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Letter to the Editor

The continuum of informed consent models in transgender health

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Using the 'Informed Consent Model' (ICM), clinicians prescribing hormone therapy to trans patients do not require a letter from mental health professionals attesting to their gender identity and/or gender dysphoria (and/or equivalent diagnostic or assessment category). Patients who are trans have a gender identity that does not correspond to the gender they were assigned at birth. A reaction to the paternalism and pathologization of trans people that have plagued trans healthcare, the proliferation of ICMs echoes the growing commitment to autonomy and patient-centred care by clinicians working with trans communities. The World Professional Association for Transgender Health's Standards of Care (WPATH SOC) Version 7 acknowledges the validity of ICMs (1).

Despite their prevalence and history in North America, ICMs remain poorly understood by medical professionals and are often treated as a monolithic concept (2,3). Existing research shows that ICMs are associated with good patient outcomes, but rarely distinguishes different types of ICMs (2,4). Given the increased prominence of ICMs, a clear understanding of the complexity and differences of practice within ICMs is crucial to the ongoing development and evolution of clinical care for trans patients. The prevalence of ICMs is likely to continue increasing, and ICMs are expected to feature more prominently in the upcoming WPATH SOC Version 8.

ICMs operationalize a commitment to autonomy (5) and range from exclusively relying on the patient's decisional autonomy to exclusively relying on a thorough, independent assessment of the patient's gender identity and/or gender dysphoria in determining eligibility for hormones. In between, all shades of grey flourish. Along this continuum, three positions deserve highlighting for their differing levels of commitment to trans autonomy. We propose calling them Strong ICMs, Weak ICMs and No-Letter Models. Under Strong ICMs, eligibility for hormones solely requires informed consent. Under Weak ICMs, the patient's autonomy is centred, but an assessment of gender identity and/or gender dysphoria by the prescribing clinician is nevertheless a criterion for eligibility. Under No-Letter Models, hormones are prescribed without a referral letter from an external mental health professional, but eligibility for hormones remains based on a more comprehensive assessment of gender identity and/or gender dysphoria.

Strong ICMs see adequate informed consent as the sole precondition for eligibility to hormone therapy. Although they may explore the patient's gender experience and history, the aim is to elucidate and best meet the patient's embodiment goals rather than establish eligibility for hormones. Strong ICMs recognize that using independent assessments of gender identity and/or gender dysphoria to establish eligibility may be distressing and contribute to the pathologization of trans communities (6,7). Advocates of Strong ICMs frequently foreground the need to improve informed consent processes to better guide patient decision-making, and study the effects of different hormone regimens with regard to safety and fulfilling patients' goals.

Weak ICMs view initiating hormone therapy as a collaborative decision and accord substantial weight to both the patient's decisional autonomy and the prescribing clinician's independent assessment of gender identity and/or gender dysphoria. The patient's decision to initiate hormone therapy is firmly emphasized and plays a prominent role in assessments of gender identity and/or gender dysphoria. Advocates of Weak ICMs see their primary role as facilitating access to hormone therapy while playing a secondary safeguarding role in turning away patients for whom hormone therapy would not be indicated because they are confused or misled about their gender identity, have severe, unaddressed behavioural health concerns, or do not genuinely experience gender dysphoria. For greater clarity, we are not here speaking of turning away patients due to contraindications related to physical health. However, prescribing clinicians should be mindful not to treat such contraindications as absolute, as the balance of risks and benefits may still favour offering hormone therapy (8).

While No-Letter Models are frequently labelled as ICMs, the name is a misnomer, as they continue to rely on comprehensive

assessments of gender identity and/or gender dysphoria to determine eligibility for hormone therapy (5). While No-Letter Models do not require a referral letter by an external mental health professional, the prescribing clinician or a member of an interdisciplinary team conducts a thorough assessment of gender identity and/or gender dysphoria. Unlike Strong and Weak ICMs, No-Letter Models do not distinctively emphasize the patient's decisional autonomy or the informed consent process in determining eligibility for hormones. Oftentimes, assessments are still conducted by a mental health professional, albeit as part of an interdisciplinary team. Advocates of No-Letter Models emphasize their role in reducing financial barriers to accessing hormone therapy and the related risk of unsupervised use of grey market sex hormones because of multiple barriers to obtaining letters of referral (5). However, in our experience, the requirement of a thorough assessment constitutes a barrier to accessing care (5,6).

The three positions described do not exhaust the approaches to care falling under the ICM label. Between Strong ICMs' exclusive investment in decisional autonomy, Weak ICMs' non-exclusive focus on decisional autonomy, and No-Letter Models' traditional approach to eligibility assessment lies a continuum that belies categorization in discrete families. The three positions are salient not because of exhaustiveness but because of their unique logics and corresponding relationship to informed consent.

Two misconceptions occasionally appear in discussions of ICMs. The first is that Strong ICMs are hormones-on-demand. While a patient's request for hormones plays a central role in Strong ICMs, decisional autonomy is broader than requests and invokes the rich spectre of informed consent. Patients' capacity to consent remains required, as does adequate disclosure of relevant information. Advocates of Strong ICMs have been leading voices in criticizing clinicians working in trans health for providing insufficient or inadequate information to patients, which undermines rather than fosters trans patients' decisional autonomy (9).

The second misconception is that any clinician who obtains informed consent before prescribing hormones falls under ICMs (3). This misconception arises from a terminological confusion between informed consent and Informed Consent Models. All prescribers are required to obtain free and informed consent. What defines ICMs is not the presence of informed consent but rather the role of informed consent in determining eligibility for hormone therapy.

Clinicians' choice between Strong ICMs, Weak ICMs, No-Letter Models and intermediary approaches is influenced by a variety of factors. Although the decision is sometimes framed as an attempt to balance autonomy and non-maleficence, the presumption that stronger ICMs pose a greater risk of harm is not grounded in evidence (2,4,6). Factors influencing clinicians' choice of approach non-exhaustively include attitudinal, epistemic, institutional and social ones.

At the attitudinal level, a prominent factor is clinicians' view of transness and medical transition. Clinicians who are trans, who view transgender modalities as reflecting human diversity rather than pathology and/or who view them as treasured rather than undesirable are more likely to favour a stronger ICM approach. Clinicians may also be influenced by the strength of their commitment to building the therapeutic alliance and by the importance they place on promoting social justice in ethical decision-making. At the epistemic level, clinicians may be influenced by their degree of comfort, familiarity and knowledge of trans healthcare; their view of the effectiveness of assessments in preventing negative outcomes; their posture towards scientific uncertainty in ethical decision-making; and their degree of deference to trans communities, who tend to be hostile towards assessments of gender identity and/or gender dysphoria (6). At the institutional level, clinicians with poor institutional and peer support may be less inclined to adopt stronger ICMs. This factor may play a determinative role for those working with minors or in conservative institutions. Healthcare infrastructure and financial considerations may also influence clinicians' approaches. At the social level, fear of litigation and public condemnation are prominent factors influencing clinicians' approach. This is especially true for clinicians working in conservative states, where trans healthcare is increasingly subject to popular and political opprobrium. Clinicians' desire to build positive connections to trans communities outside of the immediate clinical context may also influence the adoption of stronger ICMs, which are favoured by trans communities. In our experience, practitioners who have personal connections to trans individuals, notably family members or partners, are also much likelier to adopt a Strong ICM.

As the foregoing discussion illustrates, ICMs are neither monolithic nor a panacea for the pathologizing history of trans healthcare. ICMs exemplify diverse attachments and relationships to transness and decisional autonomy, some of which may fall short of the ideals of depathologized, patient-centred care. Going forward, clinicians, theorists, researchers and advocates should be attentive to the diversity of ICMs and to their respective virtues and vices. Future research should strive to elucidate the outcomes of different ICMs and avoid treating them as a monolithic category.

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