SEGM
SOCIETY FOR EVIDENCE BASED GENDER MEDICINE

SEGM Response to "AusPATH Public Statement on Gender Affirming Health Care, including for trans youth"

Executive Summary

This paper reviews the accuracy of AusPATH's assertions about what researchers have found and the quality of research which AusPATH have relied upon to make their claims. AusPATH presents gender affirmation for youth as if it were an 'open-and-shut case' and the numerous studies cited appear to give the public statement weight and authority. However, close and independent inspection of the references reveals that AusPATH relies on poor quality research, fails to highlight the methodological limitations of most studies and at times misrepresents or exaggerates the research findings and conclusions. AusPATH also mischaracterises psychotherapy for gender dysphoria as potentially harmful.

The recent public statement by AusPATH asserts, with some certainty, that gender-affirming interventions for young people are safe and evidence-based. The statement promulgates the notion that the debate is settled, and there is no longer any doubt about whether or not gender-affirming interventions for youth 'work' as intended. AusPATH also fails to mention the risks associated with gender-affirming medical interventions, many of which are significant and lifelong. Contrary to AusPATH's position, recent systematic and independent reviews have found that the research supporting youth transition is severely limited, rendering any conclusions uncertain. As a result, a number of countries have curtailed youth transition, given the inadequacy of the evidence base and safety concerns.

SEGM supports the provision of safe, effective, evidence-based health care for youth with gender dysphoria. SEGM concurs with the findings of these reviews and as a result, recommends that established psychological treatment models for working with distressed youth should be the first-choice, safest treatment for youth with gender dysphoria. SEGM acknowledges the limited evidence base for psychotherapy for gender dysphoria and calls for well-designed clinical trials that evaluate all potential treatment options. Until such time as the evidence base is of sufficient quality, SEGM recommends avoiding the pharmacological and surgical risks of gender-affirming treatments, except within rigorous research contexts that are approved and monitored by the appropriate Human Research Ethics Committee.

1. The lack of evidence for mental health benefit

i. Social Transition

AusPATH claims social transition "**has been shown to provide benefits** [our emphasis] to many trans people, including trans youth", but the three references they cite (Durwood et al., 2017; Olsen et al., 2016; Russell et al., 2018) do not support this claim. The studies found good mental health in youth who had socially transitioned, but each was unable to prove causation; that is, there is no proof that social transition actually *resulted* in good mental health. AusPATH has made the common error of assuming that correlation equates to causation when it does not. Further, the correlation reported is compromised by selection bias, as subjects were mostly recruited from pro-transition networks and groups. AusPATH fails to mention two recent studies which contradict their assertion, as they found that early social transition is not followed by improved psychosocial outcomes (Sievert et al., 2020; Wong et al., 2019;).

Both the World Professional Association for Transgender Health (WPATH) Standards of Care Version 7 (Coleman et al., 2011) and the Endocrine Society Guidelines (Hembree et al., 2017) acknowledge that childhood gender dysphoria does not persist into adulthood in the vast majority of cases. These documents also highlight the lack of evidence that social transition benefits psychological wellbeing. The Endocrine Society Guidelines warn that social transition can increase the likelihood of persistence of gender dysphoria into adolescence, potentially exposing youth to the risks of medical and surgical interventions unneccesarily.

ii. Medical and surgical affirmation

a) Limitations of the Dutch studies

AusPATH goes on to claim that "medical and surgical affirmation can frequently alleviate gender-related distress and **yield a variety of benefits to the individual** [our emphasis]". It is important to note that there are no studies that have assessed long-term adult outcomes of individuals who underwent youth transition. AusPATH cites two studies by de Vries et al. (2011, 2014), the originators of the so-called Dutch protocol, which was the forerunner of gender-affirming medical care for youth with gender dysphoria. These studies are generally considered the foundation of youth gender-affirming care.

Crucially, these studies, along with all other studies of gender-affirming interventions, had no control group. It is ordinary good medical practice to make comparisons like this in order to be sure an intervention 'works' as intended and that clinicians are not biased by misinterpreting what they see (satisfied patients are likely to remain in treatment whilst those with complications may not return to the clinic). Thus, it is impossible to say whether any improvements occurred over time because of, or despite, the gender affirming interventions. Additionally, all subjects received psychotherapy alongside gender-affirming medical interventions. Thus, the study design makes it impossible to ascertain whether the observed improvements happened simply because of the passage of time, or as a result of gender-affirming medical interventions or psychotherapy.

De Vries et al. (2014) found that gender-affirming interventions were associated with mixed results on a range of instruments and outcome measures. Whilst they were able to show that gender dysphoria improved, scores reflecting psychological improvement were contradictory. There were modest improvements on the Youth Self Report (YSR) and Child Behaviour Checklist (CBCL) (Achenbach and Rescorla, 2001) however no significant improvements were found on instruments assessing depression, anxiety and anger. The mean score on the Childrens Global Assessment Scale (CGAS) (Schaffer et al., 1983) improved marginally from 71.13 to 79.93. These scores remained within the range classified as "No more than a slight impairment in functioning" (71-80) throughout the study period. It is not clear whether these mixed results translated into any clinically meaningful change. The high drop-out rate and the death of one patient from post-operative complications further undermine their conclusions. Further, a recent attempt to replicate the findings of the Dutch researchers reported that puberty blockers resulted in no psychological benefit (Carmichael et al., 2021).

This raises important questions about whether the results reported by de Vries et al. (2014) are convincing enough to warrant the use of treatments with irreversible effects and numerous medical risks. Their methodology makes it impossible to parse whether the modest changes on the CBCL, YSR and CGAS were a result of the psychological support that all subjects received, or due to the passage of time. The creators of the Youth Self Report and Child Behaviour Checklist warn that "improvement in scores from before to after services does not prove that the services were responsible for improvement. Other explanations are possible, such as (a) childrens' problems tend to decrease as they get older; (b) the people providing the data may report improvements because they believe that the services helped, and (c) the test-retest attenuation effect (a general tendency for people to report fewer problems at a second assessment." (Achenbach and Rescorla, 2001, p.183).

These uncertainties are underscored by three related studies which indicate that gender dysphoric adolescents receiving no medical treatment also experience improvements in their psychological function and gender dysphoria (Costa et al., 2015; Smith et al., 2001; van de Grift et al., 2017). One study reported on 14 adolescents who sought gender reassignment but who were disqualified from treatment due to "psychological or environmental factors". This study found that at follow up, 11 of 14 no longer wished to transition whilst 2 only slightly regretted not transitioning (Smith et al., 2001).

In addition, the sample studied by the Dutch bears very little resemblance to the current cohort of trans-identifying youth. De Vries et al. only studied youth with documented childhood-onset gender dysphoria who had no significant psychiatric comorbidity and who were all high functioning (GAF>70) prior to beginning treatment. In contrast, the most common presentation of gender dysphoria in youth today consists of adolescent-onset GD with one or more significant comorbid psychiatric disorders (especially depression, anxiety disorders, self-harming behaviours and Autism Spectrum Disorder) in up to 75% (Aitken et al., 2015; de Graaf et al., 2017; de Graaf and Carmichael, 2019; Kaltiala-Heino et al., 2015). The same researchers

have also found that there has been a reversal of the sex distribution, with natal females now replacing natal males as the most likely to present with gender dysphoria.

Two lead authors of the Dutch protocol, Annelou de Vries and Thomas Steensma, have themselves recently cautioned that their findings may not apply to this current cohort (de Vries, 2020; Tetelepta, 2021), implying that their protocol is potentially being misused in a patient group for which it was never designed. The implication is that the current widespread use of gender-affirming interventions constitutes an uncontrolled experiment on thousands of youth worldwide. This view is supported by a recent evidence review which concluded that gender-affirming treatments for youth are experimental and should only be administered in research settings (Heneghan and Jefferson, 2019).

Finally, de Vries et al. (2014) measured outcomes only 18 months, on average, after subjects completed treatment. It should be noted that this very short time frame is the longest follow-up period of any available research on youth transition. AusPATH ignores research findings that indicate that regret only appears at least 7-10 years post-transition, on average. This has been reported by the same Dutch group of researchers (Wiepjes et al., 2018) and by Dhejne et al. (2011)

b) Widespread research uncertainties and methodological problems

Many of the studies cited by AusPATH as support for their assertion *do not* provide evidence that medical interventions result in improved mental health. For example, Van der Miesen et al. (2020) acknowledge the uncertainty of their findings, with the authors warning that "The present study can, therefore, not provide evidence about the direct benefits of puberty suppression over time and long-term mental health outcomes. Conclusions about long-term benefits of puberty suppression should thus be made with extreme caution." Mahfouda et al. (2019) warn that the evidence for cross-sex hormones in adolescents is "scarce and preliminary" and that additional studies are needed. Costa et al. (2015) found no difference after 18 months between a group of youth who had received only psychological support and a group who received psychological support plus puberty blockers.

AusPATH also cites a paper by Olson-Kennedy et al. (2018) which reports good outcomes for adolescents who had undergone mastectomy as young as age 13. The paper is controversial as most countries do not perform gender-affirming surgeries on minors. The authors used an unvalidated "Chest Dysphoria Scale" which they had designed themselves and which did not assess quality of life, depression, anxiety or functioning. Hence, the study could not ascertain whether improvements on this scale reflected any meaningful improvements in psychological functioning or well-being. Again, the time between surgery and follow-up assessment was too short to identify regret, which usually emerges long after transition (Dhejne et al., 2011; Wiepjes et al., 2018)

2. The evidence of unwanted effects and harms

i. Medical risks and safety concerns

AusPATH makes no mention of well-documented risks, which might understandably lead readers to assume there are no safety concerns. There is evidence of significant physical harm from medical interventions for gender affirmation, including significant impacts on the heart, bones, brain, immune system, fertility, endocrine system and more (Alzahrani et al., 2019; Auer et al., 2018; Biggs, 2021; Goodman and Nash, 2019; Klink et al., 2015; Nota et al., 2018; Nota et al., 2019; Vlot et al., 2015; Vlot et al., 2017).

ii. The risk of regret and detransition

AusPATH asserts that regret and detransition rates are very low if guidelines such as the WPATH Standards of Care (Coleman et al., 2012) are followed. The three references cited to support this claim in fact utilised a treatment protocol that predates and deviates from the WPATH guidelines. De Vries et al. (2014) state that no subjects regretted gender-affirming treatment. However, of the sample of 70, 1 died of post-vaginoplasty complications, 4 refused or failed to return their questionnaire, 1 dropped out of care and 3 were medically ineligible for surgery due to health problems such as uncontrolled diabetes or obesity. These participants (13% of subjects) who had negative or unknown outcomes were excluded from the data analysis. It is possible that some or most of the "excluded" subjects may have regretted their treatment. It would be more accurate to say that the regret rate could be as high as 13%. The claim of a zero regret rate glosses over the uncertainties.

Wiepjes et al. (2018) also report an apparently low regret rate, but the conclusion is not as clear-cut as AusPATH believes. In this study, subjects were only categorised as experiencing regret if they had experienced all of three factors: a vaginoplasty or oophorectomy (ie. gonadectomy); subsequently taking exogenous natal sex hormone replacement; and with expressions of regret noted in the medical record. As many transgender people do not undergo genital or gonadal surgery, they could never be classified as regretters by Wiepjes et al. Most concerningly, 36% of the sample were lost to follow-up. Testimonials by detransitioners suggest that many do not return to the clinic that they feel provided them with inappropriate or harmful treatment (Vandenbussche, 2021). As a result, Wiepjes et al. are likely to have significantly underestimated the rate of regret and they acknowledge this in their paper.

AusPATH's claim that most people detransition because of external pressures is based on a flawed study by Turban et al. (2021) which used a biased questionnaire completed by individuals who currently identified as transgender. This means their sample was unlikely to be representative of most detransitioners, as people who have detransitioned generally no longer identify as transgender. Turban et al.'s (2021) findings are contradicted by Vandenbussche (2021), who found that most people (70%) detransition because they realise that their gender dysphoria was related to other issues. The other most common reasons for detransition were health concerns (62%) and finding that transition did not relieve dysphoria (50%). A detailed

report, albeit of one case, where transition resulted in serious psychological deterioration (D'Angelo, 2020) illustrates some of these complex issues.

iii. The risk of iatrogenesis

The third reference, Brik et al. (2020) does not examine regret at all. Instead, it reports that the vast majority of children who are prescribed puberty blockers go on to cross-sex hormones. Only 3.5% decided at the end of the study period that they would no longer pursue gender - affirming treatments. Rather than supporting AusPATH's claim of a long-term low regret rate, this study in fact raises the possibility that treatment with puberty blockade locks youth into a medical transgender trajectory. Gender affirming clinicians might argue that it simply shows that the clinicians made the correct assessment to commence puberty blockade. However, the finding in itself should raise alarm as it is vanishingly rare for any doctors to have 96.5% diagnostic accuracy, especially when there is no diagnostic test and when the problem being treated involves subjective/psychological experience.

The practice of administering puberty blockers as providing a 'pause' to think is belied by the finding that the vast majority will continue along the medical transition pathway. Thus, in order to obtain meaningful consent for puberty blockade, clinicians should inform minors that by commencing this treatment, it is highly likely that they will continue on to cross-sex hormones and potentially surgical treatments as well. We believe this should only be done in randomised trials which make clear that the child is consenting to the possibility of damaged sexual function (something they cannot really understand before puberty and the development/maturation of sexual function). There are no randomised trials in this field, even comparing which stage of puberty might be the better for long term outcomes, rather than the earlier stages when distress might be most heightened but could perhaps be managed in other ways.

Finally, whilst robust evidence documenting the natural history of childhood-onset gender dysphoria shows that the vast majority of children, namely 61-98%, ultimately reidentify with their birth sex during puberty (Steensma et al., 2013), the natural history of adolescent-onset gender dysphoria is largely unknown. No studies to date have evaluated the rates of resolution of gender dysphoria in the new and growing cohort of youth with adolescent-onset gender dysphoria. It is not known whether some or most adolescents would experience symptomatic and psychological improvements if their developmental trajectories were not altered by gender-affirming medical interventions. This is underscored by Smith et al. (2001), who found that gender dysphoria and psychological problems improve over time in youth who received no gender-affirming treatment.

3. Independent reviews lead to changing practices in Europe

i. Independent systematic reviews of puberty blockade and cross-sex hormones

Whilst AusPATH have no doubts that gender-affirming interventions are beneficial to youth with gender dysphoria, other independent expert bodies around the world are reporting concerns about the serious limitations of the available data and safety. The UK National Institute for Health and Care Excellence (NICE) recently reviewed the evidence regarding puberty blockers and cross-sex hormones (National Institute for Health and Care Excellence, 2021a; National Centre for Health and Care Excellence, 2021b). NICE concluded that studies evaluating the use of puberty blockers for adolescents were of very low certainty and subject to bias and confounding. Similarly, they reported that the potential benefits of cross-sex hormones are of very low certainty and must be weighed against the many known and unknown long-term risks of these treatments. Concurrently, the UK Tavistock Gender Identity Development Service ceased referring youth for puberty blockade after a highly publicised judicial review in late 2019 (Royal Courts of Justice, 2020).

ii. Systematic review and quality appraisal of treatment guidelines

Further, a recent systematic review and quality appraisal examined international clinical guidelines for gender minority/trans people (Dahlen et al., 2021). The review found that the World Professional Association for Transgender Health (WPATH) Standards of Care Version 7 (Coleman et al., 2012), the guidance which AusPATH endorses, rated very poorly on a number of key indices. All six independent reviewers would not recommend the use of these guidelines in their current form and only one would recommend their use in modified form. The authors concluded that the WPATH Standards of Care "**cannot be considered 'gold standard'**" [our emphasis]. We believe that high-quality healthcare guidelines cannot be produced by single special-interest groups acting in isolation but require rigour and independent quality assurance processes.

iii. European clinics curtail endocrine treatment

Two European countries, which had been forerunners in transgender medical intervention, have also recently changed their position on the endocrine treatment of youth after extensive evidence reviews. The Karolinska Hospital in Sweden recently halted the routine administration of puberty blockade to adolescents with GD. Another large Swedish Hospital, Lund, soon followed suit. These prestigious hospitals will now only administer puberty blockers in the context of a clinical trial, a position that SEGM believes is appropriate for experimental treatments. In Finland, after reviewing the available data, the Council for Choices in Health Care recommended that youth (and adults) with gender dysphoria should receive psychological intervention as the gold standard first-line treatment, with hormonal intervention considered as second-line (Council for Choices in Health Care in Finland, 2020a; Council for Choices in Health Care in Finland, 2020b).

4. The role of psychotherapy in the treatment of gender dysphoria

i. Psychological interventions are the foundation of youth mental health care

These developments, reflective of the weak evidence base for gender-affirming interventions, highlight the need for alternative treatment approaches for youth gender dysphoria. The only currently available alternative consists of psychological intervention. AusPATH, however, neglects to mention these important recent developments and argues that there is no reason to consider psychotherapy a useful treatment approach for gender dysphoric teens (other than as an adjunct to gender affirmation). They then quote a statement by the judge in the recent *re: Imogen* case, asserting that psychotherapy for gender dysphoria is "risky and unproven". This is not a scientific or medical view backed up by peer-reviewed studies, and it is likely the judge was misinformed by similar (or the same) 'experts' who write their own special-interest guidelines. The recent European reviews mentioned above, in addition to the review by Heneghan and Jefferson (2019), suggest that it is medical gender-affirming treatment that is risky, unproven and "experimental", rather than psychotherapy, being a safer option.

AusPATH opines that psychotherapeutic approaches are experimental and risky, although they do not call for research to test their opinion. Yet, individual and family psychological interventions (which include psychodynamic, psychoanalytic, cognitive-behavioural and systemic approaches) have long been the established foundations of child and adolescent mental health care for a very wide range of situations associated with psychological distress (Carr, 2006); Thapar, et al., 2015). This includes conditions associated with distress about the body and with identity struggles. It is simply incorrect to argue that psychotherapy is not in line with "orthodox" practice.

Given the independently assessed evidence and the fact that European experts in the field of gender medicine are expressing caution about gender-affirming interventions for youth, and the established role of psychological interventions in youth mental health care, it is arguable that AusPATH's approach breaks with ordinary Good Medical Practice.

ii. The efficacy of psychotherapy

The efficacy of psychodynamic psychotherapy, in particular, for a wide range of conditions is supported by a substantial evidence base (Royal Australian and New Zealand College of Psychiatrists, 2021; Shedler, 2010), including for children and adolescents (Midgley et al., 2021). One major youth gender clinic in Hamburg already provides psychodynamic psychotherapy as a primary intervention. (Sievert et al., 2021).

iii. Limited evidence base for psychotherapy for gender dysphoria

AusPATH correctly states that the evidence for psychotherapy is sparse. Presently, the only available evidence showing that psychotherapy can ameliorate gender dysphoria in youth consists of case reports or small case series (eg. Bonfatto and Crasnow, 2018; Churcher Clarke and Spiliadis, 2019; D'Angelo, 2020; Davenport and Harrison, 1977; Forester and Swiller, 1972;

Greenson, 1966; Hakeem, 2012; Kirkpatrick and Friedman, 1976; Lemma, 2018; Lothstein, 1980; Lothstein and Levine, 1981; Spiliadis, 2019).

iv. The conflation of ethical psychotherapy with Conversion Therapy

There is no evidence for AusPATH's claim that psychotherapy for gender dysphoria can cause harm. AusPATH goes much further, however, mischaracterising ethical psychotherapy by conflating it with "Conversion Therapy". AusPATH warns that psychotherapy "may involve pressure on the person to conform to the gender assumed for them at birth". This reveals a fundamental misunderstanding of psychotherapy, which *by definition* should take a supportive and neutral position of exploration. Ethical psychotherapy seeks neither to convert *nor* to affirm the patient's gendered experience, as both constitute undue influence and would be considered a violation of appropriate therapeutic boundaries. It is wrong to deliberately discredit psychotherapy to support AusPATH's ideological commitment to gender affirmation.

Conclusion and recommendations

The significant methodological shortcomings of the current observational research show that high-quality research is urgently needed. It is particularly perplexing that despite the long history of transgender medicine, there have been no clinical trials, whether evaluating the efficacy of psychological interventions for gender dysphoria or pharmacological and surgical interventions. It is ordinary good practice for doctors to monitor, check and test their theories, and to seek independent validation (rather than 'marking their own homework'). This is because medicine has a long history of enthusiastically embracing unproven but ultimately harmful treatments, and scientists have a deep understanding of the biases of invested clinicians. SEGM concurs with the findings of major systematic reviews that the current evidence for gender affirmation is uncertain. The viable treatment alternative is psychological intervention, the orthodox foundation of contemporary child and adolescent mental health care. Established psychological treatment models for helping distressed youth should be the first-choice treatment for youth with gender dysphoria.

SEGM calls for robust testing of the harms and benefits of all parts of the gender-affirming pathway, so that in the future, patients can have reliable data about what works, for whom, why, when and how often. More work comparing the clinical and cost-effectiveness of different models and modalities is required. In the meantime, SEGM recommends avoiding the pharmacological and surgical risks of gender-affirming treatments, except within rigorous research contexts that are approved and monitored by the appropriate Human Research Ethics Committee.

Society For Evidence-Based Gender Medicine

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