

Engagement Report for Clinical Commissioning Policies

Policy Unique Reference Number	E03X16
Policy Title <i>Must be an exact match to the URN List title. If a different title is needed then discuss first with the CET and amend the URN List</i>	Prescribing of Cross-Sex Hormones as part of the Gender Identity Development Service for Children and Adolescents
Accountable Commissioner	Bernie Stocks
Lead Clinical Reference Group	E03 Paediatric Medicine
Collaborating Clinical Reference Groups	

Which stakeholders were contacted to be involved in the policy development?	The list of Paediatric Medicine Clinical Reference Group Members, and stakeholders* * (specifically attendees from the 23 July 2015 GIDS Specification Review Stakeholder event including stakeholders and support groups, parents of clients of the service, adolescents with GD who had not used the service and health professionals, some of which are from the service provider. NHS England commissioning and contracting staff).
Identify the relevant Royal College or Professional Society to the policy and indicate how they have been involved	The British Society for Paediatric Endocrinology and Diabetes (BSPED) has considered the policy proposition, consider it to be an appropriate policy and have no concerns or comments to raise.
Which stakeholders have actually been involved? State reason for any difference from previous questions	All of the stakeholders above were invited to comment.

<p>Identify any particular stakeholder organisations that may be key to the policy develop that have been difficult to engage. Indicate why they have been difficult to engage</p>	<p>All key organisations have commented.</p>
<p>How have the stakeholders been involved? What engagement methods have been used?</p>	
<p>The draft policy proposition and clinical evidence review was circulated to the stakeholders and the key clinical leads from the Paediatric Medicine CRG who had been involved in the development of the Policy Proposition, to:</p> <p>Question 1: establish whether any amendments to the policy are required on the basis of stakeholder opinion and to,</p> <p>Question 2: receive views on the NHS England proposal to not routinely commission CS hormones for young people below 16 years.</p> <p>Five responses were received, one from BSPED and four from support organisations. These all request changes to the document. Please see Appendix A. Please see Appendix B for The Endocrine Society Guidelines 2009.</p>	
<p>What has happened or changed as a result of their input?</p>	<p>The Policy Working Group considered the responses from Stakeholders 1 to 5 and the recommendation is included at Appendix A.</p>
<p>How have stakeholders been informed of progress with policy development as a result of their input?</p>	<p>This engagement report, along with the updated policy proposition will be circulated as part of the public consultation. Stakeholders will be notified and invited to comment further.</p>
<p>What level of wider public consultation is recommended by the CRG for the NPOC Board to agree as a result of stakeholder involvement? (see Appendix One)</p>	<p>Public consultation for a period of 30 days as supported by stakeholders.</p>

Appendix A Stakeholder responses

Responder	Feedback received	PWG Response	Resulting Action
<p>Stakeholder 1 – stakeholder organisation/ comments:</p>	<p>1.1 Q1 - response: 1.1.2 The Evidence Review is gravely biased. It attempts to justify not routinely commissioning cross sex hormones before the 16th birthday. An unbiased research question would be: what evidence is there to justify or not justify providing cross sex hormones at a minimum age of 14 in individually tailored treatment packages? 1.1.3 The draft service specification acknowledges that young people request treatment on a case by case basis (page 8). The gender identity development service claims to deliver tailored treatment packages (page 12). It does not do so. Instead it applies rigid requirements, including a minimum age of 16 for cross sex hormones (page 25). 1.1.4 The Endocrine Society recommendation (page 3 of the service specification) is misquoted.</p>	<p>1.1.2 The PWG notes the comment and can confirm that standard evidence review methodology was used, also that Endocrine Society Guidelines are 'We recommend treating transsexual adolescents (Tanner stage 2) by suppressing puberty with GnRH analogues until age 16 years old, after which cross-sex hormones may be given.' but go on to suggest that there is less evidence to support the use of cross sex hormones from a younger age of 'around 16'. The PWG noted that the additional evidence would not materially change the proposed commissioning position. 1.1.3 The PWG noted that the comment relates to the service specification, rather than the policy, so is out of scope. The comment relates to the service provider, whereas it is NHS England which has developed the specification which the provider delivers to. NHS England carefully</p>	<p>1.1.2 No action required. 1.1.3 No action required. 1.1.4 No action required.</p>

	<p>Actually, cross sex hormones can be administered from about age 16.</p> <p>1.1.5 The Evidence Review has identified many examples where respectable overseas centres do not impose a minimum age of 16 for cross sex hormones. These are described in the Clinical Commissioning Policy Proposition, E03X16/01 (page 9) and the Spack et al article (cited on page 14). Cross sex hormones are provided to patients as young as:</p> <ul style="list-style-type: none"> • 13.3 years (natal males) and 13.7 years (natal females) in Vancouver, Canada 	<p>took into account the available evidence when specifying the age at which cross sex hormones should be available.</p> <p>The PWG noted that this comment would not materially change the proposed commissioning position.</p> <p>1.1.4 The PWG noted that Comment relates to service specification so is out of scope of this document. However, The Endocrine Society Guidelines (see Appendix B) use a grading system for the strength of the recommendation, with strong recommendations have the phrase “we recommend” and the number 1, and weak recommendations use the phrase “we suggest”.</p> <p>Based on this system: we note the following: “We recommend treating transsexual adolescents (Tanner stage 2) by suppressing puberty with GnRH analogues until age 16 years old, after which cross-sex hormones may be given’</p> <p>‘2.4. We suggest that pubertal development of the desired opposite sex be initiated at about the age of 16 yr, using a gradually</p>	<p>1.1.5 No action required.</p> <p>1.16 Change wording re Rosenthal, including removing the wording ‘not before 16’.</p>
--	--	---	---

	<ul style="list-style-type: none"> • 13.9 to 14.9 years in The Netherlands • 14 years in the USA <p>1.1.6 The recommendation in the paper by S. M. Rosenthal appears to be grossly misrepresented (page 12 of the Review). The actual quote is “Occasionally, some gender-dysphoric youth first come to medical attention when they are Tanner 4/5, but < 14 years of age. Such individuals would be candidates for pubertal blockers (eg, to stop menses in an FTM adolescent), but without supportive outcome data, not currently candidates for cross-sex hormone use under most circumstances.” Rosenthal is only talking about patients < 14 years of age and contrary to what is stated in the Review does not recommend that cross sex hormone medication should be delayed until age 16.</p> <p>1.1.7 Moreover, Rosenthal states that “not only could delaying such treatment (cross sex hormones) until that age (16) be detrimental to bone health, but keeping someone (receiving hormone blockers) in a prepubertal state until this age would isolate the individual further from age-matched peers, with potentially negative consequences for emotional well-being.”</p>	<p>increasing dose schedule of cross-sex steroids. (2 ⊕○○○)’</p> <p>Therefore the PWG notes that the specification refers to the recommendation for ‘from 16’ as it is based on a higher grade of evidence.</p> <p>The PWG notes that there is the need for more evidence to be collected and that a clinical trial is being scoped currently. In the absence of further evidence, it is appropriate to base decisions on the highest level of evidence that is available currently.</p> <p>1.1.5 The PWG noted this and the current Endocrine Society Guidelines for treating transsexual adolescents (Tanner stage 2) by suppressing puberty with GnRH analogues until age 16 years old, after which cross-sex hormones may be given’ as noted above, but also encourages the creation of more evidence and notes that it is proposed to undertake a research trial in conjunction with an international partner in Holland as part of a range of collaborations with international partners.</p> <p>1.1.6 The PWG agreed</p>	<p>1.17 No action required.</p> <p>1.1.8 No action required.</p> <p>1.1.9 Remove detail of the scope of the clinical trial from the policy as it is not yet agreed, although take this comment</p>
--	---	---	--

	<p>1.1.8 The criteria for cross sex hormones (page 59 in the draft service specification) are more onerous than in the Intercollegiate Good Practice Guidelines that apply to adult services. Adults do not have to present coherently with the gender identity or engage in some meaningful activity. Furthermore adults do not have to spend 12 months on the hormone blocker. No research evidence is cited to justify these requirements.</p> <p>1.1.9 The proposed research study into lowering the age for cross sex hormones would set arbitrary requirements (page 5 of the policy proposal) that are inappropriate and unsupported by any evidence, including:</p> <ul style="list-style-type: none"> • minimum age of 15 • blockers to have started in early stages of puberty • a minimum period of two years on the blocker (note that there is inconsistency with the one year requirement in the draft service specification). • functioning in preferred gender; this is especially dangerous because it would require young people to out themselves and deny them the masculinising or feminising medication that would facilitate their acceptance in their new gender <p>1.1.10 The proposed research is arbitrarily restricted and is merely procrastination. The Tavistock's clinicians previously used this tactic to delay the introduction of hormone blockers before Tanner stage 5. They were clearly</p>	<p>that Rosenthal does not use the words 'age 16' in his summary and the wording in the Clinical Evidence Review has been changed accordingly to 'There was no relevant evidence available in this review on the effects and harms of cross-sex hormone therapy after 15th birthday in patients with persistent gender dysphoria in whom irreversible physical changes have already occurred after onset of puberty. Rosenthal et al. (2014) noted that occasionally, some gender-dysphoric youth first come to medical attention when they are Tanner 4/5, but < 14 years of age. Such individuals would be candidates for pubertal blockers, but without supportive outcome data, not currently candidates for cross-sex hormone use under most circumstances'.</p> <p>1.1.7 The PWG noted that the Evidence Review did not generate any evidence to support the use of Cross Sex Hormones earlier than 16 years, and notes that the service is developing a proposal for a research clinical trial.</p>	<p>into account.</p> <p>1.1.10 No action required.</p> <p>1.1.11 No action required.</p> <p>1.2 No action required.</p>
--	---	---	---

	<p>informed about the Dutch approach in 2005 but delayed bringing their own protocol in line with it until 2011.</p> <p>1.1.11 There is ample evidence of sound practice elsewhere that justifies introducing now a minimum age of 14, rather than 16. This requires amending the age stated on pages 17, 25, 30 and 59 of the draft service specification.</p> <p>1.2 Q2 response – see above</p>	<p>1.1.8 The PWG noted that as this comment refers to the specification review, not the policy and so will not be considered here. The PWG also notes that Appendix 7 of the specification is ‘Guidance for Discussions relating to young people wanting to commence cross sex hormones’ and is therefore neither criteria or requirements, but is to enable clinicians to come to a balanced view regarding starting cross sex hormones.</p> <p>1.1.9 The PWG noted that a proposal for a research clinical trial is being developed to seek to develop evidence, the scope of which is yet to be agreed. In the light of comments received, remove this section from the policy proposition.</p>	
		<p>1.1.10 The PWG noted that the scope of the clinical trial is yet to be agreed. The PWG noted that the comment is opinion.</p>	

		<p>1.1.11 The PWG notes that the current evidence base does not give enough information to support the use of cross sex hormones below 16.</p> <p>1.2 The PWG noted that no action is required.</p>	
<p>Stakeholder 2 - stakeholder organisation/ comments:</p>	<p>2.1 Q1 response</p> <p>2.1.1 A very interesting read and I am glad to see that the NHS is hoping (after undergoing an NHS Ethical Review) to do research into the use of CSH's from the age of 15 in some patients. This research is vital as there does not seem to be any relevant research into this and without this research you cannot reach an informed decision about this.</p> <p>2.1.2 At what stage of the process is this yet:-</p> <ol style="list-style-type: none"> 1. No proposals have yet to be drafted before being submitted to the Ethical Review panel 2. Proposals have been drafted but have not yet been submitted 3. Proposals have been submitted. but have not been considered by the panel 4. Awaiting the approval from the panel to start the research. <p>2.2 Q2 response</p> <p>2.2.1 In some specific cases I think this is acceptable eg those suffering gender dysphoria who might have severe co-morbidity symptoms. For those clients who have been living in their acquired gender for a number of years and have adjusted well, then I think that CSH's should be considered provided that they can demonstrate that they are fully cognisant of the effects of the</p>	<p>2.1. The PWG noted this comment and that a proposal for a research clinical trial is being developed, the scope of which is yet to be agreed, therefore the section outlining the possible scope of that should be removed from the policy proposition as it is not yet agreed.</p> <p>2.2 The PWG noted this comment but agreed that the additional evidence would not materially change the proposed commissioning position.</p>	<p>2.1 PWG to remove detail of the scope of the clinical trial from the policy proposition.</p> <p>2.2 No action required for this document, although consider in the scoping of the clinical trial.</p>

	<p>CSH's (eg on sterility, change in body shape etc). I think that a blanket ban is both unfair and inappropriate if it is simply based on age and other factors are not taken into account.</p>		
<p>Stakeholder 3 – stakeholder organisation/ comments:</p>	<p>3.1 Q1 response - 3.1.1 We seek unreserved assurance that the review of the evidence was not influenced directly or indirectly by any professionals who have or are working at the Tavistock and Portman NHS Trust in the Gender Identity clinic or anyone who has any association with that team current and past. We request this to test the independence of the consideration in the light of NHSE declining expert opinion and assistance from a world leader in this field. Involvement of the current provider staff or past professionals would be wholly inappropriate and unethical and would immediately invalidate the deliberation on this serious and vital matter.</p> <p>3.1.2 Limited evidence is quoted as a reason not to prescribe CHS</p>	<p>3.1.1 The PWG noted that the evidence review was undertaken by an external organisation.</p> <p>3.1.2 The PWG noted that the NHS England clinical commissioning policy is to be based on the best available evidence; the Endocrine Society Guidelines recommend that maturity is taken into</p>	<p>3.1.1 No action required.</p> <p>3.1.2 No action required.</p>

	<p>under 16. This is not good reason to withhold care from a high risk group, indeed many medical advancements have been made in the face of a lack of a volume of evidence base. The Dutch state that the age of 16 for CSH has been decided somewhat arbitrarily with no evidence base - withholding care from under 16s is similarly arbitrary.</p> <p>3.1.3 Existing guidelines and evidence has been misquoted and used to justify a procedure that once again insists on strict timeframes without any evidence or consideration for individual care. The draft service specification refers to treatment on a case by case basis and delivery of tailored treatment. This is categorically not appropriate when arbitrary age limits are imposed, including the minimum age limit for CSH of 16, and the research paper has a minimum age of 15.</p> <p>3.1.4 Incidence / prevalence of gender dysphoria in adolescence (Di Ceglie 2010): The research</p>	<p>account and the strongest evidence currently available is to start cross sex hormones from 16...the process should be started 'at a time when the individual will be able to make informed mature decisions and engage in the therapy, while at the same time developing along with his or her peers. Growth targets reflect personal preferences, often shaped by societal expectation's'. The PWG notes that the proposed research trial would seek to generate additional evidence. The research trial will take place with the Dutch team whose current clinical policy is to not prescribe cross sex hormones before the age of 16 apart from in carefully selected cases of clients aged 15 years and above who have had early intervention, have received hormone blockers for a number of years, and are well known to the service.</p> <p>3.1.3 The PWG noted that physical intervention is one aspect of treatment; this comment is made in relation to the specification so is out of scope of this document, also that this is opinion. The PWG noted that the</p>	<p>3.1.3 No action required.</p> <p>3.1.4 No action required.</p> <p>3.1.5 Wording to be changed in the Policy Proposition document to reflect this revised wording accordingly.</p> <p>3.1.6 No</p>
--	---	---	--

	<p>quoted examines the wrong cohort of children. The proposition is addressing the incidence of gender dysphoria in young people who have entered puberty therefore the research relied upon here is irrelevant and selective.</p> <p>3.1.5 What is the evidence for stating “identity may change...particularly during adolescence”?</p> <p>3.1.6 It is an abuse to withhold blockers (which should be available on demand on an individualised basis) and fast track care. CSH can then be prescribed as soon as appropriate thereafter using the usual parameters for consent and the Fraser Guidelines. The policy document and presumably the group deliberating this topic appear to not have the wider contextual understanding of equality, the duty of care and legal / human rights for these young people.</p>	<p>additional evidence would not materially change the proposed commissioning position.</p> <p>3.1.4 The PWG concluded that the reference is appropriately included as it provides evidence as to the level of persistence in this population.</p> <p>3.1.5 The PWG understands that a person’s Gender Identity may or may not change over time and similarly the way a young person chooses to express their gender identity may or may not change over time.</p> <p>3.1.6 The PWG noted that the practice of the service is that a referral to the Paediatric Endocrine Liaison Clinic for blockers is provided after an appropriate multidisciplinary team (MDT) assessment has been concluded, in line with national and international guidelines. The PWG understands that blockers are not ‘withheld’ and all young people who wish to take blockers</p>	<p>action required.</p> <p>3.1.7 No action required.</p> <p>3.1.8 No action required.</p> <p>3.1.9 No action required.</p>
--	---	--	--

	<p>3.1.7 The Endocrine Society recommendation (page 3 of the service specification) is incorrect. It actually states CSH can be administered from about age 16.</p> <p>3.1.8 GIRES have identified that the Evidence Review has identified many examples where respectable overseas centres do not impose a minimum age of 16 for cross sex hormones. We agree with their findings.</p> <p>3.1.9 The recommendation in the paper by S. M. Rosenthal is grossly misrepresented (page 12 of the Review). GIRES have pointed out the extent of the inaccuracy and we will therefore not quote it in its entirety.</p> <p>3.1.10 GIRES have identified that the requirements to qualify for CSH are prejudicial to young people. We agree with their comments.</p> <p>3.1.11 Page 5 of the policy proposal cites requirements not supported by evidence:</p> <ul style="list-style-type: none"> • minimum age of 15 – parents have already been informed by clinicians that this will be 14, raising expectations and inaccurate based on this proposal • a minimum period of two years on the blocker – we note that there is inconsistency with the 	<p>are supported to do so following an appropriate assessment. Cross sex hormones are then prescribed if the client wants to receive these and provided they are able to consent and have had adequate time and opportunity to fully explore the long term implications. There are different opinions about this, all worthy of consideration. Clients follow individualised pathways and not all young people opt for physical treatments. NHS England is aware of the issues and has considered all aspects of consent. Please see specification Section 3.2.6 and Appendix 6.</p> <p>3.1.7 Please see 1.1.4 above; also the PWG noted that this comment refers to the specification and is out of scope of this review.</p> <p>3.1.8 The PWG noted that although this policy proposition is based on the strongest available evidence, more evidence is needed and acknowledges the importance of continuing to contribute to the evidence base.</p>	<p>3.1.10 No action required.</p> <p>3.1.11 Change made to policy proposition.</p> <p>3.1.12 No action required.</p> <p>3.2.1 No action required.</p> <p>3.2.2 No action</p>
--	---	---	--

	<p>one year requirement in the draft service specification, but once again, no individual care or consideration based on a case by case basis is given</p> <ul style="list-style-type: none"> • functioning in preferred gender; this is especially onerous as we know that some young people do not pass as their affirmed gender, therefore prefer to wait before transitioning. Requiring them to live as such before their appearance matches their identity exposes them to harm and risk of hate crime and prejudice. <p>3.1.12 While all research is welcomed the proposed study is merely a procrastination to delay adequate care provision to those under 16 who have entered puberty. The persistent lack of acceptance that “time is of the essence” for these young people, and the cultural inability of the national centre to listen to young people and their families is clear. The lack of therapeutic or other benefit for service users is reported daily.</p> <p>3.2 Q2 response -</p> <p>3.2.1 Young people need to be allowed to make informed decisions. This should be approached in a framework that engenders the rights of self-determination of young people the majority of which would be Gillick competent. Professionals delivering this service need education and better understanding around Gillick competency and the Fraser guidelines- there is an assumption that young people cannot make these decisions. That errs in law, ethics and health governance.</p> <p>3.2.2 Lack of evidence is cited as</p>	<p>3.1.9 See response to 1.1.6 above.</p> <p>3.1.10 The PWG noted that the additional evidence would not materially change the proposed commissioning position.</p> <p>3.1.11 The PWG noted that the scope of the clinical trial is not yet agreed, although the two years on the blocker to be changed to ‘significant period’. The service confirms its position that cross sex hormones are currently available from 16.</p> <p>3.1.12 The PWG noted that this comment is opinion, and that the additional evidence would not materially change the proposed commissioning position.</p>	<p>required.</p> <p>3.2.3 No change required.</p>
--	--	---	---

	<p>an excuse not to progress young people through a meaningful pathway to secure positive outcomes. Currently young people are held in a “holding state” with no progression and poor support while their bodies continue to develop in the wrong gender. The policy needs to provide choice for young persons to access CSH pre 16 if it is right for them as individuals. The child’s welfare must be paramount in accordance with the law - the current situation of poor therapeutic input and lack of early intervention is nothing less than negligent and reckless to the safety of these young people.</p> <p>3.2.3 This is a comment from a parent who asked her child for her thoughts:</p> <ul style="list-style-type: none"> I have asked my daughter how she feels about the current protocol and wait for cross sex hormones and this is what she said -"I think about my body a lot. I have got a boy’s body but I am a girl and this makes me feel upset, depressed and knocks my confidence and self-esteem all the time. I imagine how it could be with CSH, and it makes me feel so sad and angry when I see that my body is not like that. It doesn’t have any shape like it should have, and I am completely flat chested unlike other girls my age. It makes me angry and I think - Why am I not like other girls? And I think - Why am I told I have to wait another two years? I have never changed the way I have felt, I have felt this way my whole life. It doesn't seem right or fair that I have to wait until I become 16. What will have changed then? - 	<p>3.2.1 The PWG agrees and noted that consent to treatment is one aspect of decision-making around starting treatment. The PWG understands from the service provider that training on appropriate competence is in place. No action required.</p> <p>3.2.2 The PWG noted that the policy is based on the highest level of available evidence and the additional evidence presented here does not materially change the proposed commissioning position.</p> <p>3.2.3 The PWG noted the statement from the child and thanked them for their contribution. The PWG sought and received, confirmation from the provider that clients who choose to seek physical treatment outside the NHS may still access therapeutic support through the service and will be assessed in accordance with the scope of the specification.</p>	<p>3.2.4 No action required.</p> <p>3.2.5.1 No action required.</p> <p>3.2.5.2 This has been changed in the policy document.</p> <p>3.2.5.3 No action</p>
--	---	---	---

	<p>Nothing, but I'll be older and even more behind where I should be.</p> <ul style="list-style-type: none"> • There are other people who will be 16 before me and who are much younger than me emotionally and they will get cross sex hormones before I do, there are people who will have been on hormone blockers for less time than me and that is not a fair system. I believe I will have been ready for CSH years before I get them; I am ready for them now. • I have felt so sad about my body that we have talked about going abroad to America for treatment; this would be difficult though as it costs a lot of money and I would feel bad about that as my family could use the money for other things. But what is hardest and what makes me not want to go to America even though I feel bad about my body, is that if we went to America I would not be able to see anyone at the Tavistock and I have been going for a really long time, and I wouldn't be able to go to their young person's groups and I really enjoy going to them. I rely on this support and if we went abroad, the help from the Tavistock would stop and this makes me feel like I have to choose, to wait for the CSH over here or lose what help I have from the Tavistock and go to America, and that stresses me out, so I try not to think about it. If we could go to America and get the cross sex hormones and I would still be able to see [x] at the Tavistock and go to the young person's group then I think we would have gone by now." <p>I did not put words in my daughter's mouth I just asked her</p> 	<p>3.2.4 The PWG noted this comment and that it relates to the specification and is out of scope.</p> <p>3.2.5.1 The PWG noted that evidence has been considered in the drafting of this document.</p>	<p>required.</p> <p>3.5.2.5 No action required.</p> <p>3.5.2.5 No action required.</p> <p>3.2.5.6 No action required.</p>
--	---	--	---

	<p>what she felt about having to wait until she is 16 for the CSH and that was her reply.</p> <p>3.2.4 Hours have been spent deliberating during NHS events, yet both the service specification and the CSH proposals once again are not patient led and the young person's voice has been ignored.</p> <p>3.2.5 We have sought advice from [x] of [town in a different country], and have received the following, which I have included in full. I think this gives a fair indication of the history and the processes that the [x] hospital follow, which also explains why so many families choose to seek care abroad.</p> <ul style="list-style-type: none"> • Page 2 2 “for this policy, there would be additional costs for earlier access in some cases to c-s hormones.” What costs? Oestrogen and testosterone have minimal cost. It's GnRH analogues that are expensive. But a real cost that may never have been calculated thus far is the economic cost of suicidal attempts, Emergency room visits and psychiatric hospitalization, and the long term cost in emotional wellbeing, work productivity and sheer misery “paid” by these patients and families when effective treatment always seems “too little, too late.” • E13/S(HSS)e NHS Standard Contract p. 1 Current DSM terminology removes “GID” in favour of “gender dysphoria” • Surgical intervention “at age 18” The Benjamin and Endocrine Society “Standards” are guidelines and not meant to disregard the particular needs of an individual patient. They 	<p>3.2.5.2 The PWG notes that Gender Identity Disorder (DSM) should be removed in favour of gender dysphoria.</p> <p>3.2.5.3 This comment is related to surgery which is currently part of the adult service specification in England and is out of scope of this document.</p>	
--	---	---	--

also remain a work in progress. For example, I know no one who would subject a large-breasted patient to wait 4-5 years in binders before mammoplasty available. Around age 15 seems common in USA.

- Whereas it had been common to wait until around age 18 before doing genitoplastic surgery (SRS), in the USA that is the age of leaving high school and many students live in residential Colleges and universities where they must have single rooms post-op to perform necessary vaginal dilations several times daily. Surgeons report that their worst surgical outcome is in this situation because without maternal oversight, the dilatations which are so critical to maintain patency in the first post-op year, are not done frequently enough and the tissues undergoes stenosis, making vaginal sexual penetration impossible and creating a cycle of surgical “releases” of the scarred tissue. Therefore, especially if the patient plants to leave home after high school, it is best for her to have genitoplastic surgery in the summer before final year of high school, when she is likely to be 17 years old.
- p. 4 2.2 Service description/care pathway - This is a commendable team, but is there not an imbalance with all these specialists in London and none elsewhere? What such centralisation?
- p.10 response time to evaluation is only part of the necessary measure. 18 weeks from referral to evaluation seems long but not if the intake social worker

3.5.2.4 The PWG noted that the service is provided from Leeds, London, Bristol, Bath, Barnstaple and Exeter.

3.5.2.5 The PWG noted that this comment refers to the specification rather than the policy and following referral, an assessment is undertaken to determine the nature of the client’s gender identity development, and if the client wishes it, they may then be subsequently referred to the Paediatric Endocrine Liaison Clinic according to the scope set out in the specification.

3.5.2.6 The PWG noted that this section is a patient/clinician story to support the point that the stakeholder is making and notes the points made, although the additional evidence would not materially change the proposed

remains in touch with the family. However, patients are seriously distressed if they have reason to believe that their evaluation is going to lead to medical intervention and that treatment takes an inordinate amount of time to initiate. If it were another 18 weeks, the patient and family would be looking at 36 weeks from referral to medical therapy.

- Appendix p. 13:
F) “The adolescent has reached Tanner 5.” I do not understand what this statement means, why it is here?.
(Editorial comments) I have come to the time when I can no longer work from the documents sent to me. I think it will be more helpful to give the “backstory” known but to a few.
 - In 1985, I began with an “n of 1,” a software designer 2 years out of [x] College who was assigned female at birth based on normal female anatomy. Clearly transgender, she lived among male roommates who knew the story and accepted[x] for the man he was, as did the college registrar who made sure that his (legal female) birth name never appeared on any class lists. [x] asked me to help him virilize, which was not approved by his parents. I subsequently took care of 200 trans adults from age 21-60, starting all on hormonal replacement therapy. With the sudden dearth of available endocrinologists, three

commissioning position.

psychotherapists with very active practices urged me to medically treat their patients. Both my Chief of Endocrinology at [x] children's hospital and his predecessor, [] the founder of the Division, urged me to provide care to learn as much as possible about the adults because we were all beginning to hear what the Dutch were starting to do with pubertal suppression. My mentors had my malpractice insurance extended to cover my being a paediatrician taking care of adults, as long as I brought fellows in adult endocrinology out to that practice, where I could teach them.

- And what did I learn first and teach later? That treating individuals who were only able to be their true selves in the context of marriage and family, a non-supportive workplace and parents/siblings was physically less than physically the way they wished they looked, especially for heights in FTMs and general appearance in MTF's despite fairly massive oestrogen doses. Breast development in the MTFs was not usually close to what it would have been had they gone through a normal female puberty at the

age of adolescence. Thus, virtually all had breast augmentation when they had feminizing genitoplasty. Over 8 years I had 4 deaths by the patient's own hand. 3 were clear suicides and one was either a suicide or a mistake in appreciating the potency of a narcotic in the context of addiction. Some patients were doing well; others were pleased to have made gender affirmation but miserable otherwise. When [] of [] looked at his life's work with 3500 patients, he found that 1200 had died. And of what? No, not from complications of hormonal therapy but of "psychosocial death", suicide, substance abuse, alcoholism, homelessness, unemployment, dislocation from family and friends, etc" And all of this occurred in a country where medical expertise in transgenderism was guaranteed in a society more accepting of gender variance and more open about sexuality than any other. I came to understand why something different needed to be done and that any paediatrician who begins working with adolescents should see the outcome for adults. In

Crigler's words, paraphrasing William Gladstone's famous statement, "we paediatricians suffer from the perspective of seeing the outcome of what we do or don't do, of seeing treatment delayed or denied.

- I began to bring these sad but courageous adults to clinical teaching sessions at [x] children's hospital and soon brought in teens on the cusp of potential pubertal suppression. When we decided to become the first academic paediatric centre to medically treat trans youth, I had to consult with every imaginable clinical chief and administrator. The vote was a resounding "yes" and I asked each how they came to that decision so readily in the face of potential donors and the community "haters". They said it was because they had "met" my patients, first the painful adults and then the hopeful teens, who should not be condemned to a shattered life.
- A few gleanings from years past:
- [x] warned that if we open our clinic to the public, we will be initially swamped by pent-up demand. Indeed this is our biggest challenge and the pinch-point is getting patients through

the psychological evaluation and testing. We have adapted—reducing the testing in stable older teens where the testing outcome is fore-ordained. We have appealed and successfully lobbied our hospital to provide funds for more evaluators. I don't believe that anyone who is on the cusp of an initial or new treatment should have to wait more than 6 weeks. There is something fundamentally flawed with a program, hospital or health system that expects the same number of professionals to care for two or three times as many patients or by making the queue that much longer.

- Look at the de Vries et al article on psychosocial outcome published in Paediatrics in October 2014. They list the start age of the 55 patients: many are 15.
- All was going along smoothly until I created a row early on the 2nd day I saw the draft about age at cross steroids written as "at or above age 16." I asked that the matter be tabled until I could make necessary phone calls but that if the language was not changed to "around age 16," giving

	<p>leverage to the clinician, then I would immediately resign from the Task Force and not sign it. Further, I was prepared to write a counter argument to any specific ages when patients are so different physically and developmentally. I put in a phone call to [x] in [x] and told her what I was prepared to do and she was in complete support because it reflected her mode of clinical care. Later in the day I asked for the age matter to be brought back up for discussion and I think the Task Force had come to their senses on their own by then because the discussion was so favourable, but the knowledge that [x] agreed carried the day.</p>		
Stakeholder 4 – stakeholder organisation/comments:	<p>4.1 ‘Regarding the administering of blockers and hormones to Adolescents. After reading all the information and evidence base provided, also what we have experienced in our group and the wider community. We feel that giving blockers pre-15 years should be considered on an individual basis and where clinically indicated. After much consideration and soul searching we feel 16 years is where clinically appropriate and based on individual need an appropriate age to initiate cross sex hormones.’</p>	4.1 The PWG noted this comment	4.1 No action
Stakeholder 5 - BSPED	This is an appropriate policy and no change is required.	5.1 The PWG notes this comment.	5.1 No change required.

Appendix B

Endocrine Treatment of Transsexual Persons: An Endocrine Society Clinical Practice Guideline

Wylie C. Hembree, Peggy Cohen-Kettenis, Henriette A. Delemarre-van de Waal, Louis J. Gooren, Walter J. Meyer, III, Norman P. Spack, Vin Tangpricha, and Victor M. Montori¹

Address all correspondences and requests for reprints to: The Endocrine Society, 8401 Connecticut Avenue, Suite 900, Chevy Chase, Maryland. E-mail: govt-prof@endo.society.org. Telephone: 301-941-0200.

DOI: <http://dx.doi.org/10.1210/jc.2009-0345>

Received: February 13, 2009

Accepted: June 04, 2009

First Published Online: July 02, 2013

- See more at: <http://press.endocrine.org/doi/full/10.1210/jc.2009-0345#sthash.8qLUL6gG.dpuf>

The Task Force used the best available research evidence that Task Force members identified and two commissioned systematic reviews (21, 22) to develop some of the recommendations. The Task Force also used consistent language and graphical descriptions of both the strength of a recommendation and the quality of evidence. In terms of the strength of the recommendation, strong recommendations use the phrase “we recommend” and the number 1, and weak recommendations use the phrase “we suggest” and the number 2. Cross-filled circles indicate the quality of the evidence, such that ⊕○○○ denotes very low quality evidence, ⊕⊕○○ denotes low quality, ⊕⊕⊕○ denotes moderate quality, and ⊕⊕⊕⊕ denotes high quality. The Task Force has confidence that persons who receive care according to the strong recommendations will derive, on average, more good than harm. Weak recommendations require more careful consideration of the person’s circumstances, values, and preferences to determine the best course of action. Linked to each “recommendation” is a description of the “evidence” and the “values” that panelists considered in making the recommendation; in some instances, there are “remarks,” a section in which panelists offer technical suggestions for testing conditions, dosing, and monitoring. These technical comments reflect the best available evidence applied to a typical person being treated. Often this evidence comes from the unsystematic observations of the panelists and their values and preferences; therefore, these remarks should be considered suggestions. - See more at: <http://press.endocrine.org/doi/full/10.1210/jc.2009-0345#sthash.8qLUL6gG.dpuf>

Conclusions

We recommend treating transsexual adolescents (Tanner stage 2) by suppressing puberty with GnRH **analogues until age 16 years old, after which cross-sex hormones may be given.** We suggest suppressing endogenous sex hormones, maintaining physiologic levels of gender-appropriate sex hormones and monitoring for known risks in adult transsexual persons. - See more at: <http://press.endocrine.org/doi/full/10.1210/jc.2009-0345#sthash.8qLUL6gG.dpuf>

Summary of Recommendations

1.0 Diagnostic procedure

1.1 We recommend that the diagnosis of gender identity disorder (GID) be made by a mental health professional (MHP). For children and adolescents, the MHP should also have training in child and adolescent developmental psychopathology. (1 ⊕⊕○○)

1.2 Given the high rate of remission of GID after the onset of puberty, we recommend against a complete social role change and hormone treatment in prepubertal children with GID. (1 ⊕⊕○○)

1.3 We recommend that physicians evaluate and ensure that applicants understand the reversible and irreversible effects of hormone suppression (e.g. GnRH analog treatment) and cross-sex hormone treatment before they start hormone treatment.

1.4 We recommend that all transsexual individuals be informed and counseled regarding options for fertility prior to initiation of puberty suppression in adolescents and prior to treatment with sex hormones of the desired sex in both adolescents and adults.

- See more at: <http://press.endocrine.org/doi/full/10.1210/jc.2009-0345#sthash.8qLUL6gG.dpuf>

2.0 Treatment of adolescents

2.1. We recommend that adolescents who fulfill eligibility and readiness criteria for gender reassignment initially undergo treatment to suppress pubertal development. (1 ⊕○○○)

2.2. We recommend that suppression of pubertal hormones start when girls and boys first exhibit physical changes of puberty (confirmed by pubertal levels of estradiol and testosterone, respectively), but no earlier than Tanner stages 2–3. (1 ⊕⊕○○)

2.3. We recommend that GnRH analogs be used to achieve suppression of pubertal hormones. (1 ⊕⊕○○)

2.4. We suggest that pubertal development of the desired opposite sex be initiated at **about the age of 16 yr.** using a gradually increasing dose schedule of cross-sex steroids. (2 ⊕○○○)

2.5. We recommend referring hormone-treated adolescents for surgery when 1) the real-life experience (RLE) has resulted in a satisfactory social role change; 2) the individual is satisfied about the hormonal effects; and 3) the individual desires definitive surgical changes. (1 ⊕○○○)

2.6 We suggest deferring surgery until the individual is at least 18 yr old. (2 ⊕○○○)

- See more at: <http://press.endocrine.org/doi/full/10.1210/jc.2009-0345#sthash.8qLUL6gG.dpuf>

In summary, neither biological nor psychological studies provide a satisfactory explanation for the intriguing phenomenon of GIDs. In both disciplines, studies have been able to correlate certain findings to GIDs, but the findings are not robust and cannot be generalized to the whole population. - See more at: <http://press.endocrine.org/doi/full/10.1210/jc.2009-0345#sthash.8qLUL6gG.dpuf>

2.4 Recommendation

We suggest that pubertal development of the desired, opposite sex be initiated at the age of 16 yr, using a gradually increasing dose schedule of cross-sex steroids. (2 ⊕○○○)

2.4 Evidence

In many countries, 16-yr-olds are legal adults with regard to medical decision making. This is probably because, at this age, most adolescents are able to make complex cognitive decisions. Although parental consent may not be required, obtaining it is preferred because the support of parents should improve the outcome during this complex phase of the adolescent's life (61).

For the induction of puberty, we use a similar dose scheme of induction of puberty in these hypogonadal transsexual adolescents as in other hypogonadal individuals (Table 9). We do not advise the use of sex steroid creams or patches because there is little experience for induction of puberty. The transsexual adolescent is hypogonadal and may be sensitive to high doses of cross-sex steroids, causing adverse effects of striae and abnormal breast shape in girls and cystic acne in boys.

In FTM transsexual adolescents, suppression of puberty may halt the growth spurt. To achieve maximum height, slow introduction of androgens will mimic a "pubertal" growth spurt. If the patient is relatively short, one may treat with oxandrolone, a growth-stimulating anabolic steroid also successfully applied in women with Turner syndrome (73, 74, 75).

In MTF transsexual adolescents, extreme tall stature is often a genetic probability. The estrogen dose may be increased by more rapid increments in the schedule. Estrogens may be started before the age of 16 (in exceptional cases), or estrogens can be prescribed in growth-inhibiting doses (61).

We suggest that treatment with GnRH analogs be continued during treatment with cross-sex steroids to maintain full suppression of pituitary gonadotropin levels and, thereby, gonadal steroids. When puberty is initiated with a gradually increasing schedule of sex steroid doses, the initial levels will not be high enough to suppress endogenous sex steroid secretion (Table 7). The estrogen doses used may result in reactivation of gonadotropin secretion and endogenous production of testosterone that can interfere with the effectiveness of the treatment. GnRH analog treatment is advised until gonadectomy.

2.4 Values and Preferences

Identifying an age at which pubertal development is initiated will be by necessity arbitrary, but the goal is to start this process at a time when the individual will be able to make informed mature decisions and engage in the therapy, while at the same time developing along with his or her peers. Growth targets reflect personal preferences, often shaped by societal expectations. Individual preferences should be the key determinant, rather than the professional's deciding a priori that MTF transsexuals should be shorter than FTM transsexuals.

- See more at: <http://press.endocrine.org/doi/full/10.1210/jc.2009-0345#sthash.8qLUL6gG.dpuf>

For public consultation