AMA Journal of Ethics®

November 2016, Volume 18, Number 11: 1147-1155

SECOND THOUGHTS

Informed Consent in the Medical Care of Transgender and Gender-Nonconforming Patients

Timothy Cavanaugh, MD, Ruben Hopwood, MDiv, PhD, and Cei Lambert, MFA

Abstract

Informed consent as a model of care has evolved as an alternative to the standard model of care recommended by the World Professional Association for Transgender Health's *Standards of Care*, version 7, which emphasizes the importance of mental health professionals' role in diagnosing gender dysphoria and in assessing the appropriateness and readiness for gender-affirming medical treatments. By contrast, the informed consent model for gender-affirming treatment seeks to acknowledge and better support the patient's right to, and capability for, personal autonomy in choosing care options without the required involvement of a mental health professional. Clinicians' use of the informed consent model would enable them both to attain a richer understanding of transgender and gender-nonconforming patients and to deliver better patient care in general.

Introduction

Informed consent is a concept that is familiar to clinicians. On a practical, day-to-day basis, informed consent is often implied rather than explicitly ensured, and whether explicit or implied, informed consent is the ethical and legal basis for most patient care decisions. It requires that clinicians or someone administering treatment, such as a pharmacist, effectively communicate anticipated benefits and potential risks of a treatment, as well as the reasonable alternatives to that treatment. It relies on the patient's capacity for understanding and weighing these options. Integral to the practice of informed consent is the principle of respect for patient autonomy—that is, respect for a person's right of self-determination—and the belief that clinicians will work to facilitate patients' decisions about the course of their own lives and care.

In the field of transgender health, the "informed consent model" of care has evolved as an alternative to the "standard model of care" as recommended in the *Standards of Care*, version 7, established by the World Professional Association for Transgender Health (WPATH) [1]. This article presents a brief overview and comparison of these two approaches and advocates for an informed consent approach to care as more patient-centered and respectful of the patient's sense of agency.

WPATH *Standards of Care*

WPATH is an international multidisciplinary organization that seeks to further the understanding of transgender health and to promote quality, evidence-based care for transgender and gender-nonconforming persons. Since the 1970s, WPATH has advocated on behalf of transgender persons and worked to ensure the competency of mental health and medical professionals. Toward these ends, it developed the *Standards of Care* (*SOC*), first published in 1979. The original *Standards of Care* admonished psychiatrists and psychologists to determine the persistence of the patient's dysphoria "independent of the patient's verbal claim" and referred to a patient's verbal reports as "possibly unreliable or invalid sources of information" [2]. While the *SOC* allows for some flexibility in interpretation and application of these standards, until recently, the *SOC* prescribed a standard period of three to six months of psychotherapy and/or a period of "real-life experience," i.e., living full-time in one's identified gender, prior to any medical intervention. (Real-life experience, for reasons most obvious to the patient, can be impractical, undesirable and even dangerous. Additionally, the term "real-life" can be insulting to the patient's sense of self and lived experience.) Psychotherapy was deemed necessary to manage what's now called "gender dysphoria," or the "discomfort or distress that is caused by a discrepancy between a person's gender identity and that person's sex assigned at birth (and the associated gender role and/or primary and secondary sex characteristics)" [3], as well as to explore gender-related concerns. Based on the *SOC*, patients were required to obtain referral letters from mental health professionals documenting their eligibility and readiness for medical treatment; one letter was required prior to initiating hormone therapy and chest surgery and two letters were required prior to any genital surgery [4]. In a sense, transgender persons were required to prove the authenticity of their gender identity to clinicians before gaining access to gender-affirming care.

The seventh and most recent version of the *Standards of Care*, published in 2012, represents a significant change in approach and recognizes the informed consent model, but still retains a strong emphasis on the need for mental health evaluation before accessing gender-affirming treatments. Psychotherapy is "highly recommended" though not required [5]; it is used to explore the personal meaning and psychic impact of gender dysphoria. However, referral letters are still needed for interventions; the section titled "Criteria for Hormone Therapy" states that "a referral is required from the mental health professional who performed the assessment" [6]. The purpose of the mental health assessment is to assess "gender identity and gender dysphoria, … the impact of stigma attached to gender nonconformity on mental health, and the availability of support" [7]. While the *SOC* acknowledge that the clinician prescribing hormones can assess mental health issues if "also qualified in this area" and experienced in transgender health [6], the presumption is that this is best accomplished by a mental health professional. Surgical interventions still require one or two referral letters from mental health professionals,

and a 12-month period of "living in a gender role that is congruent with … [the person's] gender identity" is still a criterion for genital surgeries [8]. Because the *SOC* place what some regard as an undue burden on persons seeking gender-affirming hormone or surgical treatment, the guidelines have sometimes been viewed as paternalistic and as supporting a form of gatekeeping that actually limits access to gender-affirming care [9, 10].

These standards are based in the concept of nonmaleficence—first, do no harm—and are meant to ensure that gender-affirming medical treatments are not undertaken recklessly. But the *SOC* bespeak a professional discomfort with, and a degree of uncertainty concerning, treatment for gender dysphoria, as well as a cultural unease with issues of gender identity diversity. We are only just beginning to see transgender health addressed in medical schools and mainstream medical circles, and few clinicians have experience with evaluating and treating transgender patients [11, 12]. Within the context of a pervasive and continued cultural discomfort with gender variant identities, it is perhaps understandable that clinicians might focus on and even overestimate the potential for harm of gender-affirming treatments and the possibility that some patients might experience future regret. Historically, scientific data on which to base treatment guidelines and discussions of risks and benefits has been sparse, but the accumulated experience of clinicians treating transgender patients and the results of the growing number of studies that have become available suggest that hormone therapy and surgery are relatively safe and have the potential to improve the psychological state and psychosocial functioning of transgender patients [13-15].

Informed Consent Model of Gender-Affirming Care

The informed consent model for gender-affirming treatment, proposed in a number of transgender health guidelines and by practicing clinicians [16-19] seeks to better acknowledge and support patients' right of, and their capability for, personal autonomy in choosing care options without the requirement of external evaluations or therapy by mental health professionals. Through a discussion of risks and benefits of possible treatment options with the patient—a discussion that considers the current state of scientific knowledge as well as the cultural and social context of treatment decisions and that respects the patient's capacity for self-knowledge—clinicians work to assist patients in making decisions. This approach recognizes that patients are the only ones who are best positioned, in the context of their lived experience, to assess and judge beneficence (i.e., the potential improvement in their welfare that might be achieved), and it also affords prescribing clinicians a better and fuller sense of how a particular patient balances principles of nonmaleficence and beneficence. Ultimately, clinicians' use of the informed consent model can lead to the possibility of a richer understanding of the patient and the potential for better patient care overall. However, the model does not remove the expectation that the clinician will inquire about and understand the possible impact of gender dysphoria on the patient's emotional state and psychosocial

functioning; in fact, it assumes that this will factor into the discussion of risks and benefits but allows the patients themselves to weigh these potential impacts. On the other hand, the *SOC*'s continued reliance on mental health professionals to determine eligibility and readiness for treatment perpetuates a message that neither the patient nor the prescribing clinician is capable of a nuanced discussion of gender variance and its management.

It should be emphasized that informed consent is not "hormones on demand," which would give no scope to the prescribing clinician's expertise and judgment. Rather, it facilitates the patient's and clinician's collaborative determination of the best available treatment. Clinicians do, and should, have these kinds of conversations with their patients all the time, and do not generally require the input of a mental health practitioner to help them in this decision-making process. Nor does the informed consent model preclude mental health intervention and treatment when it is deemed beneficial to the patient or in the relatively uncommon situation when a patient's psychological status is such that capacity for informed consent might be impaired. Indeed, patients can benefit from mental health support as they navigate the physical, mental, and psychosocial changes of gender affirmation processes. But the informed consent model separates supportive mental health treatment from gender-evaluating assessments.

Distrust of mental health professionals within transgender communities has arisen in response to the requirement for a referral from a mental health professional prior to accessing medical care. This requirement can easily be experienced as a hoop that patients need to jump through. As such, it might compel patients to tell a mental health professional only what they feel the clinician needs to hear in order to "get the letter." Some patients might feel tempted to tell a stereotypical narrative of gender identity development and dysphoria in which their authentic gender is described in binary terms, as either male or female, even if this narrative would not truly represent their authentic gender identity development, dysphoria, or understanding of their gender affirmation needs. When the mental health professional is no longer placed in the position of being a gatekeeper to medical treatment, the therapeutic relationship can evolve in a more trusting and open manner, be focused on emergent needs and not treatment eligibility, and have a clearer benefit as perceived by the patient.

As a result of the historic practice of close scrutiny of transgender patients seeking medical care and the discomfort of clinicians and society with gender identity diversity, patients might nonetheless still present a stereotypical narrative in a discussion of informed consent with a prescribing clinician and seek to say the "right words" necessary to ensure a prescription for hormones or another desired intervention. The informed consent model renders this subterfuge unnecessary. That is, when an informed consent process expresses respect for the patient's capacity for self-knowledge, without

requiring outside proof of this capacity or making implied demands for a stereotypical gender identity development narrative, a more accurate understanding of patients' individual gender identities along a gender spectrum—and an appreciation of their particular journey to self-realization—can result. We argue that a fuller, more trusting and respectful discussion with the clinician would enable a more complete assessment of a patient's goals for treatment and realization of the *Standards of Care*'s goal of individualized treatment.

There remains active controversy within transgender and gender-nonconforming communities over the medicalization of gender identity [20]. A more responsive informed consent model of care gives patients permission to accept or decline possibly stigmatizing diagnoses as well as potential treatments that are available to them, while ensuring gender-affirming care is accessible in an environment that expresses respect for patient autonomy.

Examination of Challenges to the Informed Consent Model of Gender-Affirming Care

Challenges to the informed consent model of gender-affirming care do exist. As mentioned earlier, prior to undergoing irreversible changes of genital surgery, the *Standards of Care* require referral letters from two mental health professionals as well as 12 months of experience living in the gender role congruent with the gender identity the patient is affirming [1]. There is no scientific evidence of the benefit of these requirements; they are based on expert consensus [1, 21, 22]. It is possible—as has occurred with gender-affirming hormone therapy, for example—that this consensus opinion will be challenged or changed in future revisions of the *SOC* as increasing numbers of professionals gain experience with, and more patients seek and undergo, genital surgery. There is a need for further research that evaluates the long-term outcomes of specific gender-affirming surgical treatments and the impact of these treatments on patient satisfaction and changes in mental health and psychosocial functioning before these requirements are reconsidered.

While most treatment in the past has been focused on adults, there has also been an increase in awareness and treatment of children and youth with gender dysphoria. Mental health support is critical to the care of gender-nonconforming youth, and many of these children might have engaged in mental health care even before seeking gender-affirming treatment [23]. Mental health professionals' growing experience with and understanding of gender identity has allowed them to better facilitate the exploration of adolescent patients' gender concerns and management of the psychological consequences of gender dysphoria, although here again there is a risk that the mental health practitioner will be viewed as a gatekeeper. Certainly developmental considerations necessitate more involvement of mental health professionals in care determination for adolescents, but these considerations do not eliminate the possibility of an informed consent model of care appropriate to the patients' age and

understanding. The medical management of gender dysphoria has become increasingly accepted as safe and beneficial to adolescents who present with persistent gender identities that are not congruent with their birth-assigned sex [24, 25]. Medically, an informed consent model allows for the tailoring and timing of puberty blockers and hormone therapy that accounts for the adolescent's physical, cognitive, and psychosocial development. It should be noted that adolescents cannot legally consent to treatment but should be able to *assent* to treatment with a developmentally appropriate understanding of consequences. Informed consent for treatment of adolescents thus can pose significant ethical and legal challenges when one or both parents are unwilling to consent to treatment.

More health insurance carriers are providing coverage of transgender-related health care services [26], and hormone therapy and gender-affirming surgical procedures may be increasingly available to those who want and need these interventions. These are positive and encouraging developments in transgender care availability and access. However, each insurance company determines its own criteria for which services will be provided and for approving coverage of these services. There are no federal guidelines for which services are required or for what constitutes proof of medical necessity for services at this time. In the experience of the authors in a large urban medical facility, the services covered and criteria for accessing them are currently not uniform; they may be based on the current WPATH *Standards of Care*, or insurance carriers may impose more stringent criteria or use a standard of care that predates the seventh version of the *SOC*. Unsurprisingly, criteria for accessing care can vary significantly across carriers. Some may mandate mental health assessment and treatment for several months in order to receive even hormone therapy if it is covered. In our experience, often requirements are misinterpreted by both patients and the insurer's staff. What's important for clinicians and patients is to recognize that, at times, these insurance requirements can undermine the use of the informed consent model of care.

Conclusion

Many transgender patients lack access to clinicians experienced in transgender care and will, out of necessity, seek care from local clinicians. Clinicians who are inexperienced and unfamiliar with the treatment of transgender persons may not feel competent to assess for gender dysphoria and may rely on a more standard approach to care and the input of mental health professionals. But even here, the informed consent model allows the clinician and patient to create a plan of care that is affirming and respectful of the patient and compels clinicians to enhance their own understanding and proficiency.

References

1. World Professional Association for Transgender Health. *Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People*. 7th version. World Professional Association for Transgender Health; 2012.

https://amo_hub_content.s3.amazonaws.com/Association140/files/Standards%20of%20Care,%20V7%20Full%20Book.pdf. Accessed August 27, 2016.
2. Harry Benjamin International Gender Dysphoria Association, Inc. The standards of care for gender identity disorders. Published February 12, 1979:4-5.
3. World Professional Association for Transgender Health, 2.
4. Harry Benjamin International Gender Dysphoria Association, Inc. The standards of care for gender identity disorders (fifth version). http://www.tc.umn.edu/~colem001/hbigda/hstndrd.htm. Published June 15, 1998. Accessed September 7, 2016.
5. World Professional Association for Transgender Health, 28.
6. World Professional Association for Transgender Health, 34.
7. World Professional Association for Transgender Health, 23.
8. World Professional Association for Transgender Health, 58.
9. Lev AI. The ten tasks of the mental health provider: recommendations for the revision of the World Professional Association for Transgender Health's *Standards of Care*. *Int J Transgend*. 2009;11(2):74-99.
10. Bouman WP, Richards C, Addinall RM, et al. Yes and yes again: are standards of care which require two referrals for genital reconstructive surgery ethical? *Sex Relation Ther*. 2014;29(4):377-389.
11. Obedin-Maliver J, Goldsmith ES, Stewart L, et al. Lesbian, gay, bisexual, and transgender-related content in undergraduate medical education. *JAMA*. 2011;306(9):971-977.
12. Sanchez NF, Sanchez JP, Danoff A. Health care utilization, barriers to care, and hormone usage among male-to-female transgender persons in New York City. *Am J Public Health*. 2009;99(4):713-719.
13. Asscheman H, Giltay EJ, Megens JA, de Ronde WP, van Trotsenburg MA, Gooren LJ. A long-term follow-up study of mortality in transsexuals receiving treatment with cross-sex hormones. *Eur J Endocrinol*. 2011;164(4):635-642.
14. Colton Meier SL, Fitzgerald KM, Pardo ST, Babcock J. The effects of hormonal gender affirmation treatment on mental health in female-to-male transsexuals. *J Gay Lesbian Ment Health*. 2011;15(3):281-299.
15. Hess J, Neto RR, Panic L, Rübben H, Senf W. Satisfaction with male-to-female gender reassignment surgery: results of a retrospective analysis. *Dtsch Arztebl Int*. 2014;111(47):795-801.
16. Deutsch MB. Use of the informed consent model in the provision of cross-sex hormone therapy: a survey of the practices of selected clinics. *Int J Transgend*. 2013(3):140-146.
17. Callen Lorde Community Health Center. Transgender health program protocols. New York, NY: Callen Lorde Community Health Center; 2011.
18. Tom Waddell Health Center. Protocols for hormonal reassignment of gender. http://www.sfdph.org/dph/ comupg/oservices/medSvs/hlthCtrs

/TransGendprotocols122006.pdf. Revised May 7, 2013. Accessed September 22, 2016.
19. Cavanaugh T, Hopwood R, Gonzalez A, Thompson J. The medical care of transgender persons. Boston, MA: Fenway Health; 2015. http://www.lgbthealtheducation.org/wp-content/uploads/COM-2245-The-Medical-Care-of-Transgender-Persons-v31816.pdf. Accessed September 22, 2016.
20. Drescher J, Cohen-Kettenis P, Winter S. Minding the body: situating gender identity diagnoses in the ICD-11. *Int Rev Psychiatry*. 2012;24(6):568-577.
21. Cascio J. Origins of the real-life test. *Trans Health*. January 20, 2003. http://www.trans-health.com/2003/real-life-test/. Accessed August 19, 2016.
22. Schall T. How accessible should transgender surgery be? *Berman Inst Bioeth Bull*. December 19, 2014. http://bioethicsbulletin.org/archive/how-accessible-should-transgender-surgery-be. Accessed August 19, 2016.
23. Vance SR Jr, Ehrensaft D, Rosenthal SM. Psychological and medical care of gender nonconforming youth. *Pediatrics*. 2014;134(6):1184-1192.
24. Deutsch MB, ed. Guidelines for the primary and gender-affirming care of transgender and gender nonbinary people. Center of Excellence for Transgender Health; June 17, 2016. http://transhealth.ucsf.edu/guidelines. Accessed August 19, 2016.
25. de Vries ALC, Cohen-Kettenis PT. Clinical management of gender dysphoria in children and adolescents: the Dutch approach. *J Homosex*. 2012;59(3):301-320.
26. Human Rights Campaign. Finding insurance for transgender-related healthcare. http://www.hrc.org/resources/finding-insurance-for-transgender-related-healthcareealthcare. Updated August 1, 2015. Accessed September 22, 2016.

Timothy Cavanaugh, MD, is a family practitioner and the medical director for the Transgender Health Program at Fenway Health in Boston.

Ruben Hopwood, MDiv, PhD, is the coordinator for the Transgender Health Program at Fenway Health in Boston.

Cei Lambert, MFA, is the transgender patient advocate at Fenway Health in Boston.

Related in the *AMA Journal of Ethics*

Affirmative and Responsible Health Care for People with Nonconforming Gender Identities and Expressions, November 2016
How Should Physicians Refer When Referral Options Are Limited for Transgender Patients?, November 2016
Informed Consent: What Must a Physician Disclose to a Patient?, July 2012
Psychiatric Diagnostic Uncertainty: Challenges to Patient-Centered Care, June 2016
Sexual Sunday School: The *DSM* and the Gatekeeping of Morality, November 2014

Should Mental Health Screening and Psychotherapy Be Required Prior to Body Modification for Gender Expression?, November 2016
Understanding Transgender and Medically Assisted Gender Transition: Feminism as a Critical Resource, November 2016
What's in a Guideline? Developing Collaborative and Sound Research Designs that Substantiate Best Practice Recommendations for Transgender Health Care, November 2016

ISSN 2376-6980