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TRANSGENDER HEALTH

The Informed Consent Model of Care for Accessing Gender-Affirming Hormone Therapy Is Associated With High Patient Satisfaction

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ABSTRACT

Background: There are 2 common approaches to assess an individual before commencing of gender-affirming hormone therapy (GAHT); a mental health practitioner assessment and approval or an informed consent model undertaken with a primary care general practitioner (GP).

Aim: In a primary care clinic practising an Informed Consent Model of care to initiate GAHT, we aimed to firstly describe the proportion and characteristics of patients referred for secondary consultation to a mental health practitioner (MH referred) and secondly, we aimed to measure patient satisfaction.

Methods: A retrospective audit of all new patients with a transgender or gender diverse identity presenting to a primary care clinic in Melbourne, Australia was performed between March 2017 and March 2019. In those newly seeking GAHT, de-identified data were obtained including presence of secondary mental health practitioner referral, time to GAHT commencement and co-occurring mental health conditions. A separate survey assessed patient satisfaction.

Outcomes: Mental health conditions and overall patient satisfaction in those referred for secondary mental health consultation (MH referred) were compared with those who were not (GP assessed).

Results: Of 590 new consultations, 309 were newly seeking GAHT. Referrals for secondary mental health assessment before GAHT occurred in 8%. The GP-assessed group commenced GAHT at median 0.9 months (0.5−1.8) after initial consultation compared with 3.1 months (1.3−4.0), $P < .001$ in the MH-referred group. The MH-referred group was more likely to have post-traumatic stress disorder (adjusted $P = .036$) and schizophrenia (adjusted $P = .011$). Of 43 respondents to the survey, a higher proportion in the GP-assessed group was extremely satisfied with their overall care compared with the MH-referred group ($P < .01$). Notably, 80% in the GP-assessed group chose to seek mental health professional support.

Clinical Implications: Initiation of GAHT can be performed in primary care by GPs using an informed consent model and is associated with high patient satisfaction. Mental health professionals remain a key source of support.

Strengths & Limitations: This retrospective audit did not randomize patients to pathways to initiate GAHT. Follow-up duration was short. Responder bias to survey with low response rates may overestimate patient satisfaction. This is one of the first studies to evaluate an informed consent model of care.

Conclusion: More widespread uptake of an informed consent model of care to initiate GAHT by primary care physicians has the potential for high patient satisfaction and may be a practical solution to reduce waiting lists in gender clinics. **Spanos C, Grace JA, Leemaqz SY, et al. The Informed Consent Model of Care for Accessing Gender-Affirming Hormone Therapy Is Associated With High Patient Satisfaction. J Sex Med 2021;18:201−208.**

Key Words: Informed Consent Model; Transgender; Gender-Affirming Hormone Therapy; Mental Health

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INTRODUCTION

Transgender health care is a rapidly growing area of medicine, with increasing demand for services currently seen worldwide. However, there is a lack of research to guide how to assess an individual before commencement of gender-affirming hormone therapy (GAHT). There is considerable debate regarding traditional modes of assessment involving a formal mental health practitioner, compared with an alternative informed consent model of care that involves a shared decision-making process between a treating clinician and a transgender (including gender diverse and non-binary) (TGD) individual seeking GAHT.

The World Professional Association for Transgender Health Standards of Care were first published in 1979 and represent one of the earliest international consensus statements about the optimal management of TGD individuals.[1] Currently, in its 7th version published in 2012, the World Professional Association for Transgender Health Standards of Care recommend a psychosocial assessment conducted by a mental health professional (in most cases, a gender-specific psychiatrist or psychologist) as the first step for a TGD individual seeking hormone therapy and outline criteria for hormone prescribing that include a requirement for "persistent, well-documented gender dysphoria".[1] However, the requirement for formal mental health practitioner approval has come under scrutiny from some members of the TGD community for being paternalistic, without scientific evidence for benefit, and the process is perceived to be "a form of gatekeeping that actually limits access to gender-affirming care".[2–8]

The informed consent model of GAHT prescription emerged in the early 2000s with the intention of depathologizing gender diversity and reducing barriers to medical care for TGD individuals.[1,3,4,8] Its hallmark is a shift from the requirement for formal psychiatric approval before accessing GAHT to a shared decision-making process between the patient and their treating clinician.[8] The primary treating clinician assesses an individual's ability to provide informed consent and then provides thorough education around GAHT placing the patient as the primary decision maker in partnership with their treating clinician. The informed consent model seeks to emphasize partnership and self-determination to tailor care to individual needs and reduce unnecessary barriers in accessing GAHT.[9] Typically, the primary treating clinician (general practitioner [GP], sexual health physician or endocrinologist) will initiate GAHT as long as the patient is able to fully understand the potential benefits, known risks and unknown risks of GAHT, and has capacity to provide consent.[8] Secondary referral to mental health professionals to provide support or counseling may occur but is not mandated. Notably, the informed consent model is acknowledged within the World Professional Association for Transgender Health Standards of Care as an accepted alternative pathway in the provision of GAHT[1] and recognized in more recent position statements from professional societies.[10,11]

The informed consent model at Equinox Gender Diverse Health Centre comprised the following 5 stages: (i) introduction to clinic services; (ii) initial medical review and referral for secondary consultation if required; (iii) hormone counseling and education; (iv) initiation of HRT; and (v) ongoing monitoring and support, with care provided by a primary care physician (GP).[9] The model is flexible, allowing for individualization based on the unique needs of each patient, and encourages the concurrent use of mental health supports as required.

Given a lack of data regarding implementation of informed consent models of care for GAHT use, at our primary care clinic specializing in TGD health, we aimed to first describe the proportion of patients referred for secondary mental health practitioner assessment before initiating GAHT; second, to describe predictors that triggered referral for formal mental health practitioner assessment before commencing GAHT; and third, to measure patient satisfaction. We hypothesized that those who underwent assessment solely by their GP would initiate GAHT earlier and be more satisfied with their care than those referred for secondary formal mental health practitioner assessment before initiation of GAHT.

METHODS

A retrospective audit was performed of new consecutive consultations at Equinox Gender Diverse Health Centre between March 2017 and March 2019. Electronic medical records were reviewed collaboratively by 2 coauthors C. S. and J. G., and deidentified data were recorded. A separate cross-sectional anonymous patient satisfaction survey available as a hard copy in the clinic waiting room and online (Qualtrics Survey Software [Utah]) via the clinic Facebook page was conducted between May and June 2019 to measure patient satisfaction. The study received ethical approval by the Austin Health Research Ethics Committee and Community Research Endorsement Panel (approval number THH/CREP/19/016).

The Equinox Gender Diverse Health Centre (hereafter known as Equinox) in inner city Melbourne, Australia, is a primary care clinic specifically serving the TGD population since February 2016. Equinox is a peer-led TGD clinic offering services in medicine, osteopathy, counseling, and social work. There is a TGD advisory committee working in conjunction with a practice manager to guide the operations of the clinic. All reception staff are TGD community members. Several clinical staff also identify as TGD. There are no out-of-pocket costs for a patient to see a doctor at Equinox with all consultations subsidized by the Australian Government (Medicare bulk-billed). Patients are able to self-initiate appointments with the primary care physicians (GPs). Equinox created Australia's first informed consent protocol for initiation of GAHT in 2017, which were endorsed by the Australian Professional Association for Trans Health and the only existing state public tertiary care gender service, Monash Gender Clinic.[12] The model was based on similar protocols used at Callen-

Lorde Community Health Center in New York, United States,[13] and primary care physicians implemented these informed consent model of care guidelines in practice in February 2017 for all attending patients.[9] The Equinox informed consent model does not state or guarantee that all patients will commence GAHT after the GP assessment alone. It does state that the GP will perform an initial assessment for all patients and the GP will refer patients for secondary mental health practitioner assessment in the settings of more complex mental health conditions such as psychosis or if the GP feels unable to adequately determine an individual's ability to provide informed consent.

All new patient consultations at Equinox were reviewed retrospectively. New consultations were divided into 5 groups to ascertain individuals who were initiated on GAHT at Equinox:

(i) individuals who were assessed solely by a GP before initiating GAHT at Equinox ("GP-assessed" group);
(ii) individuals who were initially assessed by a GP and then referred for secondary formal mental health practitioner assessment before initiating GAHT at Equinox ("MH-referred" group);
(iii) individuals who had a preexisting formal mental health assessment and initiated GAHT at XEquinox;
(iv) individuals who were already taking GAHT; and
(v) individuals who did not commence GAHT during the period of follow-up.

To compare characteristics of individuals who were assessed solely by a GP and individuals who were assess by a GP and then referred for secondary mental health practitioner assessment, comparisons were made between groups (i) and (ii).

Deidentified data were collected including age at first presentation, postcode, birth-assigned sex, gender identity, and date of first consultation. Postcodes were classified as per the Australian Standard Geographical Classification − Remoteness Areas (ASGC-RA)[14] to assess rural status. Diagnosed medical and mental health conditions were extracted from electronic medical records as entered by treating clinicians. Birth-assigned sex and gender identity were self-reported on self-designed intake forms (question stated "Please indicate your gender identity/expression" with options to circle including female, male, trans, sistergirl, brotherboy, genderqueer, transfeminine, transwoman, transmasculine, transman, non-binary, prefer not to say, and/or "other [please specify]" with a free text section).

In addition, referrals to mental health professionals (psychiatrist or psychologist), number of clinic visits before GAHT commencement, and proportion of patients who returned for review at 3 and 12 months after initiation were recorded (if eligible to do so) during the follow-up period.

The patient satisfaction survey is included in full in the Appendix 1. Participants were asked whether they had initiated GAHT under the IC model and asked to rate their satisfaction across a number of domains. Key questions included "How satisfied were you with the information provided regarding risks/benefits of hormone therapy by your treating doctor?" "How satisfied have you been with the opportunity to ask questions during your consultations with your doctors at Equinox?" "Did you feel that you were actively involved in the decision-making process to start hormones?" "Have you accessed mental health support during your transition?" and "How satisfied were you with the process or steps required to start gender-affirming hormones (either at Equinox or elsewhere)?" Responses were provided on a 5-point Likert scale (extremely satisfied, moderately satisfied, neither satisfied nor dissatisfied, moderately dissatisfied, and extremely dissatisfied). Owing to sparse responses, the latter 4 categories were grouped as one "not extremely satisfied" category and compared with extremely satisfied responses in the statistical analysis. Participants were also provided with a free-text comment box regarding their care received at Equinox.

Statistical Analysis

Demographics of patients are reported as frequencies and percentages (n [%]) for categorical variables and median and interquartile range for continuous variables. The number of co-occurring mental health conditions was compared between patients who were referred for mental health assessment and those who underwent the IC model of care using Wilcoxon rank-sum test. Further analysis of each mental health condition was compared separately using Chi-squared tests or Fisher's exact test where cell counts are low, with Bonferroni adjusted *P*-values for multiple comparisons reported. The median and interquartile range of the time to commence hormonal treatment and number of appointments before hormonal treatment between patients with and without referral for mental health assessment was also reported and compared using Mann-Whitney U test. The patient satisfaction survey responses were summarized into frequencies and percentages separately for each question, and Fisher's exact test was used to compare the extremely satisfied responses to not extremely satisfied (moderately satisfied or less). Statistical analyses were performed using R, version 3.6.1 (R foundation for statistical computing).

RESULTS

Demographics

In total, 589 new patients had new consultations at Equinox between 01 March 2017 and 28 February 2019. Their mean age was 25 years (21−30). Based on ASCG-RA criteria, 90% were from major cities, 9% from inner regional areas, and 1% from outer regional areas. There were 52% who were assigned female at birth, 46% were assigned male at birth, and the remaining 2% preferred not to say. In terms of gender identity, 39% identified as female, transfemale, or trans feminine, 31% as male, transmale, or transmasculine, 27% had a non-binary or genderqueer identity, and 3% were unassigned.

Referral for Mental Health Assessment

Of all new consultations, 53% (n = 309) initiated GAHT at Equinox, 21% (n = 126) were already taking GAHT, and the

Table 1. Characteristics that predicted referral for secondary mental health practitioner consultation before commencing GAHT

Characteristic	Informed consent group (n = 566)	MH-referred group (n = 23)	Total (n = 291)	*P* value	(Bonferroni) Adjusted *P* value
Depression: N (%)				.8872	1.0000
Missing	3 (1.1)	0 (0.0)	3 (1.0)		
No	151 (56.3)	14 (60.9)	165 (56.7)		
Yes	114 (42.5)	9 (39.1)	123 (42.3)		
Anxiety: N (%)				.1274	1.0000
Missing	3 (1.1)	0 (0.0)	3 (1.0)		
No	175 (65.3)	11 (47.8)	186 (63.9)		
Yes	90 (33.6)	12 (52.2)	102 (35.1)		
ADHD: N (%)				.6659	1.0000
Missing	2 (0.7)	0 (0.0)	2 (0.7)		
No	248 (92.5)	21 (91.3)	269 (92.4)		
Yes	18 (6.7)	2 (8.7)	20 (6.9)		
Borderline personality disorder: N (%)				.0367	.4400
Missing	3 (1.1)	0 (0.0)	3 (1.0)		
No	252 (94.0)	19 (82.6)	271 (93.1)		
Yes	13 (4.9)	4 (17.4)	17 (5.8)		
Autism spectrum disorder: N (%)				.3697	1.0000
Missing	2 (0.7)	0 (0.0)	2 (0.7)		
No	252 (94.0)	21 (91.3)	273 (93.8)		
Yes	14 (5.2)	2 (8.7)	16 (5.5)		
Post-traumatic stress disorder: N (%)				.0030	.0362
Missing	3 (1.1)	0 (0.0)	3 (1.0)		
No	260 (97.0)	19 (82.6)	279 (95.9)		
Yes	5 (1.9)	4 (17.4)	9 (3.1)		
Substance abuse/dependency: N (%)				1.0000	1.0000
Missing	3 (1.1)	0 (0.0)	3 (1.0)		
No	256 (95.5)	23 (100.0)	279 (95.9)		
Yes	9 (3.4)	0 (0.0)	9 (3.1)		
Schizophrenia: N (%)				.0009	.0112
Missing	3 (1.1)	0 (0.0)	3 (1.0)		
No	262 (97.8)	19 (82.6)	281 (96.6)		
Yes	3 (1.1)	4 (17.4)	7 (2.4)		
Bipolar disorder: N (%)				1.0000	1.0000
Missing	3 (1.1)	0 (0.0)	3 (1.0)		
No	257 (95.9)	23 (100.0)	280 (96.2)		
Yes	8 (3.0)	0 (0.0)	8 (2.7)		
OCD: N (%)				1.0000	1.0000
Missing	3 (1.1)	0 (0.0)	3 (1.0)		
No	262 (97.8)	23 (100.0)	285 (97.9)		
Yes	3 (1.1)	0 (0.0)	3 (1.0)		
Eating disorders: N (%)				1.0000	1.0000
Missing	3 (1.1)	0 (0.0)	3 (1.0)		
No	262 (97.8)	23 (100.0)	285 (97.9)		
Yes	3 (1.1)	0 (0.0)	3 (1.0)		
Schizoaffective disorder: N (%)				1.0000	1.0000
Missing	3 (1.1)	0 (0.0)	3 (1.0)		
No	263 (98.1)	23 (100.0)	286 (98.3)		
Yes	2 (0.7)	0 (0.0)	2 (0.7)		

ADHD = attention deficit hyperactivity disorder; GAHT = gender-affirming hormone therapy; MH-referred = referred for secondary consultation to a mental health practitioner.

remaining 26% (n = 154) did not commence GAHT at Equinox during the study period. Of the 309 patients who initiated GAHT at Equinox, 18 had already had a prior mental health assessment performed by the time they had their first consultation, leaving 291 individuals newly seeking initiation of GAHT at their first consultation at Equinox (GP-assessed group n = 268 [92%], MH-referred group n = 23 [8%]).

Of the 23 individuals in the MH-referred group, 12 individuals were referred to a clinical psychologist experienced in TGD health, 7 individuals to a psychiatrist experienced in TGD health, and 3 individuals were referred to both a psychologist and psychiatrist. There was no statistically significant relationship between the number of co-occurring mental health conditions and referral for mental health assessment (Wilcoxon rank-sum test $P = .12$) before initiation of GAHT.

Predictors of Mental Health Referral

Table 1 outlines the characteristics of individuals who were in the GP-assessed group compared with the MH-referred group. There were 2 conditions that were significantly more prevalent in those who underwent formal mental health practitioner assessment before accessing GAHT: post-traumatic stress disorder (PTSD) and schizophrenia (see Table 1).

Time to Commence GAHT

Time taken to commence GAHT (median 3.1 months [1.3−4.0] for the MH-referred group vs 0.9 months [0.5−1.8] for the GP-assessed group, $P < .001$) and the number of appointments attended before the commencement of GAHT (median 3 [3.0−4.8] appointments for the MH-referred group vs 2 [2.0−3.0] appointments for the GP-assessed group, $P < .001$) was significantly greater in those referred to a mental health practitioner than in those of the GP-assessed group.

Long-Term Care

There was no significant difference in the proportion of patients returning for review appointments; 98% of those in the GP-assessed group (no information available for n = 6) and 100% in the MH-referred group returned for review at 3 months or had documented that they had transferred their care to an alternative primary care clinic ($P = .235$). There were 94% in the GP-assessed group (no information available for n = 10) and 100% in the MH-referred group who were still attending for review after 12 months at Equinox or had documented that they had transferred their care to an alternative primary care clinic ($P = .173$). One individual in the GP-assessed group had temporarily stopped GAHT after 10 months of treatment owing to mental health issues and was planning to restart.

Patient Satisfaction

The anonymous survey was completed by 43 patients. 33 had accessed GAHT after being assessed solely by a GP, and 10 had undergone a mental health practitioner assessment before accessing GAHT. More than 80% of participants in both groups were overall extremely satisfied or moderately satisfied with the process required to start GAHT including the information provision regarding the risks and benefits of GAHT and the ability to ask questions (Table 2). There was a higher proportion of individuals in the GP-assessed group who were extremely satisfied compared with the mental health referral group ($P < .01$). There were otherwise no other statistical differences between proportions who were extremely satisfied in information provision, ability to ask questions, and feeling actively involved in the decision-making process to start hormones (Table 3). Notably, 80% of people accessing GAHT who had been solely assessed by a GP reported that they had chosen to access additional mental health support during their transition (Table 3). Participants were additionally able to provide open comments about their care at Equinox at completion of the survey, and all comments are listed in Appendix 2.

DISCUSSION

Our study in a primary care clinic specializing in TGD health showed that among 309 individuals who were seeking GAHT for the first time, 92% were assessed solely by their GP. A total of 8% were referred for secondary mental health assessment, the majority of which were performed by clinical psychologists specializing in TGD health. The 2 mental health conditions that predicted referral for secondary mental health assessment were schizophrenia and PTSD. Not unexpectedly, there was a longer time between initial consultation and initiation of GAHT in people referred for a mental health assessment compared with those assessed solely by their GP. There was no difference between groups in those attending follow-up review consultations at 3 months or 12 months after initial consultation. Overall, patients were highly satisfied with their care at XEquinox, with those undergoing assessment solely by their GP significantly more likely to report that they were "extremely satisfied" with the process compared with those who underwent formal mental health assessment before initiation of GAHT.

The informed consent model has many theorized benefits as a physical and emotional harm reduction strategy. Increased uptake of the informed consent model expands access to treatment, is suggested to promote patient autonomy, and strengthens therapeutic relationships.[3,15] As many TGD individuals are socioeconomically disadvantaged, the cost benefits of minimizing care providers and reducing the number of consultations required to commence GAHT are significant for the community.[16] Primary care GPs are well placed to be the first point of call and the primary provider of long-term gender-affirming care, typically in conjunction with peer support, mental health support, and other providers of gender-affirming care such as speech pathologists and surgeons. Professionals providing GAHT need not be specialists in mental health but should have mental health experience, which is in the scope of practice of primary care.[10]

Table 2. Patient satisfaction survey responses to treatment at Equinox Gender Diverse Health Centre

Group	Number	Extremely satisfied n (%)	Moderately satisfied n (%)	Neither satisfied nor dissatisfied n (%)	Moderately dissatisfied n (%)	Extremely dissatisfied n (%)
How satisfied were you with the process or steps required to start gender-affirming hormones (either at Equinox or elsewhere)? ($P < .01$)						
Informed consent group	33	28 (85%)	4 (12%)	0	1 (3%)	0
MH-referred group	10	4 (40%)	4 (40%)	0	1 (10%)	1 (10%)
How satisfied were you with the information provided regarding risks/benefits of hormone therapy by your treating doctor? ($P = .61$)						
Informed consent group	33	29 (88%)	4 (12%)	0	0	0
MH-referred group	10	8 (80%)	2 (20%)	0	0	0
How satisfied have you been with the opportunity to ask questions during your consultations with your doctors at Equinox? ($P = .56$)						
Informed consent group	33	29 (88%)	3 (9%)	0	1 (3%)	0
MH-referred group	10	10 (100%)	0	0	0	0

MH-referred = referred for secondary consultation to a mental health practitioner.

Embedding and normalizing transgender health care into routine practice will reduce barriers to accessing care. Certainly, it is evident that GAHT can be initiated in primary care, which is associated with high levels of patient satisfaction.

Mental Health Assessment

The vast majority (92%) of individuals presenting to Equinox for GAHT had the capacity to provide informed consent for GAHT with their primary care physician. The duration of time from initial visit to commencement of GAHT was significantly less in the GP-assessed group compared with those referred for mental health assessment. On average, the wait was 70% shorter for the GP-assessed group, with an average of 0.9 months between first appointment and GAHT commencement (median 2 appointments). More traditional pathways of care requiring psychiatric approval before GAHT prescription have previously been associated with long wait times.[17] Given the high rate of mental illness and suicidal ideation when individuals are on waiting lists to access gender-affirming care, facilitating timely access to GAHT using the informed consent model may be a practical approach to potentially reduce psychological distress[4,15,18,19] and additionally meet the increasing demand for TGD healthcare services being seen worldwide.[11,20–22]

Notably, use of the informed consent model did not preclude patients from accessing concurrent mental health support, and 80% chose to access counseling or psychological services independently of formal referral. Mental health practitioners continue to be valuable part of the multidisciplinary team and play a key role in supporting the TGD community. Among our survey population, there was no significant difference in the proportion of people accessing mental health support in the GP-assessed group and mental health referral group ($P = 1.00$), indicating that removal of the formal requirement for mental health review does not discourage pursuit of appropriate mental health support when the patient feels it is needed. Requirement for mental health support during such a time of significant physical and social change is not a reason to delay commencement of GAHT when the patient has the capacity to provide informed consent.[10] Indeed, the majority (56.3%) of participants in our GP-assessed group had co-occurring mental health conditions, and this did not impact their capacity to access GAHT under this model of care.

Predictors of Mental Health Referral

While there may be individual reasons for referral to mental health practitioners before commencing GAHT, analysis of our results found that 2 conditions were significantly more prevalent in the MH-referred group than in the GP-assessed group: PTSD and schizophrenia. More common conditions such as depression and anxiety did not predict mental health referral but were widely prevalent in both the GP-assessed and MH referred groups. PTSD may be associated with symptoms such as memory difficulties, distorted cognitions, intrusive thoughts, avoidance, and arousal symptoms, which in some individuals can be severe and disabling.[23] Symptoms of schizophrenia such as psychosis and consequences of schizophrenia such as executive dysfunction may also potentially hinder informed decision-making.[24] Both of these conditions can be complex and potentially impair a person's ability to process information and balance risks or benefits in order to make an informed decision. In addition, the need for often multimodal long-term mental health treatment for PTSD or schizophrenia may well trigger referral to a specialist mental health professional to optimize a person's psychological and social functioning. It is important to note that the number of individuals in the MH-referred group comprised only 23 people, and while the findings are hypothesis-generating, they require further confirmation in other cohorts. Individualized assessment of capacity for informed decision-making and stability of co-occurring mental health conditions is required for all individuals.

Provision of Long-Term Care

Our results demonstrate high numbers of participants were still returning to the clinic 3 and 12 months after commencement of GAHT, remaining well-connected with their primary healthcare providers. There was no significant difference between

Table 3. Patient satisfaction survey responses to being actively involved in decision-making and accessing mental health support

Group	Number	Yes n (%)	No n (%)	Unsure n (%)
Did you feel that you were actively involved in the decision-making process to start hormones? ($P = .21$)				
Informed consent group	33	33 (100%)	0 (0%)	0 (0%)
MH-referred group	10	8 (80%)	1 (10%)	1 (10%)
Have you accessed mental health support during your transition (including counselors, psychologists, phone services or online chat with professionals ie, Switchboard)? ($P = 1.00$)				
Informed consent group	33	26 (79%)	6 (18%)	1 (3%)
MH-referred group	10	9 (90%)	1 (10%)	0 (0%)

MH-referred = referred for secondary consultation to a mental health practitioner.

the return attendance rates for the GP-assessed or the MH-referred groups. Advocates for the informed consent model have suggested that the process can increase the quality of long-term care through promotion of a strong therapeutic relationship and potentially enabling more honest narratives as TGD people are not incentivized to provide a stereotyped narrative to fit diagnostic criteria to access GAHT.[4]

Satisfaction

We provide the first survey of patients undergoing an informed consent model of care to access GAHT, and findings are consistent with anecdotal evidence that the informed consent model is appreciated by many in the TGD community.[2,8] There were extremely high levels of satisfaction with the overall process for commencement of GAHT. Our data support the informed consent model being able to promote high levels of satisfaction, excellent engagement of patients in discussions with their health provider which may lead to strong therapeutic relationships.[3,4,8,15]

Limitations

Our study is limited by several factors, the most significant of which is the retrospective nature of the study. Individuals were not randomized to the GP-assessed group or the MH-referred group and we were unable to compare any measures of gender dysphoria or mental health outcomes before and after GAHT initiation. Long-term data on continuity of care and their health outcomes were not collected beyond a maximum of 2 years. This study was performed at a single practice where primary care physicians are experienced in TGD health and provide care only for TGD individuals, which may limit the generalizability of results to other general primary care settings. Notably, while only PTSD and schizophrenia predicted referral for secondary mental health assessment, we note significant overlap between complex PTSD and borderline personality disorder,[25] and given the nature of the study, formal assessment to confirm mental health diagnoses were not available. The patient satisfaction survey, while prospective, was small, voluntary and there may have been responder bias, leading to overestimation of the level of patient satisfaction overall.

Response rates were low with only 43 completed surveys (of 309 individuals newly commencing GAHT). However, this is one of the first studies that has described the characteristics of TGD individuals undergoing the informed consent model and evaluated patient satisfaction.

CONCLUSION

More than 90% of individuals presenting to our primary care clinic had the capacity to provide informed consent for GAHT with their treating GP. Overall high levels of patient satisfaction were seen, including in people referred for secondary mental health consultation. Mental health practitioners continue to play a key supportive role in the multidisciplinary care of TGD people undergoing GAHT, particularly in individuals with complex mental health conditions such as PTSD and schizophrenia. Given increasing numbers of TGD individuals seeking gender-affirming care worldwide and pressures on gender clinics, using an informed consent model of care in primary care clinics may be a practical solution to reduce waiting lists and is associated with extremely high levels of patient satisfaction. Further studies evaluating longer-term outcomes in more diverse primary care settings are required.

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REFERENCES

1. 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 Transgenderism 2012;13:165-232.**
2. Ashley F. Gatekeeping hormone replacement therapy for transgender patients is dehumanising. **J Med Ethics 2019; 45:480.**
3. Cavanaugh T, Hopwood R, Lambert C. Informed consent in the medical care of transgender and gender-nonconforming patients. **AMA J Ethics 2016;18:1147-1155.**
4. 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 Transgenderism 2012;13:140-146.**
5. Nelson JL. Understanding transgender and medically assisted gender transition: feminism as a critical resource. **AMA J Ethics 2016;18:1132-1138.**
6. Suess Schwend A. Trans health care from a depathologization and human rights perspective. **Public Health Rev 2020;41.**
7. Zwickl S, Wong A, Bretherton I, et al. Health needs of trans and gender diverse adults in Australia: a qualitative analysis of a national community survey. **Int J Environ Res Public Health 2019;16.**
8. Schulz SL. The informed consent model of transgender care: an alternative to the diagnosis of gender dysphoria. **J Humanist Psychol 2018;58:72-92.**
9. Cundill P, Wiggins J. Protocols for the initiation of hormone therapy for trans and gender diverse patients. Melbourne, Australia: Thorne Harbour Health; 2017. Available at: https://cdn.thorneharbour.org/media/documents/Equinox—Informed—Consent—Guidelines.pdf, Accessed November 23, 2020.
10. 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;17:570-584.**
11. Cheung AS, Wynne K, Erasmus J, et al. Position statement on the hormonal management of adult transgender and gender diverse individuals. **Med J Aust 2019;211:127-133.**
12. Erasmus J. Monash Gender Clinic: an overview of the current model of care. **Australas Psychiatry 2020;28:533-535.**
13. Protocols for the provision of hormone therapy: Callen Lorde Community Health Center. Available at: https://callen-lorde.org/graphics/2018/04/Callen-Lorde-TGNC-Hormone-Therapy-Protocols.pdf.
14. Australian statistical geographical classification - remoteness area: Australian Government Department of Health. Available at: https://www.health.gov.au/resources/apps-and-tools/health-workforce-locator. Accessed November 23, 2020.
15. Dietz E, Halem J. How should physicians refer when referral options are limited for transgender patients? **AMA J Ethics 2016;18:1070-1078.**
16. Cheung AS, Ooi O, Leemaqz S, et al. Sociodemographic and clinical characteristics of transgender adults in Australia. **Transgend Health 2018;3:229-238.**
17. Erasmus J, Bagga H, Harte F. Assessing patient satisfaction with a multidisciplinary gender dysphoria clinic in Melbourne. **Australas Psychiatry 2015;23:158-162.**
18. Bailey L, Ellis S, McNeil J. Suicide risk in the UK Trans population and the role of gender transition in decreasing suicidal ideation and suicide attempt. **Ment Health Rev J 2014; 19:209-220.**
19. Herman JL, Brown TNT, Haas AP. Suicide thoughts and attempts among transgender adults, findings from the 2015 U. S. transgender survey. Los Angeles, CA: UCLA School of Law Williams Institute; 2019. Available at: https://williamsinstitute.law.ucla.edu/publications/suicidality-transgender-adults/. Accessed November 23, 2020.
20. De Vries ALC, Cohen-Kettenis PT. Clinical management of gender dysphoria in children and adolescents: the Dutch approach. **J Homosex 2012;59:301-320.**
21. Delahunt JW, Denison HJ, Sim DA, et al. Increasing rates of people identifying as transgender presenting to endocrine services in the Wellington region. **N Z Med J 2018;131:33-42.**
22. Nolan IT, Kuhner CJ, Dy GW. Demographic and temporal trends in transgender identities and gender confirming surgery. **Transl Androl Urol 2019;8:184-190.**
23. Watts BV, Zayed MH, Llewellyn-Thomas H, et al. Understanding and meeting information needs for patients with posttraumatic stress disorder. **BMC Psychiatry 2016;16:21.**
24. Kim YT, Lee KU, Lee SJ. Deficit in decision-making in chronic, stable schizophrenia: from a reward and punishment perspective. **Psychiatry Investig 2009;6:26-33.**
25. Ford JD, Courtois CA. Complex PTSD, affect dysregulation, and borderline personality disorder. **Borderline Personal Disord Emot Dysregul 2014;1:9.**

SUPPLEMENTARY DATA

Supplementary data related to this article can be found at https://doi.org/10.1016/j.jsxm.2020.10.020.