



Gender-affirming care in the context of medical ethics – gatekeeping v. informed consent

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Introduction. For many transgender patients, access to healthcare – and specifically gender-affirming care (such as hormone replacement therapy) – is limited by a variety of different barriers. Despite evidence showing that access to medical transition is not only safe, but also improves suicide risk in transgender patients, these services are often subject to excessive gatekeeping by medical professionals and healthcare workers.

Objectives. To evaluate the ethical merits of the two most prominent models of providing gender-affirming care to patients who identify as transgender.

Methods. The author compares the gatekeeping model and the informed consent model of providing gender-affirming care, in terms of the well-recognised four fundamental ‘pillars’ of medical ethics, namely respect for autonomy, non-maleficence, beneficence and distributive justice.

Results. The gatekeeping model is found to be in violation of all four principles, while an informed consent model of care respects these ethical pillars.

Discussion. A variety of ethical factors are at play in the provision of gender-affirming care to transgender patients, and these need to be considered carefully in formulating approaches or models. There are many other factors that can present a barrier to gender-affirming care in a South African context, but an examination of the ethical considerations can be of immediate benefit to an already marginalised population.

Conclusion. Clinicians should be aware of the ethical factors in withholding gender-affirming care from transgender patients, and the potential consequences thereof. An approach based on a model of informed consent, which respects a patient’s agency over their own body, is both clinically safe and ethically sound.

S Afr J Bioethics Law 2018;11(1):24-28. DOI:10.7196/SAJBL.2018.v11i1.616

It is a well-established fact that transgender people often face difficulty in accessing healthcare^[1] – both gender-affirming as well as general healthcare. As a marginalised group, transgender people are already at a higher risk of suicide than the general population, in addition to being more likely to be unemployed or have a low income, and more likely to suffer sexual or physical assault^[1]

A 2015 Canadian study suggested that among intervenable factors that can reduce suicide risk among transgender populations, access to medical transition (i.e. gender-affirming care) was a significant role-player.^[2,3]

Furthermore, multiple studies exist to suggest that gender-affirming hormonal intervention in transgender people can be considered as generally safe, and is associated with minimal side-effects, morbidity or increases in mortality.^[4,5]

Despite these data that point towards access to gender-affirming care not only being safe, but also playing a significant role in reducing suicide risk in transgender people, there are still difficulties in accessing this care. A small study of 101 assigned-male-at-birth (AMAB) transgender people in New York City enumerated some of the most prominent barriers to accessing care as a lack of knowledge among service providers, a paucity of transgender-friendly providers and cost.^[6] Focus groups in Boston comprising both adults and youth – and both AMAB and assigned-female-at-birth (AFAB) patients – yielded similar results.^[7]

The fundamentals of medical ethics

Beauchamp and Childress,^[8] in *Principles of Medical Ethics*, first published in 1979, posited four basic ethical principles applicable to medical practice; although the specifics of actually applying these principles need to be considered on an individual case-by-case basis, and the framework itself is not flawless,^[9] these principles are widely accepted and taught in medical schools across the globe as a framework for decision-making.

The four ‘pillars’ of medical ethics are as follows:^[8,9]

(i) Respect for autonomy: this principle provides the basis for ‘informed consent’, recognising the patient as an independent agent with the capacity and right to make their own decisions with respect to their healthcare and bodies.

(ii) Non-maleficence: this principle imposes a requirement on the healthcare provider not to intentionally cause injury or harm to the patient, be it through commission or omission of an act.

(iii) Beneficence: the principle of beneficence establishes a responsibility on the provider to act in ways that are of benefit to the patient.

(iv) Justice: this is a complex and sometimes difficult-to-navigate principle that requires providers to distribute resources in ways that are fair and equitable, particularly in situations where resources are limited.

History of gatekeeping access to gender-affirming care

For many years, the Harry Benjamin International Gender Dysphoria Association has provided guidelines, standards and recommendations on the requirements for initiating gender-affirming care in transgender patients. The organisation, named after endocrinologist Harry Benjamin, one of the first physicians who worked with transgender patients, has subsequently been renamed as the World Professional Association for Transgender Health (WPATH), and continues to publish guidelines as *the Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People (SOC)*.

The most recent iteration of the SOC is Version 7, released in 2011. The document was first published in 1979; prior to the release of the 7th edition, the most recent update to the SOC was published in 2001.^[10]

According to the 2001 version of the SOC, in order to be eligible for gender-affirming hormonal interventions, adult patients needed to fulfil the following requirements (a separate set of requirements is suggested for younger patients, though this is beyond the scope of this article):

1. be of at least 18 years of age.
2. possess demonstrable knowledge of the medical effects and limitations of hormones, as well as the social benefits and risks thereof.
3. have had either: a) a documented real-life experience (RLE) of at least 3 months; or b) a period of psychotherapy of a duration specified by the mental health practitioner (usually a minimum of 3 months).'

In addition to these eligibility criteria, a further set of 'readiness criteria' are imposed:

1. The patient has had further consolidation of the patient's gender identity during RLE or psychotherapy
2. The patient has made some progress in mastering other identified problems, leading to improving or continuing stable mental health (this implies satisfactory control of problems such as sociopathy, substance abuse, psychosis or suicidality).
3. The patient is likely to take hormones in a responsible manner.'

A concession is made for patients who do not fulfil readiness criterion 3, in instances where the patient is likely to use black-market hormone therapy, as a means of harm reduction.

Although the document itself introduces these standards of care as 'flexible directions', they came to be widely known and adopted by healthcare providers – specifically, the requirements of psychotherapy and RLE. Consequently, these requirements have been the subject of criticism by activists and mental healthcare practitioners alike.^[11,12]

The document goes on to refer to the RLE as the 'ultimate diagnosis' of transgender identity, and suggests that based on the RLE, patients might decide that transition is 'not in their best interest'. In fact, detransition and rates of 'transition regret' are known to be very low, even after surgery – depending on the study cited, this rate varies from as little as 0% to a maximum of 4%, significantly lower than regret rates in cisgender patients following elective plastic surgery procedures.^[13-15]

Also worth noting is that the document positions the clinician as the ultimate assessor of whether the RLE is 'successful'. As part of this assessment, the patient must prove sufficiently able:

1. to maintain full or part-time employment
2. to function as a student
3. to function in community-based volunteer activity
4. to undertake some combination of items 1 - 3
5. to acquire a (legal) gender-identity-appropriate first name
6. to provide documentation that persons other than the therapist know that the patient functions in the desired gender role.'

Although these requirements are problematic for many different reasons, three stand out to this author as especially significant:

- (i) the subjectivity of assessing whether or not the patient is able 'to function'
- (ii) the imposition of cis-normative standards in determining whether a first name is 'gender-identity-appropriate'
- (iii) the requirement of a patient to 'out' themselves to others as a requirement for intervention.

There are many other difficulties that can be raised with RLE, in terms of intersectional feminism and queer theory; those arguments, however, are beyond the scope of this paper.

Informed consent as the basis for gender-affirming care

As already discussed, WPATH's SOC is currently in its 7th iteration. Published in 2011, the SOC Version 7 introduces significant changes to the guidelines. According to WPATH, the document has been created on the basis of the best available science and expert professional consensus, and Version 7 represents a 'significant departure from previous versions ... based upon significant cultural shifts, advances in clinical knowledge and appreciation of the many healthcare issues that can arise for transsexual, transgender, and gender nonconforming people beyond hormone therapy and surgery.'^[16]

The current edition of the SOC requires that healthcare providers educate their patients or clients not just on the diversity of gender identities and expressions, but also on the various options available for managing gender dysphoria. It is the responsibility of the provider to prepare the patient to make a fully informed decision regarding treatment options.

Furthermore, the document goes on to state that 'decisions about hormones are first and foremost the client's decisions – as are all decisions regarding healthcare,' a significant change in position from previous versions of these guidelines, and an important assertion that prioritises the patient's agency and autonomy.

Psychotherapy, although recommended, is explicitly stated *not to be an absolute requirement* for hormone therapy. The document also asserts that its suggestions are in line with the informed-consent models of treatment employed at such renowned centres for transgender healthcare as Callen-Lorde and Fenway Health.

According to WPATH, the current criteria for eligibility for hormone therapy in transgender individuals are as follows:

1. persistent, well-documented gender dysphoria
2. the capacity to make a fully informed decision and to consent for treatment
3. having reached the age of majority in a given country
4. reasonably well-controlled medical or mental health concerns, if present and significant.

It is particularly important to note that RLE is no longer listed in these criteria, although many service providers still assume that it is, and insist on it as a requirement.

Furthermore, the purpose of the document as a flexible guideline is reinforced, and acknowledgment granted to the notion that in certain cases, one or more of these criteria may be waived, again citing harm reduction (such as preventing the use of black-market hormones) as an example of when this might be done.

It should also be noted that, as outlined in criterion 4 above, the presence of comorbid mental health conditions should be managed appropriately. Such conditions, however, should not preclude access to gender-affirming care, unless they interfere with an individual's capacity to make an informed decision.

Comparison of gatekeeping and informed consent within the framework of medical ethics

Despite the support of WPATH, the Callen-Lorde Community Health Center and Fenway Community Health for an informed consent model of treatment,^[16-18] gatekeeping remains a pervasive barrier to accessing care for transgender people.^[19-22]

In light of this, the author believes that it might be of benefit to compare these two models of gender-affirming care, namely gatekeeping and informed consent, within the already-introduced framework of medical ethics.

Respect for autonomy

The argument in terms of this principle is straightforward and virtually self-explanatory. If access to care is gatekept by service providers – that is to say, if the healthcare provider makes the assessment of whether or not a patient should be allowed access to gender-affirming care – this is a blatant violation of the principle of respect for autonomy.

In contrast, an informed consent model preserves the integrity of this ethical principle by empowering a patient to make their own decision with regard to their healthcare.

Non-maleficence

A gatekeeping approach to gender-affirming care is founded on the idea that hormonal therapy may be harmful to patients – either directly, through the biological and chemical consequences of such treatment, or because of the 'social risks', or the fear that patients will regret their decision to pursue medical transition.

Although gender-affirming hormonal intervention is not without side-effects, these side-effects are well established, and are outlined comprehensively in the SOC. Furthermore, many of these side-effects (for example, the cessation of menses in AFAB patients) might be regarded as beneficial rather than detrimental in the case of transgender individuals.

As already established, hormonal therapy in transgender patients has been demonstrated scientifically to be safe.^[4,5] Furthermore, it is known that many of the irreversible effects of hormone therapy take significant periods of time to develop – notably: breast growth (onset 3 - 6 months; maximal effect 2 - 3 years) in AMAB patients, and scalp hair loss (onset <12 months; maximal effect variable), clitoral enlargement (onset 3 - 6 months; maximal effect 1 - 2 years),

deepened voice (onset 3 - 12 months; maximal effect 1 - 2 years) and facial hair growth (onset 3 - 6 months; maximal effect 3 - 5 years) in AFAB patients.^[16,23-25]

Therefore, it is established that these consequences – which are often not viewed by patients as deleterious – take time to develop; they are not instantaneous. Furthermore, there are interventions available should these effects later be viewed by the patient as undesirable – for example, surgical removal of breast tissue, or laser hair removal for unwanted facial hair.

Given the length of time needed for these changes to develop to any noteworthy extent, and acknowledging that although cessation of hormone therapy alone will not reverse these changes, there are other means by which they may be reversed, it seems fair to argue that non-maleficence is not a valid justification to gatekeep access to gender-affirming care.

As clinicians, we strive to act with our patients' best interests at heart, and that can lead to a tendency to try to 'protect patients from themselves', which, in this instance, may be motivated by fear of the effects or consequences of gender-affirming care. Two points are important to note here. Firstly, although there are side-effects associated with gender-affirming care, we should not neglect the fact that exposure to endogenous hormones for transgender persons is also not without deleterious (and often irreversible) effects; these should not be neglected when considering what is in a patient's best interests. Secondly, bearing in mind the principle of respect for autonomy already discussed, it should be reiterated that the practitioner's responsibility is to inform the patient of potential risks or side-effects, and to assess the patient's capacity to make an informed decision,^[26] without letting personal preconceptions or misgivings influence this process.

Furthermore, it can be argued that since access to medical transition improves outcomes (particularly suicide risk) for transgender patients,^[2,3] limiting access to these interventions can be seen as harmful in and of itself, and as such, is a violation of the principle of non-maleficence.

Conversely, an informed consent model of treatment that educates patients as to the risks of hormone therapy, as well as the benefits, and allows them to make a decision on their own can hardly be viewed as harmful, given that we have already established the safety of hormonal interventions.

Beneficence

The discussion around beneficence is closely related to the points already outlined in discussing non-maleficence, and so the discourse that follows will be brief. Recognising that gatekeeping is cited as a barrier to accessing care, and that the inability to access care is in fact deleterious to transgender patients, it becomes difficult to reconcile such a practice with the principle of beneficence.

In contrast, by respecting, validating and affirming a patient's identity, and their right to make their own decisions regarding their healthcare and treatment, we are directly improving outcomes for patients – there are numerous studies that show improved quality of life and outcomes in transgender patients following interventions such as hormone therapy and surgery.^[2,27,28] As such, the informed consent approach to treatment is respectful of the ethical principle of beneficence.

Justice

Within the gatekeeping model of access to care, it is the healthcare provider or clinician who ultimately assesses whether or not a patient will gain access to healthcare. These assessments might be made on several different grounds, but in accordance with the guidelines posited by editions of SOC^[10] earlier than version 7, they are usually contingent on either (i) the 'success' of the RLE, and/or (ii) a period of psychotherapy.

'Success' in terms of RLE is defined as the ability of the patient to 'prosper in the preferred gender', in terms of the patient's resolve, and their capacity to function in that gender, as well as the adequacy of social, economic and psychological supports.

It is not difficult to understand that this is a flawed metric, for a number of reasons. Much of the 'assessment' is contingent not on the patient's actual experience, but rather on how the patient is seen by outside observers – specifically the clinician or provider, but also the rest of society.

Firstly, for patients who identify outside of the gender-binary, how is 'success' defined? There is no established objective metric for 'capacity to function' in a gender; by definition, it is subjective, and patients with a non-binary identity are, from the outset, prejudiced in this assessment, as their experiences lie outside of cultural and societal norms.

Secondly, the guidelines themselves suggest that this assessment is contingent on the 'adequacy of social, economic and psychological supports'; therefore, a patient who is financially secure, for example, fulfils this criterion, whereas one who is economically disadvantaged might not.

To illustrate: consider two hypothetical transgender patients. The first patient, Sue, is AMAB, with a female gender identity, white, college-educated and gainfully employed. Sue is 5'7" tall and has a slight frame. She does not have thick facial or body hair, but anyway can afford laser hair removal, regular waxing, skin treatments, a wardrobe of flattering clothes and expensive makeup.

The second patient, Jo, is AMAB, with a female gender identity, is a person of colour, has a disadvantaged background, lives in a rural area and works a minimum-wage job. She is 6'3" tall, has broad shoulders and heavy bone structure, and dense facial and body hair. She cannot afford cosmetic treatments or products, and has only her old masculine clothes in her wardrobe.

Of these two patients, who is likely to be more 'successful' in the RLE? Almost certainly, Sue will have an easier time – she is likely to face less discrimination and prejudice, and has better access to resources, including psychotherapy. This is especially significant in the absence of hormonal intervention – which promotes the development of physical features that are concordant with an individual's gender identity.

In the example scenario, the patient who has better resources, and a more 'fortunate' genetic profile, is more likely to gain access to gender-affirming care.

Certainly, this is a blatant violation of the ethical principle of distributive justice.

(It should be noted that there is potential to discuss the implications and ramifications of what constitutes 'successful' RLE in terms of gender theory, with particular attention given to the concept of 'passing', and the distinction between gender identity and expression, but again that is beyond the scope of this article – for the purposes

of this discussion, it is assumed that these assessments are made according to binary and cis-normative standards, which themselves are flawed.)

An informed consent approach, conversely, promotes equity and fairness by allowing patients to decide on their own healthcare, without subjecting them to restrictions based on factors that are beyond their control. By refusing to prejudice a patient's right to access care based on such factors as race, social class, finances or genetics, we respect and maintain the integrity of the principle of justice.

Conclusion

In conclusion, there are several points that should be taken into account when evaluating approaches to initiating gender-affirming care in transgender patients.

It is important to recognise that there is a growing body of evidence to suggest that hormonal therapy in transgender patients is safe, and is not associated with increases in morbidity or mortality. Furthermore, there is also evidence suggesting that access to gender-affirming care is an important intervenable factor that can significantly reduce suicide risk in what is known to be a vulnerable population.

In addition, many renowned clinics and expert groups have led by example in distancing themselves from such practices as gatekeeping, opting rather to treat patients in accordance with an informed consent model of treatment. It is not without relevance to acknowledge that WPATH, at the time known as the Harry Benjamin Gender Dysphoria Association, was once the most significant proponent of a gatekeeping model of gender-affirming care, and has recognised the problems inherent in such a model. In response to this recognition, WPATH now advocates for an informed consent approach that is consistent with the model employed by leading gender clinics.

Being cognisant of these developments, and examining the two differing approaches to gender-affirming care within a framework of medical ethics, based upon Beauchamp and Childress^[8] well-recognised four pillars of medical ethics, it can be demonstrated that a gatekeeping model of care is found to be in violation of all four principles: autonomy, non-maleficence, beneficence and justice.

In stark contrast, an approach based on the principles of informed consent preserves the integrity of these pillars of medical ethics.

It should, of course, be noted that there remain additional obstacles to accessing gender affirming care – such as costs of treatment, competence of providers, and social circumstances, among others – but overcoming these barriers involves a separate, and far lengthier, discussion. Moving towards an informed consent model of care is not a silver bullet that solves all problems when considering gender-affirming care, but it is nonetheless a significant step, and one that is ethically sound.

The author therefore concludes that any approach to gender-affirming care that utilises gatekeeping, particularly in the form of enforced RLE or psychotherapy, should be regarded as unethical, and that clinicians should be aware of this when managing or interacting with transgender patients.

Acknowledgments. None.

Author contributions. Sole author.

Funding. None.

Conflicts of interest. None.

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Accepted 6 February 2018.