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Monitoring and reporting of adverse effects of testosterone prescribing for gender affirmation at general practice clinics - Data from the PUSH! Audit

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ABSTRACT

Introduction: Prescribing testosterone for gender affirming hormone therapy (GAHT) has been increasing in Australia with much of this practice done by general practitioners (GPs) and there are current AusPATH guidelines on how this can be done appropriately. There has been limited data collected from GPs about how well these patients are monitored and the adverse effects (AEs) that are experienced by this population of patients.

Objectives: The primary objective of this study was to collect data about monitoring and adverse effects of GAHT provided in GP settings.

Methods: The PUSH! Audit was a cross-sectional study that collected data from 9 GP Clinics across 5 Australian cities who provided GAHT with testosterone. Data was also collected about cisgender men who were prescribed testosterone for testosterone deficiency (TD) as a comparison group ($n = 209$).

Results: The patients in the GAHT group ($n = 277$) tended to be younger (29.8 vs 54.9), with significant prevalence of smoking (21.8%) and anxiety/depression (37.2%) although this was not significantly higher that the comparison group. Most of the GAHT group had a testosterone level recorded in their file (90.6%) and the most common route of administration of testosterone was by intra-muscular injection (89.9%). The testosterone levels were mainly in the target range for males (75.7%) with only a small percentage registering levels above the target range (5.6%). Of the measured AEs, whilst there were significant prevalence of liver abnormalities and hypercholesterolemia, this was not significantly different to the TD group. The hypertension prevalence was lower in the GAHT group. Of the reported AEs, acne (10.1%) and balding (4.7%) were the only two AEs that were significantly reported.

Conclusion: This study shows that GAHT with testosterone can be provided effectively in general practice with high levels of success and very low levels of AEs.

KEYWORDS
Adverse effects; GAHT; testosterone; transgender

Introduction

Prescribing testosterone for gender affirmation has been increasing in Australia (Cheung et al., 2018; Telfer et al., 2015). Much of this prescribing is done by general practitioners (GPs), sometimes in conjunction with endocrinologists, mental health professionals and sexual health physicians (Bretherton et al., 2019). It is expected that the number of GPs prescribing testosterone for gender affirmation will continue to grow alongside awareness and acceptance of the Informed Consent Model of care (as detailed in the Australian Professional Association for Trans Health guidelines) (AusPATH, 2022). Increases in the number of GP prescribers are likely to correspond with greater prescriber autonomy in the provision of gender affirmation care, enabling GPs to refer for specialist input only when needed, and improving access to gender affirming

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hormone therapy (GAHT) for people who are transgender (Spanos et al., 2021).

Understanding the experiences of trans men and non-binary people who are accessing testosterone as GAHT through GPs is important for the development of best practice and supportive policies. However, data describing the experiences of transgender patients who were prescribed testosterone by community-based GPs in Australia is limited, with previous research primarily situated in specialist primary care and gender affirming treatment settings (Cheung et al., 2018; Zucker, 2017). With GPs more likely to provide testosterone therapy for gender affirmation in the future, it is important to document practices and raise awareness of potential clinical effects experienced by trans patients who are prescribed testosterone as GAHT. If improperly managed, testosterone therapy is associated with increases in the risk of developing cardiovascular disease, hypertension, hyperlipidemia, liver function abnormalities and polycythemia (Irwig, 2018). However, there remains uncertainty about the health risks of testosterone as GAHT, with some studies showing no evidence of increased adverse health outcomes, in particular regarding cardiovascular risks (Asscheman et al., 2011; Hembree et al., 2017; Karalexi et al., 2022; Maraka et al., 2017; Simonsen et al., 2016) and even in Irwig's 2018 article, there was no definite clear conclusion about cardiovascular risks.

The aim of this paper is to describe the demographic and clinical characteristics, measured and self-reported adverse effects, among patients prescribed testosterone for gender affirmation in a sample of nine general practice clinics across Australia. As a secondary aim, we also compare these outcomes with those from cisgender men prescribed testosterone as hormone replacement therapy for testosterone deficiency (TD) to explore potential adverse effects specific to prescribing testosterone for GAHT.

Methods

Study design

The PUSH! Audit was a cross-sectional study conducted between May 2019 and May 2021 that aimed to describe the clinical profiles of patients using prescribed and non-prescribed testosterone or other performance and image enhancing drugs (Eu et al., 2023). For this analysis, data pertaining to patients receiving prescribed testosterone only are reported.

Setting

Data were obtained from patient management systems at nine participating community-based, GP primary care clinics in five cities in Australia who are known to provide health care for transgender patients, in a safe environment for trans people. The clinics agreed to participate after being identified through the professional networks of the study team as clinics likely to have meaningful caseloads of patients receiving testosterone therapy. Any patient who attended a participating clinic between May 2017 and May 2021 and who was prescribed testosterone for either gender affirmation or testosterone deficiency was eligible to be included in the study. Patients were identified through the patient prescription information in their files and by the GPs involved with the audit.

Data collection

All data collected was de-identified. Patient demographic and clinical characteristics were collected from patient case records, and included age (<30, 30–39, 40+ years), BMI (<25, 25–30, >30), smoking status (current smoker, ex-smoker, never-smoker) and HIV status (HIV positive, HIV negative). This information is generally updated at least once a year in medical files, or if there is a noted change. If multiple medical records were available in the patient management system for a patient, the most recently entered information was extracted. Diagnoses of anxiety and depression were extracted if there was a current diagnosis of either condition in the clinical records, as previous studies have shown high prevalence of these conditions among transgender populations (Heylens et al., 2014; Witcomb et al., 2018). Information about gender was collected, but was not reported as there were challenges collecting this information in a reliable manner, as clinical records have a variety of ways of

recording sex assigned at birth and current gender identity, which is not uniform between practices.

The most recent health monitoring tests recommended for people prescribed testosterone were collected from patient case records: blood pressure, hemoglobin (Hb), hematocrit, liver function tests (LFTs) and serum cholesterol. These indicators are measured regularly, and at least annually, as recommended by the AusPATH guidelines (AusPATH, 2022). Test results were categorized into binary variables indicating whether patients had experienced adverse health outcomes related to testosterone use and included polycythemia (red blood cell count > 18 g/dL), hypertension (blood pressure reading > 140/90 mmHg), liver abnormalities (either AST > 40 U/L, ALT > 40 U/L or GGT > 50 U/L), and hypercholesterolemia (total cholesterol level > 5.5 mmol/L). The proportion of patients who received hormonal tests (testosterone, follicle stimulating hormone, luteinizing hormone), and their hormonal test results were collected and compared between the TD and GAHT groups. We also report the proportion of patients in the GAHT group whose testosterone level was within the normal range for adults assigned male at birth (10–35 nmol/L). Self-reported adverse effects related to testosterone use (acne, balding, depression, aggression, mania/hypomania) were also collected if recorded in the patient case records.

Study size

As this was an observational patient audit, there was no minimum sample size required. Nominally a target of 200 was set as a reasonable target number to describe patient outcomes. The study recruited 277 audits for gender-affirming hormone therapy (GAHT) and 209 for testosterone deficiency (TD) in cisgender men.

Analysis

Patient characteristics and outcomes were described using descriptive statistics for patients prescribed testosterone for gender affirmation (GAHT) and cisgender men prescribed testosterone for testosterone deficiency (TD). We used a Chi-squared test of independence for categorical variables to assess differences between groups. We reported and compared information about health monitoring tests, and the administration route for testosterone use between the groups. After visual inspection of histograms and conducting the Shapiro–Wilk test for normality, we found evidence that hormonal test levels (testosterone, follicle stimulating hormone and luteinizing hormone) were not normally distributed. We therefore used the Wilcoxon rank sum test to test for differences in median hormonal test results between the TD and GAHT groups. Four adjusted logistic regressions were used to determine the odds of specific adverse clinical outcomes - liver abnormalities, hypercholesterolemia, polycythemia, and hypertension - between transgender people prescribed testosterone for GAHT and cisgender men prescribed testosterone for testosterone deficiency. Covariates included in adjusted analyses to control for potential confounding were age, BMI, HIV status and smoking. We then also reported and compared the prevalence of self-reported AEs. A two-tailed p value of 0.05 was set as the significance threshold. Analyses were performed using Stata version 17.0 for Windows (StataCorp, 2023).

Results

A total of 486 patients were prescribed testosterone across the nine participating GP clinics between May 2017 and May 2021, of which 277 patients were prescribed testosterone for GAHT and 209 were prescribed testosterone for TD (Table 1). There were significant differences in the age profile between groups, with over half of patients included in the GAHT group aged between 18–29 years, and over two-thirds of patients included in the TD group aged more than 50 years. There were significant differences in BMI between groups, with approximately half of patients in the GAHT group having a BMI less than 25 compared to one in five patients from the TD group, which was reflected in the mean values (26.4 and 28.6, respectively). No patients from the GAHT group were living with

Table 1. Demographic and clinical characteristics of transmen prescribed testosterone for gender affirming hormone treatment (GAHT) and cisgender men prescribed testosterone for testosterone deficiency (TD), $N = 486$.

Characteristics[a]	GAHT, n (%)	TD, n (%)	p value
Overall	277	209	–
Age group, ($n = 485$)			**<0.001**[b]
<30	178 (64.3)	7 (3.4)	
30–39	60 (21.7)	18 (8.7)	
40–49	20 (7.2)	36 (17.3)	
50+ years	19 (6.9)	147 (70.1)	
Age (years), mean (SD)	29.8 (9.9)	54.9 (12.1)	**<0.001**[c]
BMI group, ($n = 436$)			**<0.001**[b]
<25	118 (48.6)	42 (21.8)	
25–30	66 (27.2)	86 (44.6)	
>30	59 (24.3)	65 (33.7)	
HIV status ($n = 480$)			**<0.001**[b]
HIV positive	0 (0.0)	99 (47.6)	
HIV negative	116 (42.7)	95 (45.7)	
No recorded test	156 (56.3)	14 (6.7)	
Smoking status, ($n = 466$)			**<0.001**[b]
Current smoker	57 (21.8)	44 (21.8)	
Former smoker	32 (12.2)	66 (32.7)	
Never smoker	173 (66.0)	92 (45.5)	
Anxiety and/or depression, ($n = 485$)			0.117[b]
Yes	103 (37.2)	92 (44.2)	
No	174 (62.8)	116 (55.8)	

[a]The difference in the number of observations for each characteristic and the total number indicated in the heading comprises missing or unknown observations.
[b]Chi-squared test of independence was used; [c]Independent sample t-test was used.

Table 2. Hormonal tests and administration method of trans men prescribed testosterone for gender affirming hormone treatment (GAHT) and cisgender men prescribed testosterone for testosterone deficiency (TD), $N = 486$.

Hormonal test and administration method	GAHT, number tested (%)	TD, number tested (%)	p value
Any hormone test	251 (90.6)	181 (86.6)	0.164[a]
Testosterone test	251 (90.6)	180 (86.1)	0.122[a]
Follicle stimulating hormone test	42 (15.2)	30 (14.4)	0.804[a]
Luteinizing hormone test	59 (21.3)	39 (18.7)	0.473[a]

[a]Chi-squared test of independence was used.

Table 3. Hormonal test results of trans men prescribed testosterone for gender affirming hormone treatment (GAHT) and cisgender men prescribed testosterone for testosterone deficiency (TD), $N = 432$.

Test	GAHT, median (IQR)	TD, median (IQR)	p value
Serum testosterone levels (nmol/L)	16.0 (11.3–20.4)	14.8 (9.6–19.6)	0.132[a]
Serum follicle stimulating hormone levels (IU/L)	5.0 (2.1–8.0)	4.9 (2.0–12.0)	0.737[a]
Serum luteinizing hormone levels (IU/L)	4.0 (1.1–6.0)	2.1 (1.0–5.3)	0.206[a]

[a]Wilcoxon rank sum test was used.

HIV, compared to almost half of patients from the TD group. The proportion of patients who reported current smoking was similar between groups, however the proportion of patients who were former smokers was significantly higher in the TD group compared to the GAHT group. A high proportion of patients from both the GAHT group and the TD group had a recorded diagnosis of either anxiety or depression (37% and 44%, respectively) (Table 1).

Almost all patients prescribed testosterone for GAHT had a recorded testosterone test through their prescribing GP (Table 2). Approximately one in four patients had a recorded follicle stimulating hormone test and one in five had a recorded luteinizing hormone test. The proportion of patients prescribed GAHT and TD who received a hormone test was similar between the GAHT and TD groups (90.6% and 86.6%, respectively). The most common mode of testosterone administration was intra-muscular injections for both the GAHT and TD groups (89.9% and 80.4%, respectively), with topical administration of testosterone less common in both groups (12.6% and 30.6%, respectively).

The majority of patients (198/251; 78.8%) prescribed testosterone for GAHT who received a testosterone test were within the normal range (10–35 nmol/L). Approximately one in five (47/251; 18.73%) were below the normal range and very few were above the normal range (6/251; 2.39%). There were no significant differences in the median serum testosterone, follicle stimulating hormone, and luteinizing hormone levels between the GAHT and TD groups (Table 3).

Hypercholesterolemia, hypertension and liver abnormalities were common in the cohort, with elevated prevalence of all clinical outcomes observed among patients prescribed testosterone for testosterone deficiency. In adjusted analyses, a statistically significant reduction in the odds of hypertension (OR: 0.23; 95% CI: 0.08–0.66) among the GAHT group compared to the TD group was found. (Table 4)

The majority of patients in the GAHT group self-reported no adverse effects related to their use of testosterone (236/277; 85.2%). The most commonly reported adverse effects were acne (28/277; 10.1%) and balding (13/277; 4.7%). Very

Table 4. Differences in adverse clinical health outcomes between TD (testosterone deficiency treatment in cisgender men) and GAHT (gender affirmation hormone treatment), $N = 481$.

Outcome	Tested	Adverse outcomes, n (%)	aOR (95% CI)	p-value
1. Polycythemia				
TD	154	14 (9.1)	ref.	–
GAHT	250	4 (1.6)	0.21 (0.04–1.22)	0.083
2. Hypertension				
TD	203	50 (24.6)	ref.	–
GAHT	250	17 (6.8)	**0.23 (0.08–0.66)**	**0.006**
3. Liver abnormalities				
TD	209	56 (26.7)	ref.	–
GAHT	277	51 (18.4)	0.92 (0.41–2.07)	0.837
4. Hypercholesterolemia				
TD	174	47 (27.0)	ref.	–
GAHT	185	48 (26.0)	1.08 (0.44–2.67)	0.860

OR: odds ratio; aOR: adjusted odds ratio; ref.: reference category.
Note: Adjusted models included age, BMI, HIV status and smoking status.

few patients in the GAHT group self-reported experiences of depression (6/277; 2.2%), aggression (0/277; 0.0%), and mania/hypomania (1/277; 0.4%).

Discussion

In this study we describe the demographic and clinical characteristics and measured adverse effects of transgender patients who are prescribed testosterone as GAHT at nine general practice clinics. Our findings indicate that the majority of patients prescribed testosterone as GAHT in Australian general practice settings are receiving health monitoring tests in accordance with Australian prescribing guidelines, and have testosterone levels within the recommended range (AusPATH, 2022). There were data indicating some adverse clinical health outcomes in the GAHT group, with one in five patients exhibiting indicators of liver abnormalities (18.4%) and one in four patients exhibiting indicators of hypercholesterolemia (26.0%). However, all clinical outcomes assessed were less common among patients prescribed testosterone form GAHT compared to TD, and after adjustment, risk of hypertension was significantly lower among GAHT patients.

The demographic and clinical characteristics of transgender patients prescribed testosterone as GAHT in this study was similar to previously published data (Cheung et al., 2018). The majority patients in the GAHT group were aged 30 years or less (75.8%), and almost half were within a healthy weight range (48.6%). One in five patients reported current smoking (21.8%), nearly twice that of the Australian general population average (Australian Institute of Health & Welfare, 2014). The primary route of administration for GAHT was intra-muscular (89.9%), with a minority of patients opting for topical administration (12.6%), similar to previous Australian data (Cheung et al., 2018).

Consistent with previous research, a high proportion of transgender patients in our study had previously received a diagnosis for depression and/or anxiety before commencing GAHT (37.2%) (Bouman et al., 2017; Cheung et al., 2018). This finding reinforces the mental health challenges that transgender patients often experience, and the importance of clinicians routinely monitoring the mental health and wellbeing of their patients and supporting them to access mental health support when it is required. In a longitudinal study exploring the long-term impact of GAHT on symptoms of anxiety and depression, Aldridge et al. found several mental health benefits of GAHT, with reductions in depressive symptoms following treatment commencement (Aldridge et al., 2021). Importantly, higher levels of pretreatment social supports were also predictive of reductions in symptoms of depression. This finding underscores the important of GPs familiarizing themselves with local trans community appropriate health services and supporting patients to access trans peer support and connect with community groups.

Most patients prescribed testosterone as GAHT in our study had testosterone levels within the reference range of 10–30 nmol/L (75.7%), similar to the results in patients in the TD group. As this study did not collect information about the dose or the length of time that patients had been prescribed GAHT, we were unable to determine the reasons why a minority of GAHT testosterone levels were lower than the expected range. However, there could be a number of factors that explain low testosterone levels, including patient choice, adverse effects, inadequate replacement or the duration between intra-muscular administrations. Current Australian GAHT prescribing guidelines state that recommended ranges should

be only used as a guide when deciding on an appropriate dose, and reinforce the importance of prescribing based on how patients respond to GAHT (AusPATH, 2022). Consequently, care should be taken to avoid assuming testosterone levels lower than the normal range require further intervention until the preferences of patients have been established. Further, a substantial period of data collection occurred during COVID-19 lockdowns in Australia, which could have caused access problems for many patients and delayed their treatment. The testosterone levels which were higher than expected however remain a concern as this may increase the known adverse effects of being on testosterone. These numbers were similar between the 2 groups.

The sexuality of those prescribed testosterone for GAHT was not recorded for almost half of the patients included in our study. This finding indicates that the sexuality of this demographic is not routinely asked and recorded by GPs, reflecting the complexities of ascertaining sexual preferences when prescribing GAHT. Current Australian GAHT prescribing guidelines recommend a "Parts and Practices approach", whereby clinicians focus on the body parts that patients have, and what they are doing with them, whilst avoiding assumptions about the gender and sexuality of patients (AusPATH, 2022). Such an approach allows clinicians to ascertain sexual health risk factors and establish the need for sexual health screening and other relevant testing in a respectful and sensitive manner. However, this approach also makes it challenging for clinicians to systematically record the sexuality of patients using traditional categories of sexuality and may partially explain the high proportion of missing data in our study.

A low proportion of the GAHT group self-reported adverse effects (14.8%), with the most common being acne (10.1%) and balding (4.7%). There is currently limited information about treatment of acne and balding in people prescribed testosterone for GAHT. However, the proportion of patients who reported acne and balding in our study indicates that clinicians should discuss them as potential adverse effects of hormone therapy and discuss treatment options with patients if they occur. Nonetheless, the adverse effects of GAHT should be thoroughly discussed with patients at the commencement of treatment and during ongoing monitoring and support.

There is currently a shortage of appropriate health services that provide GAHT in Australia. There is education that can be accessed by general practices that will help increase knowledge and access for services and the findings of this study will hopefully encourage more general practices to undergo the training with knowledge that it can be done safely and effectively in general practice.

Limitations

This study had several limitations. First, due to its cross-sectional design, we were unable to assess changes in hormonal levels and adverse effects of testosterone use over time. Clinical outcomes reported may therefore not be specifically adverse to testosterone prescription. Second, although we adjusted for age, BMI, HIV status and smoking status, there were significant differences in the demographic and clinical characteristics between the GAHT and TD groups, and therefore the potential for confounding. Third, we were not able to measure the dose or the length of time that patients had been prescribed testosterone and were therefore unable to assess the impact on health outcomes according to exposure to testosterone. Fourth, whilst the reported adverse health outcomes were calculated using laboratory-based test results, the self-reported adverse and non-adverse effects depended on patients disclosing this information, and on the reported effects being recorded in their patient record. This is likely to result in under-reporting of the effects, however this bias is likely to be non-differential between the GAHT and TD groups. Fifth, the clinics selected were general practices that were known for providing GAHT and being safe spaces for transgender individuals. So, they may not accurately represent a wider selection of general practices. Sixth, as we only included the most recently recorded laboratory test results for each individual in our analysis, we were unable to determine the number of tests each individual had received, or any changes in test results over time. Last, data on

the gender identity of individuals included in our analysis was obtained from patient records, and there were variations in the way gender identity is recorded between practices. As such, there may be individuals in our study whose gender identity may be different from what is available in their patient records.

Conclusion

Contemporary Australian GAHT prescribing guidelines provide comprehensive and evidence-based guidance for clinicians, enabling an increasing number of GPs to prescribe GAHT. However, many clinicians are uncomfortable prescribing GAHT due to a lack of knowledge of adverse and non-adverse effects, and unfamiliarity with prescribing guidelines (Shires et al., 2022; Safer, 2016). This study identified hypercholesterolemia and liver abnormalities as the most common adverse clinical health outcomes experienced by those prescribed testosterone as GAHT, underscoring the need to monitor cardiovascular risk factors due to the potential increased risk from testosterone therapy (Karalexi et al., 2022). However, there was no increase in the odds of adverse clinical health outcomes among patients prescribed testosterone as GAHT compared to the testosterone deficiency group. The high proportion of patients who received health monitoring tests and low proportion who reported adverse effects demonstrates that gender affirming hormone therapy can be effectively prescribed and monitored in general practice clinics.

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