic Books, 1982
8. Spiegel AD, Kavaler F: America's first medical malpractice crisis, 1835–1865. J Community Health 22:283–308, 1997
9. White EG: The intellectual origins of torts in America. Yale L J 86:671–93, 1977
10. Atiyah PS: Medical malpractice and the contract/tort boundary. Law & Contemp Prob 49:287–303, 1986
11. Field RI: The malpractice crisis turns 175: what lessons does history hold for reform? Drexel L Rev 4:7–39, 2011
12. The Law Dictionary Featuring Black's Law Dictionary Free Online Legal Dictionary (ed 2). Available at: http://thelawdictionary.org/locality-rule/. Accessed March 30, 2016
13. Ginsberg M: The locality rule lives! Why? Using modern medicine to eradicate an "unhealthy" law. Drake L Rev 61:321–73, 2013
14. Richards EP: The locality rule. Legal Standards. Establishing the Standard of Care, in Law and the Physician: A Practical Guide. Boston, Little Brown, 1993:Chap 6. Available at: http://biotech.law.lsu.edu/books/lbb/x139.htm. Accessed March 30, 2016
15. Hall GE: The "locality" rule. JAMA 207:627–8, 1969
16. Small v. Howard, 128 Mass. 131 (Mass.1880)
17. Brune v. Belinkoff, 235 N.E.2d 793 (Mass. 1968)
18. Hall v. Hilbun, 466 So.2d 856 (Miss. 1985)
19. LCME: Liaison Committee on Medical Education. Available at: http://www.lcme.org. Accessed March 30, 2016
20. Kassebaum DG: Origin of the LCME, the AAMC-AMA partnership for accreditation. Acad Med 67:85–7, 1992
21. Accreditation Council for Graduate Medical Education. What we do. Available at: https://www.acgme.org/what-we-do/overview. Accessed March 30, 2016
22. Lewis MH, Gohagen JK, Merenstein DJ: The locality rule and the physician's dilemma; local medical practices vs the national standard of care. JAMA 297:2633–37, 2007
23. Klaidman S: Coronary: A True Story of Medicine Gone Awry. New York: Scribner, 2007
24. Gawande A: The cost conundrum: what a Texas town can teach us about health care. *The New Yorker*. June 1, 2009. Available at: http://www.newyorker.com/magazine/2009/06/01/the-cost-conundrum. Accessed November 13, 2016
25. Moses RE, Feld AD: Legal risks of clinical practice guidelines. Am J Gastroenterol 103:7–1, 2008
26. Mehlman MJ: Professional power and the standard of care in medicine. Ariz St L J 44:1166–233
27. Saver RS: Squandering the gain: gainsharing and the continuing dilemma of physician financial incentives. NW U L Rev 98:145–238, 2003
28. Recupero PR: Clinical practice guidelines as learned treatises: understanding their use as evidence in the courtroom. J Am Acad Psychiatry Law 36:290–301, 2008
29. National Guideline Clearinghouse: Inclusion Criteria: 2013 (Revised) Criteria for Inclusion of Clinical Practice Guidelines in NGC. Washington DC: National Guideline Clearinghouse, Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services, 2014. Available at: https://guidelines.gov/help-and-about/summaries/inclusion-criteria. Accessed April 26, 2017
30. Avraham R: Clinical practice guidelines: the warped incentives in the U.S. healthcare system. Am J Law Med 37:7–40, 2011
31. Shaneyfelt TM: Building bridges to quality. JAMA 286:2600–1, 2001
32. Silverman JJ, Galanter M, Jackson-Triche M, *et al*: The American Psychiatric Association practice guidelines for the psychiatric evaluation of adults. Am J of Psychiatry 172:798–802, 2015
33. Agency for Healthcare Research and Quality: Browse [Guidelines] by Clinical Specialty. Available at: https://www.guideline.gov/browse/clinical-specialty/. Washington, DC: National Guideline Clearinghouse, Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services, undated. Accessed April 26, 2017
34. Shekelle PG, Ortiz E, Rhodes S, *et al*: Validity of the Agency for Healthcare Research and Quality clinical practice guidelines: how quickly do guidelines become outdated? JAMA 286:1461–7, 2001
35. Saddichha S, Chaturvedi SK: Clinical practice guidelines in psychiatry: more confusion than clarity? A critical review and recommendation of a unified guideline. ISRN Psychiatry 828917, 2014. Available at: https://www.hindawi.com/journals/isrn/2014/828917/. Accessed July 18, 2017
36. Shaneyfelt TM, Mayo-Smith MF, Rothwangl J: Are guidelines following guidelines? The methodological quality of clinical practice guidelines in the peer-reviewed medical literature. JAMA 281:1900–4, 1999
37. American Psychiatric Association: Practice guideline for the treatment of patients with major depressive disorder (revision). Am J Psychiatry. 157(4 Suppl):1–45, 2000
38. Choudhry NK, Stelfox HT, Detsky AS: Relationships between authors of clinical practice guidelines and the pharmaceutical industry. JAMA 287:612–7, 2002
39. Cabana MD, Rand CS, Powe NR, *et al*: Why don't physicians follow clinical practice guidelines? A framework for improvement. JAMA 282:1458–65, 1999
40. Rule 702: Testimony by expert witnesses. Federal Rules of Evidence. Available at: https://www.rulesofevidence.org/article-vii/rule-702/. Accessed November 13, 2016
41. Reilly v. Pinkus, 338 U.S. 269 (1949)
42. Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993)
43. Hyams AL, Shapiro DW, Brennan TA: Medical practice guidelines in malpractice litigation: an early retrospective. J Health Pol Pol'y & L 21:289–313, 1996
44. Rubin JB, Bishop TF: Characteristics of paid malpractice claims settled in and out of court in the USA: a retrospective analysis. BMJ Open. 2013:3:e002985. Available at: http://bmjopen.bmj.com/content/bmjopen/3/6/e002985.full.pdf/. Accessed July 18, 2017

OPEN ACCESS

Clinical guidelines for children and adolescents experiencing gender dysphoria or incongruence: a systematic review of guideline quality (part 1)

Jo Taylor, Ruth Hall, Claire Heathcote, Catherine Elizabeth Hewitt, Trilby Langton, Lorna Fraser

► Additional supplemental material is published online only. To view, please visit the journal online (https://doi.org/10.1136/archdischild-2023-326499).

Department of Health Sciences, University of York, York, UK

Correspondence to
Dr Jo Taylor, Department of Health Sciences, University of York, York, UK; dohs-gender-research@york.ac.uk

Received 24 October 2023
Accepted 15 December 2023

Linked

► http://dx.doi.org/10.1136/archdischild-2023-326347
► http://dx.doi.org/10.1136/archdischild-2023-326348
► http://dx.doi.org/10.1136/archdischild-2023-326112
► http://dx.doi.org/10.1136/archdischild-2023-326500
► http://dx.doi.org/10.1136/archdischild-2023-326669
► http://dx.doi.org/10.1136/archdischild-2023-326670
► http://dx.doi.org/10.1136/archdischild-2023-326760
► http://dx.doi.org/10.1136/archdischild-2023-326681

Check for updates

To cite: Taylor J, Hall R, Heathcote C, *et al*. *Arch Dis Child* Epub ahead of print: [*please include* Day Month Year]. doi:10.1136/archdischild-2023-326499

ABSTRACT

Background Increasing numbers of children and adolescents experiencing gender dysphoria/incongruence are being referred to specialist gender services. There are various guidelines outlining approaches to the clinical care of these children and adolescents.

Aim To examine the quality and development of published guidelines or clinical guidance containing recommendations for managing gender dysphoria/incongruence in children and/or adolescents (age 0-18). A separate paper reports the synthesis of guideline recommendations.

Methods A systematic review and narrative synthesis. Databases (Medline, Embase, CINAHL, PsycINFO, Web of Science) were searched to April 2022 and web-based searches and contact with international experts continued to December 2022, with results assessed independently by two reviewers. The Appraisal of Guidelines for Research and Evaluation tool was used to examine guideline quality.

Results Twenty-three guidelines/clinical guidance publications (1998–2022) were identified (4 international, 3 regional and 16 national). The quality and methods reporting in these varied considerably. Few guidelines systematically reviewed empirical evidence, and links between evidence and recommendations were often unclear. Although most consulted with relevant stakeholders, including 10 which involved service users or user representatives, it was often unclear how this influenced recommendations and only two reported including children/adolescents and/or parents. Guidelines also lacked clarity about implementation. Two international guidelines (World Professional Association for Transgender Health and Endocrine Society) formed the basis for most other guidance, influencing their development and recommendations.

Conclusions Most clinical guidance for managing children/adolescents experiencing gender dysphoria/incongruence lacks an independent and evidence-based approach and information about how recommendations were developed. This should be considered when using these to inform service development and clinical practice.

PROSPERO registration number CRD42021289659.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Increasing numbers of children and adolescents are being referred to specialist gender services.
⇒ Several clinical guidelines of varying quality exist to support the clinical care of children and adolescents experiencing gender dysphoria/incongruence and their families.
⇒ Current systematic reviews have focused on a subset of guidelines and there is a need to assess all guidelines that may be influencing care provision for these children/adolescents.

WHAT THIS STUDY ADDS

⇒ This review identified 23 guidelines or clinical guidance publications that contain recommendations about the management of children and/or adolescents experiencing gender dysphoria/incongruence.
⇒ Few guidelines are informed by a systematic review of empirical evidence and lack transparency about how recommendations were developed. Only two reported consulting directly with children and/or adolescents during their development.
⇒ Most national and regional guidance has been influenced by the World Professional Association for Transgender Health and Endocrine Society guidelines, which themselves lack developmental rigour and are linked through cosponsorship.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Healthcare services and professionals should take into account the poor quality and inter-related nature of published guidance to support the management of children and adolescents experiencing gender dysphoria/incongruence.

INTRODUCTION

Internationally, there has been a reported increase in the number of children and adolescents describing themselves as gender questioning or identifying as transgender.[1] For some, this experience may not be distressing and require limited professional input; however, for others, difficulties in gender development can be associated with significant distress.[2] Gender dysphoria is the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition diagnostic category referring to psychological distress and/or functional impairment that results from incongruence between experienced or expressed

gender and sex registered at birth.[3] The more recently published International Classification of Diseases, 11th edition uses the broader term of gender incongruence,[4] although both terms continue to be used in clinical practice. The prevalence of gender dysphoria/incongruence in children and adolescents is currently unknown due to lack of population-level data.[2 5] However, referrals to specialist paediatric gender services have increased considerably over the last 10-15 years.[2] For example, the UK paediatric gender service received 3585 referrals in 2021–2022 compared with 210 in 2011–2012.[6]

Alongside this overall rise in numbers, there has been recognition that this population have high rates of mental health and well-being needs as well as broader psychological and social complexity.[7–10] There is a need to ensure that the increasing numbers of children and adolescents presenting with experiences of gender-related distress receive timely, appropriate and evidence-based care. Guidelines for the management of gender dysphoria/incongruence can help to ensure the needs of children and adolescents are met, and that provision is equitable and evidence based.[11]

Several clinical guidelines exist to inform care provision for this population.[12 13] Recent systematic reviews have identified and appraised guidelines for transgender care, raising concerns about their quality.[12–14] However, they each focus on a subset of guidelines: Dahlen *et al*[12] only included international guidelines and Ziegler *et al*[13 14] focused on guidelines for primary care. This systematic review builds on these reviews by appraising and synthesising all published guidance that includes recommendations regarding the care of children and adolescents experiencing gender dysphoria/incongruence. The review is reported in two papers, with this first paper describing the guidelines and examining their quality and development, and the second synthesising recommendations.[15]

METHODS

This review forms part of a linked series examining the epidemiology, care pathways, outcomes and experiences for children and adolescents experiencing gender dysphoria/incongruence (protocol registered on PROSPERO: CRD42021289659[16]). The review is reported in accordance with Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines.[17]

Search strategy

A single search strategy was used comprising two combined concepts: 'children', which included all terms for children and adolescents; and 'gender dysphoria', which included associated terms such as gender-related distress and gender incongruence, and gender identity terms including transgender, gender diverse and non-binary.

MEDLINE (online supplemental table 1), EMBASE and PsycINFO through OVID, CINAHL Complete through EBSCO and Web of Science (Social Science Citation Index) were searched (13–23 May 2021; updated 27 April 2022).

Reference lists of included guidelines and relevant systematic reviews were assessed.[12–14] International experts were contacted and key organisational websites reviewed to December 2022.

Inclusion criteria

Published articles or documents that provide at least one specific recommendation for the assessment and/or care of children and/or adolescents (age 0–18) experiencing gender dysphoria/incongruence, and which were developed by or for a professional, healthcare or government organisation or from a research study, were included in the review.

These criteria enabled us to include documents like blueprints and position statements that include recommendations developed for practice and that are available for clinicians to use. Adopting these broad criteria enabled us to map and assess the quality of all clinical guidance that is potentially influencing practice regardless of method of development or year of publication and to examine any changes in guidance and its development over time. In making this decision, we also considered the knowledge that clinical guidelines are not always informed by a systematic review of evidence or developed robustly, despite this being implied in guideline definitions.[11] The document type or title is, therefore, potentially misleading as a criterion for inclusion.

Guidelines for adults, all ages or those not specifying a target population were included if they contained explicit recommendations for children/adolescents.

Originally we planned to include publications in the English language[16]; however, in order to include the increasing number of national guidelines published in Europe, we expanded this to include those that could be reliably translated. For guidance not published in English, we requested official or reliable translations from international experts or used DeepL Pro translation services[18] where these were not available.

Selection

The results of database and other searches were uploaded to Covidence[19] and screened independently by two reviewers. Full texts for potentially relevant articles were reviewed against inclusion criteria by two reviewers independently. Disagreements were resolved through discussion and inclusion of a third reviewer where necessary.

Data extraction

We extracted data on guidance characteristics, development and content into prepiloted data extraction templates. All extraction was undertaken by a single reviewer and second checked by another.

Quality appraisal

To be eligible for appraisal, guidance needed to describe the methodology in the main or auxiliary documents,[11] in addition to meeting inclusion criteria for the review.

We used the Appraisal of Guidelines for REsearch & Evaluation (AGREE) II instrument to assess quality.[20] This validated tool was designed to assess the quality of practice guidelines but has been successfully applied to other types of guidance in this practice area.[12 13] The tool contains 23 criteria organised around six quality domains (scope and purpose, stakeholder involvement, rigour of development, clarity of presentation, applicability and editorial independence), followed by an overall assessment on quality and whether a guideline should be recommended for use in practice. The criteria and overall assessment are rated on a 7-point scale from 1 'strongly disagree' to 7 'strongly agree'. Response options for recommendation for use are 'yes', 'yes, with modifications' or 'no'. A quality score is calculated for each domain, which represents the total summed score of all reviewers' ratings as a percentage of the maximum possible domain score.[21]

Guidance was appraised independently by three reviewers using My AGREE PLUS, an online appraisal platform.[21] Following the Dahlen *et al* systematic review,[12] a colour coding

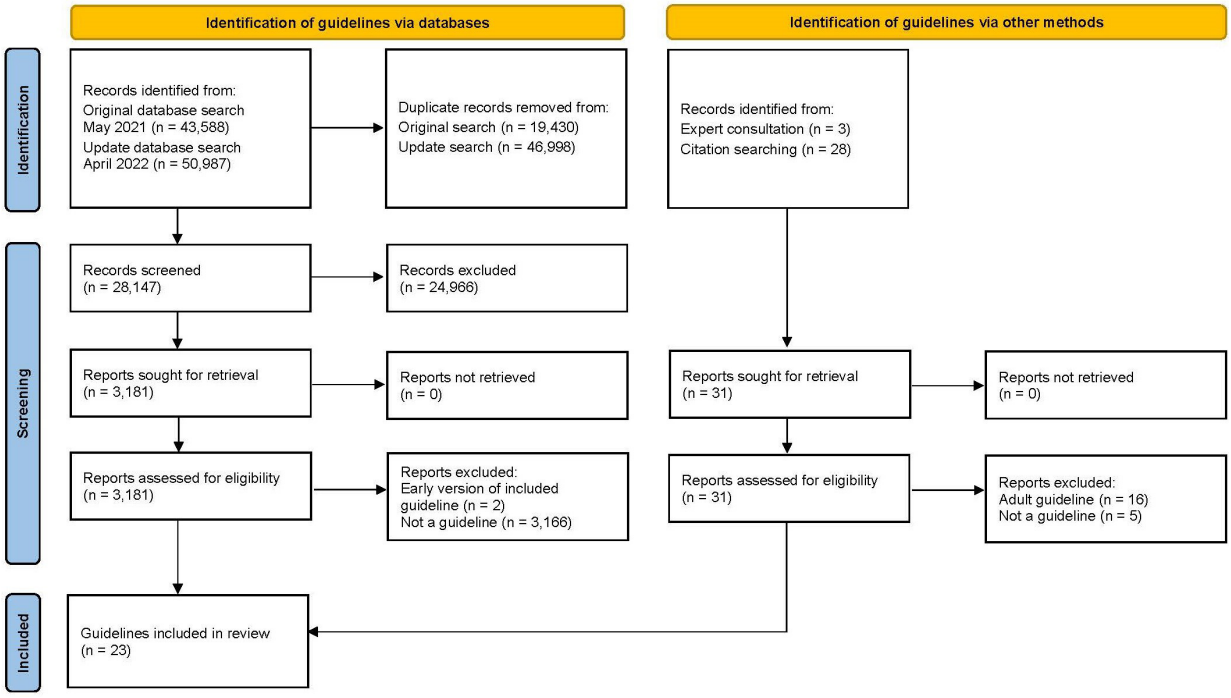

Figure 1 Study flow diagram.

scheme was used to aid visual comparison of domain scores (≤30%, 31%–69%, ≥70%). All reviewers undertaking appraisal read the AGREE II User Manual[21] and appraised and discussed the same two guidance publications first to improve reviewer competence.

Synthesis

Synthesis was undertaken using a narrative approach and involved a series of team discussions to ensure accurate interpretation of included guidance. To examine development, we reviewed reported methods against AGREE II domains, considering both quality of reporting and methods described. This included exploring how evidence was used to inform recommendations, how recommendations were developed and agreed and who was involved in this process and how the guidance referenced and used other included guidance during their development. For the latter, we produced a visual map to show these links.

RESULTS

Database searches yielded 28 147 records, 3181 of which were potentially relevant for the linked series of reviews. From these, 13 guidelines or other clinical guidance meeting our criteria were identified.[22–34] An additional 31 sources were identified as potential guidelines (via citation searching and expert consultation), 10 of which met inclusion criteria.[35–44] In total, 23 distinct clinical guidance publications (referred to in the synthesis as guidelines) were identified (see figure 1 and online supplemental table 2).

The 23 guidelines were published from 1998 to 2022, with all but two published after 2010. Four guidelines are international,[25 31 33 34] three regional (one covering Europe,[26] one Asia and the Pacific[38] and one the Caribbean[40]), and others are national, with four from the US,[22–24 44] two from Spain[32 42] and one each from Australia,[29] Canada,[37] Denmark,[36] Finland,[35] Italy,[27] New Zealand,[28] Norway,[39] South Africa,[41] Sweden[43] and the UK[30] (see figure 2). Three guidelines were translated into English.[35 39 43]

Five guidelines are position or policy statements from professional societies or organisations,[23 26 27 31 32] two are blueprints developed by multiple regional and international organisations,[38 40] and one is a practice parameter developed by a professional organisation.[22] The remaining 15 are guidelines: four were developed for national government bodies,[35 36 39 43] seven for or adopted by professional organisations,[24 25 28 30 34 41 42] three for healthcare organisations[29 37 44] and one a research study.[33]

Seven guidelines reference a previous version,[25 28 34 36 40 43 44] two of which have multiple updates.[34 36] Three guidelines were published by the developer[45–47] and as an academic paper.[28 29 41]

Seven guidelines focus on the care and/or treatment of children and adolescents experiencing gender dysphoria/incongruence[22 23 29 30 32 35 43] (one also covers practice for sexual minority children/adolescents[22]). Four guidelines cover adolescents only,[27 31 33 37] one of which is about co-occurring autism spectrum condition and gender dysphoria/incongruence.[33] One guideline, which has a specific focus on sexual function and satisfaction, covers adolescents and adults,[26] and 10 guidelines cover all transgender and/or gender diverse people but include chapters or sections specific to children/adolescents.[25 28 34 36 38–42 44] The final guideline is about psychological practice for adults but contains one section about adolescents.[24]

The target audience is generally broad, with 11 guidelines targeting healthcare providers[27–29 31 32 34–36 39 41 44] and five healthcare providers plus other stakeholders, for example, social care professionals or policymakers.[26 37 38 40 43] Two are for psychiatrists,[22 30] one for psychologists,[24] one for paediatricians,[23] one for endocrinologists[25] and two do not specify.[33 42]

Multiple areas of practice are covered in the guidelines. These include care models, principles and practices; service composition, roles and expertise; assessment; psychosocial care; information and advocacy; social transition; puberty suppression; masculinising/feminising hormones; surgical interventions;

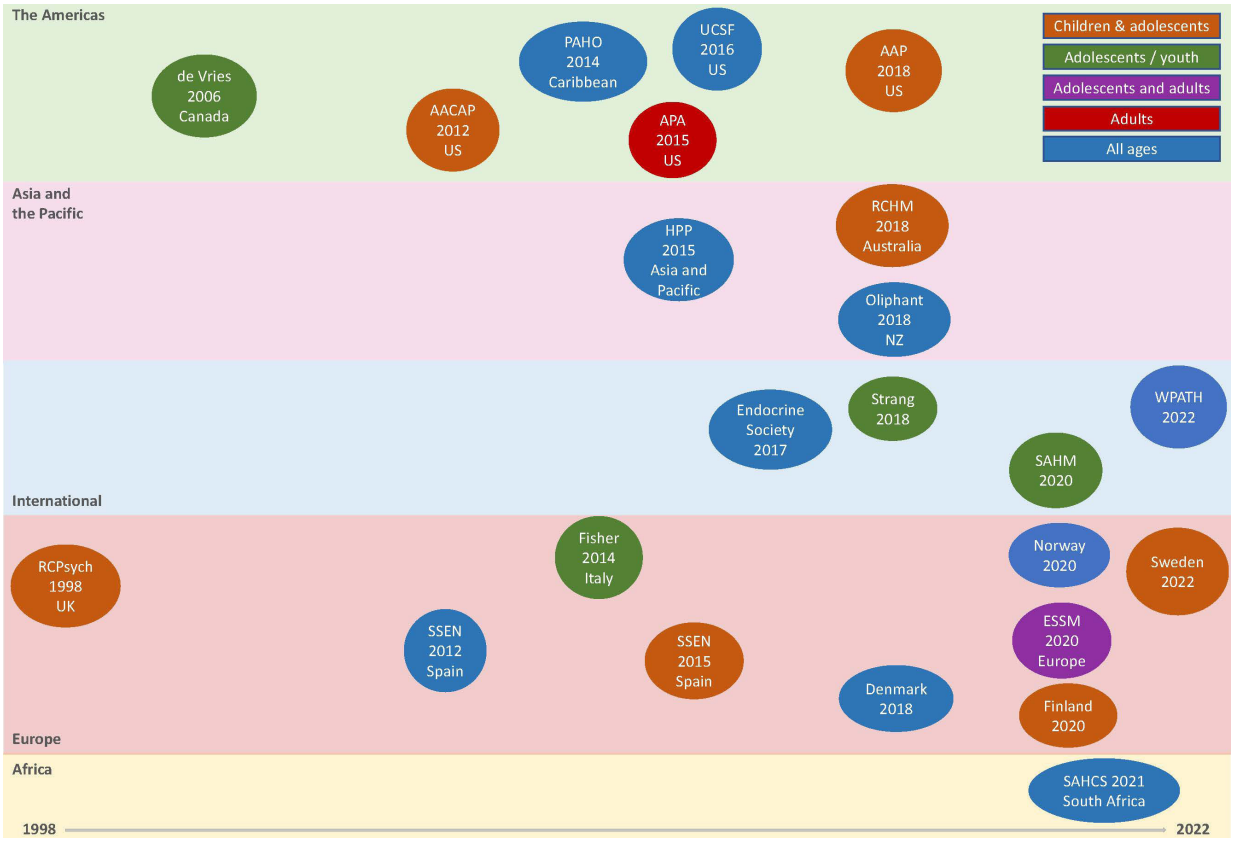

Figure 2 Regional timeline for guidelines. Presents a timeline for the included guidelines by geographical region, country and target population. AACAP, American Academy of Child and Adolescent Psychiatry; AAP, American Academy of Pediatrics; APA, American Psychological Association; ESSM, European Society for Sexual Medicine; HPP, Health Policy Project; PAHO, Pan American Health Organisation; RCHM, Royal Children's Hospital Melbourne; RCPsych, UK Royal College of Psychiatrists; SAHCS, South African HIV Clinicians Society; SAHM, Society for Adolescent Health and Medicine; SSEN, Spanish Society for Endocrinology and Nutrition; UCSF, University California, San Francisco; WPATH, World Professional Association for Transgender Health.

fertility care; other interventions (eg, voice therapy); sexual health and functioning; and physical health and lifestyle. Content varies depending on guideline scope and audience. More guidelines focus on medical treatments than psychosocial care.

Guideline methods and quality

Of the 23 guidelines, four provided no information about the process of development and could not be appraised.[30 32 36 42]

The 19 guidelines reporting methods varied in approach and quality of reporting. Most were developed by a core group of clinical experts with broader consultation with other professional stakeholders, although the nature of consultation and stakeholders varied. Few provided clear information about how experts were recruited or selected. Of the 16 that reported wider consultation,[22–25 28–30 33 34 37–41 43 44] only two described a formal consensus methodology[33 34] and a third reported a modified consensus process, but no details are provided.[44] Across guidelines, it was unclear how input from wider stakeholders informed recommendations.

Ten guidelines reported engaging with service users or service user representatives.[24 28 29 34 35 38–41 43] Methods varied, with two reporting separate research or consultation,[24 35] but most consulting with service users alongside other stakeholders during development or by obtaining their views on draft guidelines, although details are limited. Three of these guidelines also published a draft guideline for public comment,[24 34 39] which may have involved contributions from the transgender and gender diverse community although again details are limited. Only two guidelines reported consulting directly with children/adolescents or their parents,[29 43] and a second guideline listed them as potential stakeholders but it was unclear whether their views were included.[34] Others consulted with transgender or gender diverse adults or organisations representing children/adolescents experiencing gender dysphoria/incongruence or the broader transgender community.

Most guidelines reference evidence sources to support recommendations. However, only five described using a systematic approach to searching and/or selecting evidence, and in most cases, this covered one or two specific aspects of practice.[22 25 34 35 43] Three of the guidelines that reviewed evidence,[25 34 43] and another guideline not reporting a systematic approach to finding evidence,[44] reported appraising the quality and strength of evidence they reviewed. The Finnish guideline chose not to appraise quality in their systematic review because they determined all studies were poor quality on the basis of study design.[35]

Across guidelines, it was difficult to detect what evidence had been reviewed and how this informed development of recommendations, and the links between specific recommendations and evidence were often unclear or missing. For example, all but seven guidelines[27 28 30 38 40–42] describe insufficient evidence about the risks and benefits of medical treatments for adolescents, particularly in relation to long-term outcomes. At the same time, many of these guidelines then cite this evidence or

Table 1 Critical appraisal domain scores

Guideline ID	Scope and purpose	Stakeholder involvement	Rigour of development	Clarity of presentation	Applicability	Editorial independence
AACAP 2012	65	39	44	63	7	31
American Academy of Paediatrics 2018	70	26	12	30	6	69
American Psychological Association 2015	74	74	24	50	18	14
Council for Choices in Healthcare Finland 2020	91	69	51	72	56	0
de Vries 2006	63	31	10	74	17	6
Endocrine Society 2009	65	33	44	70	22	31
Endocrine Society 2017	63	33	42	72	21	92
European Society for Sexual Medicine 2020	63	52	39	70	7	58
Fisher 2014	65	20	12	35	17	44
Health Policy Project 2015	63	63	16	24	33	6
Norwegian Directorate of Health 2020	76	81	30	57	47	17
Oliphant 2018	44	39	12	33	21	0
Pan American Health Organisation 2014	52	44	13	31	21	0
Royal Children's Hospital Melbourne 2018	81	59	19	41	19	14
Society for Adolescent Health and Medicine 2020	41	24	17	41	7	0
South African HIV Clinicians Society 2021	59	59	21	43	24	69
Strang 2018	87	31	18	37	15	19
Swedish National Board of Health & Welfare 2022	91	87	71	83	25	36
UCSF 2016	70	41	23	37	26	0
WPATH 2012	85	61	26	56	17	17
WPATH 2022	83	63	35	56	24	39

≥70%, 31%–69%, ≤30%.
AACAP, American Academy of Child & Adolescent Psychiatry; UCSF, University of California, San Francisco; WPATH, World Professional Association for Transgender Health.

refer to guidelines that recommend these treatments to support a similar recommendation. Only the Swedish guideline makes a different recommendation, linking the lack of evidence about medical treatments to their recommendation that these should be provided under a research framework and for exceptional cases until this is established.[43] The Finnish guideline also takes a more cautious approach and recommends that medical interventions, which are described as experimental on the basis of their own evidence review, must be provided at the two central research clinics in Finland, and that data on the effects of these treatments should be systematically collected.[35]

Table 1 shows the AGREE II domain scores for the appraised guidelines. Most scored well regarding clarity of scope and purpose and scored poorly regarding applicability, editorial independence and rigour of development. Guidelines often differed between domains, although overall few guidelines scored highly across the domains. Only six guidelines scored higher than 30% for rigour,[22 25 26 34 35 43] and only the Swedish guideline scored higher than 70%.[43] In the stakeholder involvement and clarity of presentation domains, guidelines varied considerably. For example, in certain guidelines, it was not always easy to discern a recommendation from a suggestion, and recommendations were not always specific or unambiguous. Additionally, in guidelines covering all age groups, the terms adults and people were sometimes used interchangeably without defining them, making it difficult to assess whether recommendations about people were referring to children and/or adolescents.

Online supplemental table 3 shows the overall scores and assessment of whether guidelines should be recommended for practice. Only two guidelines were recommended for practice by all three appraisers: the Swedish[43] and Finnish[35] guidelines. These guidelines were the only two that scored higher than 50% for rigour of development due to their evidence-based approach and transparent reporting of this. They were also the only guidelines, which included a formal ethics review and they both scored highly on stakeholder involvement.

Links and influences between guidelines

All but two guidelines,[30 36] both of which contain no reference list and do not report methods of development, cite at least one other guideline. Figure 3 shows the different ways in which guidelines reference or use other guidelines and the level of influence guidelines have on each other. Examples of different links include citing another guideline as a resource for the reader, citing a guideline to justify or support a single or multiple recommendations, explicitly adopting another guideline's recommendation(s), recommending that another guideline be used alongside their own or reviewing other guidelines to inform the development of recommendations.

The links examined show that early versions of two international guidelines, the Endocrine Society[25] and World Professional Association for Transgender Health (WPATH)[34] guidelines (specifically the 2009 Endocrine Society guideline[48] and WPATH V.7 published in 2012)[49] have influenced nearly all the national and regional guidelines identified. The two guidelines also have close links, with WPATH adopting Endocrine Society recommendations in its own guideline and acting as a cosponsor for and providing input on drafts of the Endocrine Society guideline. Due to the considerable influence of these two guidelines, the quality of the current and preceding versions for both was appraised.

The type of relationship between the Endocrine Society and WPATH guidelines and other guidelines varied. For example, WPATH V.7[49] formed the basis of an initial draft of the Australian guideline[29]; the American Psychological Association (APA)[24] recommends using their guideline in tandem with WPATH[49] and Endocrine Society[48] guidelines; the guideline developed in New Zealand[28] is offered as additional guidance to WPATH[49] and adopts numerous recommendations from this and Endocrine Society[25] guidelines; the regional blueprints[38 40] adopt WPATH[49] criteria for hormone treatments; and the Norwegian guideline[39] describes their overall approach and principles as consistent with WPATH[49] and Endocrine Society,[25] along with

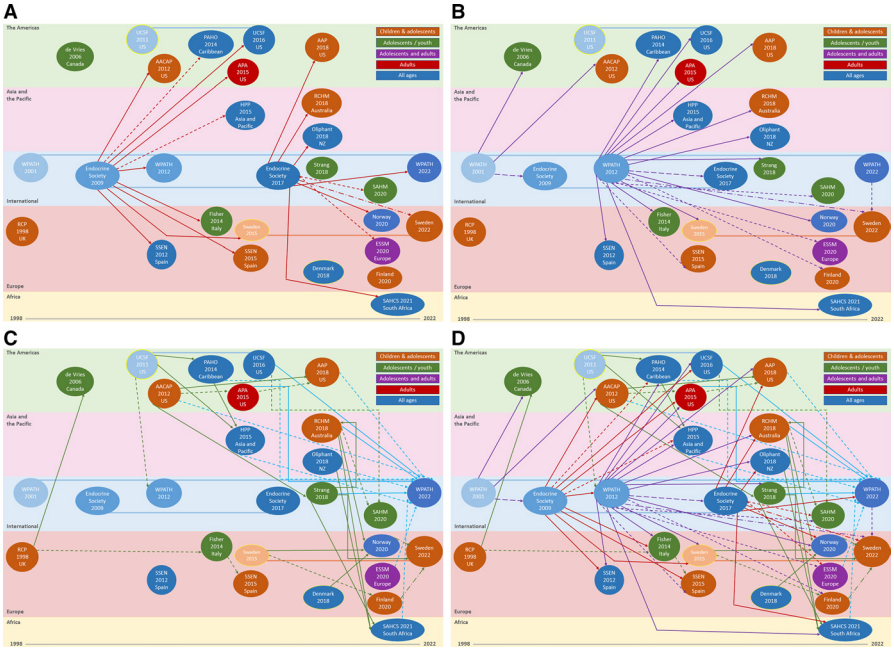

Figure 3 Links between guidelines. (A–D) show how the guidelines have influenced each other using the regional timeline shown in figure 2. (A) Shows how guidelines have cited and drawn on the Endocrine Society guidelines (indicated by red arrows). (B) Shows how guidelines have cited and drawn on the World Professional Association for Transgender Health (WPATH) guidelines (indicated by purple arrows). (C) Shows how guidelines have cited and drawn on other guidelines (indicated by green arrows). A different colour (blue) was used to show how the latest Endocrine Society and WPATH guidelines have cited and drawn on these other guidelines. (D) Shows all the links between the guidelines. Link symbol: Solid line: guideline has been adapted from the source guideline, has adopted numerous key recommendations from the source guideline or used the source guideline as evidence to support numerous key recommendations or recommends using the source guideline alongside its own. Short-dashed line: included reference to the source guideline or has adopted one or two key recommendations or used the source guideline as evidence to support these. Long dashed line: co-sponsor with direct involvement in development process. Long and short dashed line: critically reviewed recommendations from source guideline as key element of development process. Guidelines circled in yellow are those for which there are no available references to assess any potential links with other guidelines.

the Australian,[29] Danish[36] and Swedish 2015[50] guidelines. The updated 2022 Swedish guideline[43] took a different approach, which involved examining the WPATH,[49] Endocrine Society,[25] Finnish[35] and Norwegian[39] recommendations against their own evidence review and knowledge base to consider whether to adopt them (with the process reported in a separate Appendix published alongside the guideline[51]). The basis for decisions to adopt WPATH or Endocrine Society recommendations in other guidelines is unclear.

The Endocrine Society and WPATH V.7 guidelines contain few references to other guidelines. However, WPATH V.8 published in 2022 identifies numerous national and regional guidelines published as early as 2012 as potentially valuable resources and cites the APA,[24] Australian,[29] New Zealand[28] and University California, San Francisco[44] guidelines multiple times to support recommendations, all of which were themselves influenced considerably by WPATH V.7.

DISCUSSION

This systematic review identified 23 guidelines or clinical guidance publications (4 international, 3 regional and 16 national), nine of which focus solely on the management of children and/or adolescents experiencing gender dysphoria/incongruence.[23 27 29–32 35 37 43] Guidance quality and methods reporting varied considerably, and only five reported using a systematic approach to using evidence to inform recommendations.[22 25 34 35 43] Links between evidence and recommendations are often unclear, and information about how recommendations were developed in the absence of reviewing evidence is limited. There is also limited guidance on how to implement recommendations, and in some cases, a lack of clarity as to what is being recommended and for who. Although consultation with stakeholders was common, only 10 involved service users or their representatives, and it was unclear how this influenced recommendations. Only two reported consulting directly with children/adolescents or their parents, so few guidelines have been informed by an understanding of the needs and preferences of this population.

The findings from this review, therefore, raise questions about the credibility of currently available guidance, despite the majority being published in the last 5 years. Most guidelines have not followed international standards for guideline development set out by the AGREE2 initiative,[20] and/or provide insufficient information about their development. Because of this, the review team only recommended two guidelines for practice—the Finnish guideline published in 2020[35] and the Swedish guideline published in 2022,[43] neither of which were included in previously published systematic reviews.[12 13] These are the only guidelines to publish details of how developers reviewed and utilised the evidence-base and the decision-making behind their recommendations. For example, they explicitly link the lack of robust evidence about medical treatments for adolescents, as established from their own systematic reviews,[52 53] with the recommendation for a more cautious approach to treatment and the need for gender services providing these treatments to collect outcome data, with Sweden recommending that medical

treatments should only occur under a research framework. They are also the only guidelines which have been informed by an ethical review conducted as part of guideline development. However, even these guidelines, like others, lack clear recommendations regarding certain aspects of practice and would benefit from more detailed guidance regarding implementation of recommendations.

Although other guidance mostly acknowledges the lack of robust evidence regarding medical treatments for adolescents, some then suggest existing evidence is sufficient to recommend them. Others have instead used a consensus or expert-led approach that results in the same recommendation or have adopted recommendations from the Endocrine Society guideline[25 48] or WPATH V.7,[49] despite the latter having been published a decade earlier in some cases. These two guidelines are themselves linked through cosponsorship and like other guidelines lack a robust and transparent approach to their development. Although it is not uncommon to adopt an expert consensus-based approach when evidence is limited, it is less common for guideline developers to draw so heavily on other guidelines.[11] This relationship may explain why there has until recently been an apparent consensus on key areas of practice for which evidence remains lacking.[54]

Previous systematic reviews have also found guidelines to be lacking in methodological quality, transparency and clarity,[12 13] and Dahlen *et al* recommend clinicians proceed with caution due to the gap between clinical practice and research in this area. Although neither highlight the interdependent nature of available guidance, this is not surprising due to their focus on a subset of mainly international guidelines. However, a recent BMJ article,[55] which too highlights the lack of an evidence-based approach, draws attention to the different conclusions in the Swedish and Finnish guidelines about the risks and benefits of medical treatments, which marks a considerable departure from all other guidance.

The different conclusions in recently published guidelines and concerns about guideline quality, combined with limited evidence about the most appropriate assessment and care pathways for children and adolescents experiencing gender dysphoria/incongruence has led to clinical uncertainty in practice and changing service provision and policy.[55] Large well-designed and conducted research that assesses long-term care outcomes for this population is urgently needed to inform future clinical guidelines, which themselves must be underpinned by an evidence-based and transparent approach that includes direct consultation with children and adolescents and their families.

Strengths and limitations

This review followed a published protocol and used robust search strategies. A systematic approach to appraise quality was used, although the AGREE2 tool was developed to appraise clinical guidelines rather than the broader set of guidance included in this review. A detailed examination of how guidance was developed facilitated new insights about the links between published guidelines. The search strategy may not have identified all guidelines not published in English. As searches were conducted to April 2022, this review does not include more recently published guidance; as this is a rapidly evolving area this is a limitation.

CONCLUSIONS

Most clinical guidance lacks an evidence-based approach and provides limited information about how recommendations were developed. The WPATH and Endocrine Society international guidelines, which like other guidance lack developmental rigour and transparency have, until recently, dominated the development of other guidelines. Healthcare professionals should consider the lack of quality and independence of available guidance when utilising this for practice. Future guidelines should adhere to standards for guideline development and provide greater transparency about how recommendations are developed and links between evidence and recommendations. The views of children, adolescents, parents and carers should also inform future guideline development.

Contributors LF and TL contributed to the conception of the review. JT, RH, LF, and TL designed the review methods. JT, RH and CH carried out screening, extraction and critical appraisal. JT, CEH, RH, LF, and TL contributed to data synthesis. JT drafted the manuscript. All authors contributed to interpretation of results and reviewed the manuscript prior to submission. CEH accepts full responsibility for the finished work and/or the conduct of the study, had access to the data, and controlled the decision to publish.

Funding This work was funded by NHS England to inform the Cass Review (Independent review of gender identity services for children and young people). The funder and Cass Review team had a role in commissioning the research programme but no role in the study conduct, interpretation or conclusion.

Competing interests None declared.

Patient consent for publication Not applicable.

Ethics approval Not applicable.

Provenance and peer review Commissioned; externally peer-reviewed.

Data availability statement Data sharing is not applicable as no datasets were generated and/or analysed for this study.

ORCID iDs
Jo Taylor http://orcid.org/0000-0001-5898-0900
Catherine Elizabeth Hewitt http://orcid.org/0000-0002-0415-3536

REFERENCES

1 Zhang Q, Goodman M, Adams N, *et al*. Epidemiological considerations in transgender health: a systematic review with focus on higher quality data. *Int J Transgend Health* 2020;21:125–37.
2 Thompson L, Sarovic D, Wilson P, *et al*. A PRISMA systematic review of adolescent gender dysphoria literature: 1) epidemiology. *PLOS Glob Public Health* 2022;2:e0000245.
3 American Psychiatric Association. *Diagnostic and statistical Manual of mental disorders: DSM-5*5th edn. Washington, DC: American Psychiatric Publishing, 2013.
4 World Health Organisation. ICD-11: International classification of diseases for mortality and Morbidiy Statistics (11th revision); 2022.
5 Zucker KJ. Epidemiology of gender dysphoria and transgender identity. *Sex Health* 2017;14:404–11.
6 The Tavistock and Portman NHS Foundation Trust. Number of referrals to GIDS (gender identity development service). 2023. Available: https://gids.nhs.uk/about-us/number-of-referrals/
7 Frew T, Watsford C, Walker I. Gender dysphoria and psychiatric comorbidities in childhood: a systematic review. *Aust J Psychol* 2021;73:255–71.
8 Surace T, Fusar-Poli L, Vozza L, *et al*. Lifetime prevalence of suicidal Ideation and suicidal behaviors in gender non-conforming youths: a meta-analysis. *Eur Child Adolesc Psychiatry* 2021;30:1147–61.
9 Kozlowska K, McClure G, Chudleigh C, *et al*. Australian children and adolescents with gender dysphoria: clinical presentations and challenges experienced by a multidisciplinary team and gender service. *Human Systems* 2021;1:70–95.

10 Thompson L, Sarovic D, Wilson P, *et al*. A PRISMA systematic review of adolescent gender dysphoria literature: 2) mental health. *PLOS Glob Public Health* 2022;2:e0000426.
11 Lunny C, Ramasubbu C, Puil L, *et al*. Over half of clinical practice guidelines use non-systematic methods to inform recommendations: a methods study. *PLoS One* 2021;16:e0250356.
12 Dahlen S, Connolly D, Arif I, *et al*. International clinical practice guidelines for gender minority/Trans people: systematic review and quality assessment. *BMJ Open* 2021;11:e048943.
13 Ziegler E, Charnish E, Carroll B, *et al*. A critical review of clinical practice guidelines for care of transgender and gender diverse children and youth for use by primary care practitioners. *Transgend Health* 2022;7:397–406.
14 Ziegler E, Carroll B, Charnish E. Review and analysis of international transgender adult primary care guidelines. *Transgend Health* 2021;6:139–47.
15 Taylor J, Hall R, Heathcote C, *et al*. Clinical guidelines for children and adolescents experiencing gender Dysphoria or Incongruence: a systematic review of recommendations (part 2). *Arch Dis Child* 2024;0:1–10.
16 Fraser L, Hall R, Taylor J, *et al*. The epidemiology, management and outcomes of children with gender-related distress / gender dysphoria: a systematic review. PROSPERO 2021 CRD42021289659; 2021.
17 Page MJ, McKenzie JE, Bossuyt PM, *et al*. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ* 2021;372:n71.
18 DeepL SE. Deepl pro; 2023.
19 Veritas Health Innovation. *Covidence systematic review software*. Melbourne, Australia: Veritas Health Innovation, 2023.
20 Brouwers MC, Kho ME, Browman GP, *et al*. AGREE II: advancing guideline development, reporting and evaluation in health care. *CMAJ* 2010;182:E839–42.
21 AGREE Next Steps Consortium. The AGREE II Instrument [Electronic Version].2017. Available: http://www.agreetrust.org
22 Adelson SL, American Academy of Child and Adolescent Psychiatry (AACAP) Committee on Quality Issues (CQI). Practice parameter on gay, lesbian, or bisexual sexual orientation, gender nonconformity, and gender discordance in children and adolescents. *J Am Acad Child Adolesc Psychiatry* 2012;51:957–74.
23 Rafferty J, COMMITTEE ON PSYCHOSOCIAL ASPECTS OF CHILD AND FAMILY HEALTH, COMMITTEE ON ADOLESCENCE, *et al*. Ensuring comprehensive care and support for transgender and gender-diverse children and adolescents. American academy of paediatrics (AAP). *Pediatrics* 2018;142:e20182162.
24 American Psychological Association. Guidelines for psychological practice with transgender and gender nonconforming people. *Am Psychol* 2015;70:832–64.
25 Hembree WC, Cohen-Kettenis PT, Gooren L, *et al*. Endocrine treatment of gender-dysphoric/gender-Incongruent persons: an endocrine society clinical practice guideline. *J Clin Endocrinol Metab* 2017;102:3869–903.
26 T'Sjoen G, Arcelus J, De Vries ALC, *et al*. European society for sexual medicine position statement "assessment and hormonal management in adolescent and adult trans people, with attention for sexual function and satisfaction. *J Sex Med* 2020;17:570–84.
27 Fisher AD, Ristori J, Bandini E, *et al*. Medical treatment in gender dysphoric adolescents endorsed by SIAMS-SIE-SIEDP-ONIG. *J Endocrinol Invest* 2014;37:675–87.
28 Oliphant J, Veale J, Macdonald J, *et al*. Guidelines for gender affirming healthcare for gender diverse and transgender children, young people and adults in aotearoa. *N Z Med J* 2018;131:86–96.
29 Telfer MM, Tollit MA, Pace CC, *et al*. Australian standards of care and treatment guidelines for transgender and gender diverse children and adolescents. *Med J Aust* 2018;209:132–6.
30 The Royal College of Psychiatrists. Gender identity disorders in children and adolescents guidance for management, council report Cr63, January 1998. *Int J Transgend* 1998.
31 Society for Adolescent Health and Medicine. Promoting health equality and nondiscrimination for transgender and gender-diverse youth. *J Adolesc Health* 2020;66:761–5.
32 Esteva de Antonio I, Asenjo Araque N, Hurtado Murillo F, *et al*. Position statement: gender dysphoria in childhood and adolescence. working group on gender identity and sexual development of the Spanish society of endocrinology and nutrition (GIDSEEN). *Endocrinol Nutr* 2015;62:380–3.
33 Strang JF, Meagher H, Kenworthy L, *et al*. Initial clinical guidelines for co-occurring autism spectrum disorder and gender dysphoria or Incongruence in adolescents. *J Clin Child Adolesc Psychol* 2018;47:105–15.
34 Coleman E, Radix AE, Bouman WP, *et al*. Standards of care for the health of transgender and gender diverse people, version 8. *Int J Transgend Health* 2022;23(Suppl 1):S1–259.
35 Council for Choices in Healthcare in Finland. Medical treatment methods for Dysphoria associated with variations in gender identity in minors – recommendation. 2020. Available: https://palveluvalikoima.fi/en/recommendations#genderidentity
36 Danish Health Authority. Guide on Healthcare related to gender identity. 2018. Available: https://www.sst.dk/-/media/English/Publications/2018/Guide-on-healthcare-related-to-gender-identity.ashx?sc_lang=en&hash=0FF626604C50D5EED94852CA5D042A8E
37 de Vries AL, Cohen-Kettenis PT, Delemarre-Van de Waal H. Clinical management of gender Dysphoria in adolescents. caring for Transgender adolescents in BC: suggested guidelines. Transcend Transgender Support & Education Society and Vancouver Coastal Health's Transgender Health Program; 2006. Available: https://rainbowhealth.wpenginepowered.com/wp-content/uploads/2009/05/Guidelines-adolescent.pdf
38 Health Policy Project, Asia Pacific Transgender Network, United Nations Development Programme. Blueprint for the provision of comprehensive care for Trans people and Trans communities in Asia and the Pacific. Futures Group, Health Policy Project; 2015. Available: https://www.undp.org/asia-pacific/publications/blueprint-provision-comprehensive-care-trans-people-and-trans-communities-asia-and-pacific
39 Norwegian Directorate of Health. Gender Incongruence: national professional guideline; 2020. Available: https://www.helsedirektoratet.no/retningslinjer/kjonnsinkongruens
40 Pan American Health Organisation, World Professional Association for Transgender Health. Blueprint for the provision of comprehensive care for Trans persons and their communities in the Caribbean and other Anglophone countries. John Snow, Inc; 2014. Available: https://www.paho.org/en/node/50469
41 Tomson A, McLachlan C, Wattrus C, *et al*. Southern African HIV clinicians' society gender-affirming healthcare guideline for South Africa. *South Afr J HIV Med* 2021;22:1299.
42 Moreno-Pérez O, Esteva De Antonio I, Grupo de Identidad y Diferenciación Sexual de la SEEN (GIDSEEN). Clinical practice guidelines for assessment and treatment of transsexualism. SEEN identity and sexual differentiation group (GIDSEEN). *Endocrinol Nutr* 2012;59:367–82.
43 The Swedish National Board of Health and Welfare. Care of children and young people with gender Dysphoria - national knowledge support with recommendations for the profession and decision makers. 2022. Available: https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2022-12-8302.pdf
44 University of California San Francisco Gender Affirming Health Program. Guidelines for the primary and gender-affirming care of Transgender and gender Nonbinary people. University of California San Francisco; 2016. Available: https://transcare.ucsf.edu/guidelines
45 Oliphant J, Veale J, Macdonald J, *et al*. Guidelines for gender affirming Healthcare for gender diverse and Transgender children, young people and adults in Aotearoa, New Zealand. Transgender Health Research Lab, University of Waikato; 2018. Available: https://researchcommons.waikato.ac.nz/handle/10289/12160
46 Telfer M, Tollit MA, Pace CC. Australian standards of care and treatment guidelines. for Trans and gender diverse children and adolescents. The Royal Children's Hospital; 2020. Available: https://www.rch.org.au/uploadedFiles/Main/Content/adolescent-medicine/australian-standards-of-care-and-treatment-guidelines-for-trans-and-gender-diverse-children-and-adolescents.pdf
47 Tomson A, McLachlan C, Wattrus C, *et al*. Southern African HIV Clinicians society gender-affirming Healthcare guideline for South Africa – expanded version. Southern African HIV Clinicians Society; 2021. Available: https://sahivsoc.org/Files/SAHCS%20GAHC%20guidelines-expanded%20version_Oct%202021(3).pdf
48 Hembree WC, Cohen-Kettenis P, Delemarre-van de Waal HA, *et al*. Endocrine treatment of transsexual persons: an endocrine society clinical practice guideline. *J Clin Endocrinol Metab* 2009;94:3132–54.
49 Coleman E, Bockting W, Botzer M, *et al*. Standards of care for the health of Transsexual, Transgender, and gender-Nonconforming people, version 7. *Int J Transgend* 2012;13:165–232.
50 The Swedish National Board of Health and Welfare. Good care for children and young people with gender Dysphoria. National knowledge support. 2015. Available: https://etik.barnlakarforeningen.se/wp-content/uploads/sites/16/2022/03/1.-SoS-God-va%CC%8Ard-av-barn-....pdf
51 The Swedish National Board of Health and Welfare. Appendix - knowledge base with method description - care of children and young people with gender Dysphoria. 2022. Available: https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2022-12-8302-kunskapsunderlag-med-metodbeskrivning.pdf
52 Pasternack I, Söderström I, Saijonkari M, *et al*. Medical approaches to treatment of Dysphoria related to gender variations. A systematic review. n.d. Available: https://app.box.com/s/y9u791np8v9gsunwgpr2kqn8swd9vdtx
53 Ludvigsson JF, Adolfsson J, Höistad M, *et al*. A systematic review of hormone treatment for children with gender dysphoria and recommendations for research. *Acta Paediatr* 2023;112:2279–92.
54 Biggs M. The Dutch protocol for juvenile transsexuals: origins and evidence. *J Sex Marital Ther* 2023;49:348–68.
55 Block J. Gender dysphoria in young people is rising—and so is professional disagreement. *BMJ* 2023;380:382.

April 29, 2023

Representative Dan Rayfield
Oregon House Speaker
District 16
900 Court St. NE
Salem, OR 97301

Delivered via email to: rep.danrayfield@oregonlegislature.gov

Speaker Rayfield:

Thank you for your question regarding House Bill 2002 (2023). You asked whether HB 2002, which generally requires health insurance carriers to provide coverage for medically necessary gender-affirming treatment, would also require coverage for medical procedures associated with a gender detransition.

As you know, Section 20 of the B-Engrossed version of HB 2002 defines the phrase "gender-affirming treatment" as follows:

> *"Gender-affirming treatment" means a procedure, service, drug, device or product that a physical or behavioral health care provider prescribes to treat an individual for incongruence between the individual's gender identity and the individual's sex assignment at birth.*

The reference to an "incongruence" between an individual's gender identity and that person's sex assigned at birth has raised a question of whether this definition would exclude detransition procedures. We do not believe it does.

ORS 174.100(4) provides the following definition of "gender identity" that applies to Oregon statutes unless the context or a specially applicable definition requires otherwise:

> *"Gender identity" means an individual's gender-related identity, appearance, expression or behavior, regardless of whether the identity, appearance, expression or behavior differs from that associated with the gender assigned to the individual at birth."*

This definition would apply for purposes of HB 2002. Importantly, this definition does not focus solely on an individual's subjective sense of his or her own gender, but includes other objective facets of gender identity such as "appearance, expression or behavior."

Given this definition, we believe that detransition procedures *would be* included in the definition of "gender affirming treatment" under HB 2002. To illustrate, an individual who previously received gender affirming treatment and who is now seeking to reverse the effect of that treatment *would be* seeking treatment for an incongruence between their gender identity (namely, their appearance) and their sex assigned at birth. This conclusion is supported by HB 2002's explicit inclusion of "revisions to prior forms of gender affirming treatment" in the same section's list of prohibited exclusions.

Finally, HB 2002 specifically requires the department to adopt rules implementing the bill. If a question remains on this issue after HB 2002 becomes law we would be glad to address that as part of such rulemaking.

Please feel free to contact me if you have any further questions or concerns.

Sincerely,

Andrew R. Stolfi
Oregon Insurance Commissioner
Director, Oregon Department of Consumer and Business Services

350 Winter St. NE
P.O. Box 14480
Salem, OR 97309
503-378-4100
dcbs.info@dcbs.oregon.gov
oregon.gov/dcbs