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**NHS England
Clinical Commissioning Policy Proposition:**

**Prescribing Cross Sex-Hormones
as part of the
Gender Identity Development Service for
Children and Adolescents**

GIRES Response

19 April 2016

Recommendation:

For cross sex hormones, GIRES recommends that the London clinicians should now, urgently and in consultation with stakeholders, develop and apply a set of reasonable readiness criteria, excluding age.

Overall Assessment of the Policy Proposition:

- The present treatment protocol is **no cross-sex hormones before age 16 for anyone and even then a requirement for a prior period of at least 12 months on hormone blockers**. Both of these criteria are arbitrary and unsupported by evidence. Moreover, they are applied rigidly.
- The decision in the Clinical Commissioning Policy Proposition to continue with that protocol is based on an Evidence Review that, as described below, appears biased and flawed.
- The Evidence Review should therefore be withdrawn, pending substantial revision
- Bias is evident in the negative language of 'effects and harms', which should be replaced by 'benefits and harms'. The first time the word 'benefits' is used is in the conclusion. The benefits of treatment, are not properly covered in this document. Nor are the harms of non-treatment.

Bias is clearly demonstrated in the Engagement Report for Clinical Commissioning Policies. In response to the proposal that evidence should have been gathered on "providing cross sex hormones at a minimum age of 14 in individually tailored treatment packages", the PWG (Policy Working Group, which is a subset of the Clinical Reference Group) stated that "the additional evidence would not materially change the proposed commissioning position" (1.1.2).

- There is a significant and uncorrected flaw in the Evidence Review. It misquoted Rosenthal (2014), and claimed wrongly that this article stated that transgender youth aged < 14 should “not be considered for CSH before 16 years of age” (Page 7). The PWG undertook in the Engagement Report to change the wording in the Review (1.1.6). Then, in an e-mail dated 29/3/16, sent on behalf of Specialised Services in NHS England, there is a statement that “The evidence review has been completed, and is not being amended.” It was suggested that this concern be raised in the formal response to consultation, which GIREs is now doing. The stance taken by NHS England may not withstand the scrutiny of a reasonable and logical analysis.
- Another flaw is inaccurately quoting of the results from the study by De Vries et al in the Policy Proposition (Page 10). The Proposition states “Satisfaction with body image ... decreased after starting cross sex hormones and prior to sex realignment”. Actually, no assessment was made at that point. T2 in the study is after cross sex hormones **and** sex realignment surgery. Moreover, gender dysphoria and body image difficulties **remitted** at T2.
- The PWG stated in the Engagement Report (1.1.7) that “the Evidence Review did not generate any evidence to support the use of Cross Sex Hormones earlier than 16 years”. Actually, the Review did demonstrate that, in reputable treatment centres, cross sex hormones are provided to patients as young as:
 - ~ 13.3 years (natal males) and 13.7 years (natal females) in Vancouver, Canada
 - ~ 13.9 to 14.9 years in The Netherlands
 - ~ 14 years in the USA
- The PWG did not respond properly to the forgoing point, but merely said that it had been “noted” (1.1.5). A proper response would be to take careful account of the principles established in the Bolam case, and reinforced in the Bolitho case. Bolam established that standards must be in accordance with a responsible body of opinion, as is constituted by the above examples of practice. Bolitho confirmed that Bolam still stands except when a judge can be satisfied that the body of expert opinion cannot be logically supported at all.¹ There is no indication that the above practices cannot be logically supported. Actually, it might be argued that there is no logical support for continuing the present arbitrary practice as proposed in the Clinical Commissioning Policy Proposition. That would imply that the NHS England commissioners and providers of gender identity services for children and adolescents might be at judicial risk if they so continue.
- The Ethical Review section of the Policy Proposition only takes partial account of the opinions of a single author (Abel). Abel is not a medical ethicist – by looking at the profile Abel seems to me a lawyer. It is not clear from his profile what qualifications he has. When he wrote his article, was obviously unaware of the later follow up work published by De Vries et al and Katchadourian et al in 2014. The non-maleficence argument should be applied to **not** providing cross-sex hormones. As is pointed out by WPATH and others, ‘**withholding treatment is not a neutral option**’. Not treating is potentially more harmful than intervening with hormone-blockers and cross-sex hormones. Why is the Policy Proposition evading the question of the harm to mental and physical health of **not** treating?

¹ - Timms Solicitors: <http://www.timms-law.com/bolitho-test>

- Beneficence is misapplied in the Policy Proposition. The statement that “only a subset of patients on hormone blockers decide to proceed to cross sex hormones” ignores the fact that the majority do, 87% of natal females and 65% of natal males.². In any case, this is beside the point. The question is how best to help those patients who do opt for cross sex hormones? Also, the Policy Proposition claims that there is a significant prevalence of desistance, for which there is no supporting evidence. In the Khatchadourian et al study, only 3 out of 39 natal female patients **temporarily** desisted. It appears that none of the natal males did so.
- The policy proposition ignores what Abel had to say about autonomy: “the ethical principle of respect for autonomy cannot be dismissed ... (it) is the strongest factor supporting progressive hormone treatments, including cross-sex hormone therapy”. However, even adults do not have a right to treatment. Treatment ought to be given because not treating has worst effects.
- Although the Policy Proposition states “Both genders showed improvement in symptoms with cross sex hormones” it ignores the obvious implication that this treatment is beneficial.
- Inadequate weight is given to peer reviewed authoritative articles which recommend practices that are at variance with the Policy Proposition, for instance the statements that:
 - ~ “The age criterion of 16 years for the start of CSH may be problematic especially for transwomen, as growth in height continues as long as cross-sex steroids are not provided (causing the growth plates to close). Therefore, psychological maturity and the capacity to give full informed consent may surface as the required criteria for puberty suppression and CSH in cases that meet other eligibility criteria.”³
 - ~ “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.”
- The Policy Proposition ignores the implications of the Gillick case and the related Fraser Guidelines. Under 16, a child/ young person (of any age) may be considered Gillick competent if they have sufficient understanding of the effects (beneficial and harmful) of treatment, and the effects (beneficial and harmful) of non-treatment, as ascertained by using the Fraser Guidelines, enabling the child /young person, to give informed consent. Specifically, the Guidelines provide a set of criteria which must apply when medical practitioners are offering contraceptive services to under 16's without parental knowledge or permission. The Guidelines state that all the following requirements should be fulfilled:⁴

² - Khatchadourian K, Amed S, Metzger D.L. 2014 Clinical management of youth with gender dysphoria in Vancouver. J Pediatr 164(4):906-11

³ - De Vries A.L.C., McGuire J.K., Steensma T.D., Wagenaar E.C.F., Doreleijers T.A.H., Cohen-Kettenis P.T. 2014 Young adult psychological outcome after puberty suppression and gender reassignment. Pediatrics 134(4):696-704.

⁴ - General Practice Notebook: <http://www.gpnotebook.co.uk/simplepage.cfm?ID=x20050425225930411760>

- ~ the young person will understand the professional's advice
- ~ the young person cannot be persuaded to inform their parents
- ~ the young person is likely to begin, or to continue having, sexual intercourse with or without contraceptive treatment
- ~ unless the young person receives contraceptive treatment, their physical or mental health, or both, are likely to suffer
- ~ the young person's best interests require them to receive contraceptive advice or treatment with or without parental consent

Notes:

- ~ although these criteria specifically refer to contraception, the principles are deemed to apply to other treatments, including abortion
 - ~ the Fraser guidelines referred specifically to doctors but they are considered to apply to other health professionals, including nurses. They may also be interpreted as covering youth workers and health promotion workers who may be giving contraceptive advice and condoms to young people under 16, but this has not been tested in court.
- There is no clear recognition in the Policy Proposition that the welcome and valuable respite provided by GnRHa, is **not** a treatment that addresses gender dysphoria, which persists through puberty blocking.⁵ GnRHa is only a first stage of treatment and has also a diagnostic purpose. The treatment for gender dysphoria involves enabling the child to live in the role consistent with the real innate gender identity – this nearly always requires cross-sex hormones. It appears that these are being unreasonably withheld to the detriment of young people who therefore continue to experience gender dysphoria, causing ‘psychological torture’ for years longer than necessary.⁶ Withholding treatment is not a ‘neutral’ option.⁷ It has a devastating effect on mental health, and contributes to social dysphoria because the physical changes experienced by their gender-matched peers are not occurring in the gender dysphoric youngsters.⁸ “There is no legal reason and no clinical reason for imposing strict age related criteria”.⁹

⁵ - De Vries A.L.C., McGuire J.K., Steensma T.D., Wagenaar E.C.F., Doreleijers T.A.H., Cohen-Kettenis P.T. 2014 Young adult psychological outcome after puberty suppression and gender reassignment. *Pediatrics* 134(4):696-704.

⁶ - Delaying treatment causes ‘**psychological torture**’ (Kreukels and Cohen-Kettenis) Puberty suppression in gender identity disorder: the Amsterdam experience, *Nat. Rev. Endocrinol.* 7, 466–472 (2011); published online 17 May 2011)

⁷ - World Professional Association for Transgender Health Standards of Care, Version 7, page 21: http://www.wpath.org/uploaded_files/140/files/Standards%20of%20Care,%20V7%20Full%20Book.pdf

⁸ - Rosenthal S.M. 2014 Approach to the patient: transgender youth: endocrine considerations. *J Clin Endocrinol Metab* 99(12):4379-89.

⁹ - E-mails to GIRES dated 4 April 2016 from Dr Simona Giordano, Reader in Bioethics at the School of Law, University of Manchester, Co-director of the Research Centre at the Centre for Social Ethics and Policy, Programme Director for Post Graduate Studies in Healthcare Ethics and Law and the University of Manchester, former Director of the medical ethics teaching in undergraduate medical education, at the Medical School in Manchester, and author of *Children with Gender Identity Disorder, a clinical ethical and legal analysis*, Routledge, London-New York, 2013

- The services for children and adolescents should focus on eligibility and readiness criteria.

“...psychological maturity and the capacity to give full informed consent may surface as the required criteria for puberty suppression and cross sex hormones in cases that meet other eligibility criteria. (De Vries, 2014).

... So, doing research around an arbitrary age is clearly a wasted exercise. It will not provide useful information or data. It is hard to see how this could be ethical. It will result in unnecessary delay for yet another cohort of young people.

- The data that the researchers are hoping to collect could be obtained simply by providing treatment and observing its effects through a cohort study.
- GIRES therefore welcomes the PWG’ decision, in its Engagement Review, to remove from the Policy Proposition detail of the scope of the clinical trial based on a yet another arbitrary age (1.1.9).
- Other centres outside the UK do treat adolescents who are younger than 16 with cross-sex hormones. Of course, they need to meet certain criteria. NHS England and its providers should establish different criteria from arbitrary age limits. It should learn from practices in other countries, where the protocols are demonstrably more flexible in their response to the needs of their young patients.
- In the event that NHS England and its providers do insist on a clinical trial, even if it uses criteria other than arbitrary age limits, they should be prepared to justify not simply changing the protocol. Here the Bolam and Bolitho cases cited above seem relevant, as does the Declaration of Helsinki (see end of Detailed Comments)

Detailed Comments

Policy: P5. *Some experts have suggested that cross sex hormones could be used from the 15th birthday.*

Response:

This is an opaque comment. Which experts? How independent are they of the present NHS England services for gender variant children and adolescents? No researchers or providers of these therapies around the world has set out to test the validity of establishing yet another arbitrary age. In some countries only at the age of 16 minors acquire a statutory right to consent to medical treatment, unless found to lack capacity. Yet even within such a legal framework, providers have managed to respond with humanity and common sense, as well as taking clinical responsibility for balanced decisions to provide cross-sex hormones to adolescents, younger than 16. In the UK however, we are even better placed, legally, to introduce a more flexible approach because our system permits under 16s to be regarded as (Gillick) competent to make their own decisions and to be capable of giving informed consent.

Some experts overseas have for many years been providing cross-sex hormones much younger than the 16th, or indeed younger than the 15th birthday, based on the needs and competence

/capacity of the particular young person, as well as the likely detrimental effect of withholding this treatment, which prolongs their gender dysphoria, impedes their social integration with their peer group and, in the case of trans girls, encourages the unwelcome increase in height.

Gender dysphoria per se, is not diminished by hormone-blockers, but by cross-sex hormones

Policy P5: *“Treatment from the 15th birthday will be not routinely commissioned in view of the limited available evidence on comparative effects and harms of cross sex hormones at the 15th birthday, as compared to initiating cross sex hormones at the 16th birthday or older;”*

Response: As above, why are the *benefits* not highlighted here? Cross-sex hormones (as above) alleviate dysphoria, and they enable young people to develop, physically, in line with their peers:

- Bone density is restored.
- The fatigue and lack of energy, hot flushes etc are alleviated.
- Height is better controlled.

Policy P5: *“changes in the current protocol should only be considered in the context of a research study for young people – the scope of which is yet to be agreed.”*

Response: **This is a case in which a clinical research could potentially be unethical. It is uncertain that it would provide data that could not be collected by a cohort study – that is a study of the effects of treatment on people who have received or are receiving that treatment. A phase 2 study would be impossible and would violate basic ethical standards of research ethics and laws and regulations on medical research. Therefore it is not clear what the research in question would seek to achieve – if it is an understanding of the benefits and harms in the long term of CSH the only ethical way to obtain this information is via a cohort study – there is simply no other alternative.** A research study merely serves to delay the inevitable, to the obvious detriment of the young people caught in this situation.

Many are already putting themselves in danger by self-medicating. More will do so. They do this despite knowing that in such circumstances the UCLH endocrinology service will reject them. By contrast, the adult services can allow the provision of a ‘bridging prescription’ so that people are brought into a properly prescribed and monitored situation. This raises questions of medical ethics. A treatment of known value is deliberately withheld because a young person has ‘broken the rules’.

Those who do not obtain treatment with cross sex hormones from overseas or by self-medicating will experience further deterioration in mental health.

It would have been sensible to look at the practices of other providers in The Netherlands, Germany, Belgium, Scandinavia, USA, Canada, who are providing earlier intervention in individual cases, and learning why they do that. The arbitrary 15th birthday is not a valid starting point for this research, so we welcome withdrawal of the research proposal.

The only fair and safe way to do this is to provide according to carefully assessed need: is the young person experiencing extreme gender dysphoria related to the body?; are they Gillick competent and therefore able to give informed consent; have the Frasier guidelines

been implemented to explain benefits of treatment and any potentially harmful consequences (e.g fertility issues) and how they may be prevented; do they understand the benefits of treatment and the consequences of non-treatment.

The following comment by Dr Wylie Hembree, who is chairing the Endocrine Society's review of its Guidelines is pertinent:

Using the rationale for waiting until 16 yo to allow the person to become mature enough to consent makes no sense since we have no reasonable means of assessing this attribute, other than many people think this is true. The REAL question to be asked, in my mind, is the individual assessment of the HARM waiting until age 16 yo could do to the person. This focus allows the mental health professional who earlier assessed persistence of gender dysphoria, the person administering puberty blockade, the parents and the adolescent all to be involved in the discussion and the decision. The HARM of early sex steroid treatment is how invasive would be the reversal of the physical changes (not to mention psychological changes) should gender dysphoria desist. How likely is that? The most helpful focus I have found is the assessment of HARM by waiting until 16 yo.

Policy P6

“hormone blockers, which are gonadotropin-releasing hormone analogues and suppress the onset of puberty.”

Response: That's not strictly accurate. Puberty has started, but only just at Tanner 2. A more accurate statement would be: “suppress further pubertal development”.

Policy P7

Response: (I suggest changes to how the following is expressed:

*Cross sex hormones: is where a patient takes the hormones **that are consistent with their gender identity** –of the preferred gender: for example:*

- *a trans man (female to male) or a non-binary person, assigned female, may ~~will~~ take testosterone, which is a masculinising hormone*
- *a trans woman (male to female) or a non-binary person, assigned male, may ~~will~~ take oestrogen, which is a feminising hormone*

The gender identity isn't 'preferred' – it just is

*Gender dysphoria is a condition where a person experiences discomfort or distress because there is a mismatch between their **gender identity and their sex assigned at birth (and associated primary and secondary characteristics, and the gender role typically associated with the assigned sex)***

biological sex and gender identity.

It's important that people understand that it's not necessarily all about the body; the role and expression feel wrong too.

P7 Policy: Use of the term “effects”

Response: Again, the use of the term 'effects', rather than 'benefits' is disingenuous

It should read throughout '**benefits and potential harms**'

P8 Policy:

"...of pre pubertal children who present with the features of a gender dysphoria, the dysphoria only persists in 10 to 20% throughout childhood, adolescence and into adulthood..."

Response

This a) outdated, and b) misleading.

The label gender dysphoria is applied by others: clinicians, parents etc, when what they are often witnessing is gender non-conformity. This may dissipate, or evolve as non-binary identities or be the precursor to lesbian, gay or bisexual identities. This is not 'desistance', it is a misreading (misdiagnosis) of certain behaviours. It should be pointed out that the reverse statistic applies to those who are gender dysphoric during puberty. The vast majority continue to be dysphoric until treated with cross-sex hormones.

Policy P8: *"Based on data from the national gender identity development service, the likely target population for this policy (i.e. adolescents aged over 15 but under 16 with gender dysphoria in whom cross sex hormones might be considered as a therapeutic option) is likely to be very small relative to the total number of referrals to the service."*

Response: Because the proposed clinical trial has been removed from the Policy Proposition, this section should be deleted. In any case, it is hard to understand how this estimate was calculated. Is the 2 year wait whilst on blockers factored in? Does this impact on the anticipated low numbers?

Again the wording should include 'benefits' rather than 'effects'.

The present protocol has established cross-sex hormone treatment only for the treatment of gender dysphoria after the 16th birthday, despite the fact that gender dysphoria may have been experienced for many years. This therefore leaves young people, under that age, UNTREATED for gender dysphoria, regardless of their medical need, their wishes and their competence to give informed consent.

P 8 Policy: *"A review was undertaken to identify the current evidence on use of cross sex hormone therapy for adolescents with persistent gender dysphoria after their 15th birthday."*

Response: The arbitrary 15th birthday cut-off, rather than assessing according to need and competence, means this research would be virtually meaningless. No studies have used this particular criterion, for very good reason, it's a nonsense.

P 9 Policy:

However, the median age at start of cross sex hormones for natal males was 17.9 years with a range of 13.3 to 22.3 years and for natal females 17.3 years with range of 13.7 to 19.8 years

Response: It is not clear at what age the older patients came into the system. Those who present at 21, may not get cross-sex hormones until 22. These figures mean nothing unless one looks at the age at which treatment is sought. But what it does show is that people much younger than 15 are being treated with cross-sex hormones elsewhere,

P9 Policy

- *“Cross sex hormones were generally well tolerated in natal males, although twelve of the 39 natal female patients had minor complications from **male (testosterone)** female cross sex hormones: seven developed severe acne, one developed androgenic alopecia, three had mild dyslipidaemia and one had mood swings.”*

Response: The above must be an error I think?

Policy p9

- *“Delemarre-van de Waal et al. (2006) reported significant decrease in growth potential under GnRH therapy.”*

Response: I don't think it is helpful to express this as above. Annelou De Vries talked about decreased 'velocity'.

The growth spurt in assigned males is 'hampered' (but that is helpful if you identify as a girl or at the feminine end of the gender spectrum) and the introduction of oestrogen caps growth so helps to reduce final height to female range, which is a good reason for intervening early.

And, because fusion of the growth plates is delayed, this is an opportunity to give those assigned female, growth stimulating medication to enable the achievement of typical male height.

In fact, Annelou De Vries (Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment) says:

“The age criterion of 16 years for the start of CSH may be problematic especially for transwomen, as growth in height continues as long as cross-sex steroids are not provided (causing the growth plates to close). Therefore, psychological maturity and the capacity to give full informed consent may surface as the required criteria for puberty suppression and CSH in cases that meet other eligibility criteria.”

Policy: P10

“Satisfaction with body image and levels of gender dysphoria were unchanged with hormone blockers, but decreased after starting cross sex hormones.”

Response This must be an error. It is the opposite. Satisfaction would increase with the addition of cross-sex hormones, as stated in the above Overall Assessment.

Policy p10

“Depression levels decreased after starting hormone blockers, but partially increased after starting cross sex hormones and prior to sex realignment, with natal females demonstrating higher levels of depression. Anxiety levels appeared to increase after starting cross sex hormones but anger levels decreased.”

Response: Actually T2 in the above study is after cross sex hormones and sex realignment surgery, not after CSH alone. In any case, the authors' conclusion is that “puberty suppression, followed by cross-sex hormones and gender reassignment surgery, provides gender dysphoric youth who seek gender reassignment from early puberty on, the opportunity to develop into well-functioning adults”.

Policy p10 *“Abel et al. (2014) considered the key ethical principles affecting decisions about early prescribing of cross sex hormones. The principle of non-maleficence (“first, do*

no harm”) offers the strongest ethical argument against early cross sex hormone therapy because the long-term effects of this are not well known and it has potential for sterility.”

Response: This paper was the work of a single author. So, it is incorrect to add “et al” to the reference.

The Policy Proposition presents a distorted and ill-founded argument. The paper by Abel takes no account of the later follow up work published by De Vries et al and Katchadourian et al in 2014. The long-term effects of treatment, including blockers, cross-sex hormones and surgery are reasonably now well-known. People in the Dutch program are not suffering bad effects from these treatments. The non-maleficence argument should be applied to not providing cross-sex hormones. As is pointed out by WPATH and others, **‘withholding treatment is not a neutral option’**. It is ‘doing’ something, and that something is causing harm. For this reason ‘omission of treatment’ is a criminal offence in some countries. Not treating is potentially more harmful than intervening with hormone-blockers and cross-sex hormones. Why is the Policy Proposition evading the question of the harm to mental and physical health of NOT treating?

Abel does say that “For many adolescents, the eventual feeling of comfort within one’s body far outweighs the ‘harm’ of losing the ability to procreate. In any case, gamete storage can be undertaken. It’s not ideal, but a young Gillick competent person has the right to choose – where is the end of the quote?

Beneficence is misapplied. The statement that “only a subset of patients on hormone blockers decide to proceed to cross ex hormones” is unsubstantiated. Abel does not provide a reference to substantiate this claim which therefore can and should be entirely dismissed. In fact, published research shows that the majority do, 87% of natal females and 65% of natal males.¹⁰. In any case, this is beside the point. The question is how best to help those patients who do opt for cross sex hormones? Also, the Policy Proposition claims that there is a significant prevalence of desistance, for which there is no supporting evidence. In the Khatchadourian et al study, only 3 out of 39 natal female patients desisted. It appears that none of the natal males did so.

The Policy Proposition ignores what Abel had to say about autonomy: “the ethical principle of respect for autonomy cannot be dismissed ... (it) is the strongest factor supporting progressive hormone treatments, including cross-sex hormone therapy”. See comments above. However, not everyone finds the 4 principles helpful in medical ethics.

Abel was not suggesting that cross sex hormones should not be used before the age of 16: he simply said that further research should inform practice and was pointing out that young people should be able to consent to CSH.

What Abel argues is debatable, because even if children don’t have capacity to consent, they still have a moral (and legal) entitlement to receive treatment that is in their best interests. So capacity is only a part of the issue. Of course in the case of CSH it is unlikely that the treatment can be in a child’s best interests if that child does not have an understanding of the pros and cons of it and of the alternatives. However, to say that the only relevant consideration is capacity clouds other important considerations: a balance needs to be made of benefits and harm of treating versus non treating. *What is likely to happen to that child in the short and long term if treatment is withheld is a central*

¹⁰ - Khatchadourian K, Amed S, Metzger D.L. 2014 Clinical management of youth with gender dysphoria in Vancouver. J Pediatr 164(4):906-11

consideration, which should not automatically become secondary to considerations around capacity.

Policy: P11

'The possibility of desistence ...'

Response: this is another deliberate skewing of the argument. Children up to the age of puberty may evolve as LGB or their cross-gender behaviours and expressions fade (possibly not in the longer term, but that follow-up hasn't been done). But this is not the stage or age group being discussed here.

Desistance, when it occurs, almost always relates to the time when the young person enters puberty. Few, if any desist after that, especially if they have been administered hormone-blockers and have experienced improved mental health.

Those who continue to feel gender dysphoric after the commencement of puberty continue into adulthood, and are comfortable with the medical interventions. So desistance is not an issue at the point of providing cross-sex hormones. If they were going to desist, they would already have done so.

In the De Vries article none of the cohort regretted or suffered as a result of treatment with cross-sex hormones. None desisted. In any case, cross-sex hormones are partially reversible, and reproductive capacity can be sustained in several different ways.

The Kreukels and Cohen-Kettenis article (Nat. Rev. Endocrinol. 7, 466–472 2011) also noted that in the early days, before hormone-blockers were introduced during puberty, "despite many years of psychotherapy, the gender dysphoria of most adolescents with GID does not often abate".

Policy p11: *"The inability to predict which patients will persist with treatment, detracts from the argument for beneficence."*

Response: Clinicians do not need to 'predict' which patients (clients) will persist, because the patients (clients) themselves will decide, at around Tanner 2, either that they wish to try the fully reversible GnRHa, or they don't want to because they identify as LGB or perhaps in some other way. Nobody is forced to go onto the analogue. If they do start the analogue, this also provides a 'breathing space' which the Dutch describe as 'diagnostic'. But the decision to take cross-sex hormones is at a later stage when the young person is already on the analogue, so the 'inability to predict' argument is irrelevant.

Policy p11: *Both genders showed improvement in symptoms with cross sex hormones".*

The Policy Proposition ignores the implications of this statement, which is that cross sex hormones are beneficial.

Policy P12

"Are the effects and harms of cross sex hormone therapy for adolescents after their 15th birthday with persistent gender dysphoria different for patients in whom irreversible physical changes have already occurred after onset of puberty?"

Response: We do not see the point of this question. The 15th birthday is arbitrary. Physical development will differ greatly depending on individual physiology and the stage at which hormone blocking commenced.

Intervention is progressively more urgent with those coming into the service at later stages of puberty. There seems to be little understanding that for those assigned male, they continue to virilise well past Tanner 4/5. Immediate intervention can help to reduce the increased density and strength of facial hair in trans girls/women. Earlier intervention with estradiol will also cap growth which is vital in those who may otherwise become taller that is common for girls. Trans men's breast development can be halted and may even regress somewhat. The gradual virilisation in terms of facial hair, musculature etc., helps them the fit in with their peer-group

Policy P12: *“Rosenthal et al. (2014) expressed the opinion that transgender youth who are at Tanner stage 4 to 5 but less than 14 years of age, should only be considered for pubertal suppression but not for cross sex hormones before 16 years of age”*

Response Rosenthal is misquoted here. He said:

“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 (e.g. to stop menses in an FtM adolescent) but without supportive outcome data, not currently candidates for cross-sex hormones in most circumstances”

He is referring to >14s, and **says nothing about 16 years of age.**

Rosenthal also says:

“not only could delaying such treatment (cross sex hormones) until that age (16) be detrimental to bone health, but keeping someone (on blockers) in a pre-pubertal state until this age would isolate the individual further from the age-matched peers, with potentially negative consequences for emotional wellbeing”.

In other words, it appears that the author's of the Policy Proposition are deliberately misusing Rosenthal's text and trying to make it the opposite of what he is saying

Policy P12

In conclusion, given the current accepted practice in most countries of offering cross sex hormones at 16 years of age or greater, there is insufficient evidence available on the effects and harms of cross sex hormones at a younger age to warrant a change to the current protocol.

Response:

This is misleading. Other centres are providing cross-sex hormones at earlier ages depending on the criteria applicable to that particular young person.

In the UK, we have already dragged behind and failed in our care of our young gender non-conforming children and adolescents. This has led to families taking the drastic step of travelling abroad for treatment.

The UK was 6 years behind, for instance, The Netherlands, Belgium, Germany, USA, Canada, Australia in providing GnRHα for pubertal children;

The UK was 9 years behind in accepting that it was clinically appropriate to initiate such treatment according to Tanner Stage, not chronological age.

Currently, in this document, the arguments for treating young people with cross-sex hormones earlier than 16, or even earlier than 15, are actually supported by many of the authors cited in the NHSE document above, but their evidence has often been ignored misrepresented, so that it appears to support the most conservative approach.

Further Considerations - Bolam Principles

Doctors providing this treatment are protected by the Bolam defence, (despite the Bolitho case which the NHS England Commissioners incorrectly deemed to reduce the protection of the Bolam defence during our discussion with them on 24 March 2016).

Bolam stands, except when "a judge can be satisfied that the body of expert opinion cannot be logically supported at all".

Bolam Principles: "*If a doctor reaches the standard of a responsible body of medical opinion, he is not negligent*".

- 1) it must be established that there is a [duty of care](#) (between a doctor and patient this can be taken for granted).
- 2) it must be shown that the duty of care has been breached. This is where the Bolam test is relevant, because falling below the standard of a responsible body of medical men means that person will be considered negligent.
- 3) it must be shown that there was a [causal](#) link between the breach of duty and harm.
- 4) it must be shown that the harm was not too [remote](#).

The Bolam defence could be used to defend a service providers who follow the lead of others around the world who provide cross-sex hormones for patients under 16 based on a set of criteria that are not directly linked to age.

Moreover, it is more likely that the UK service providers will be challenged because they do NOT provide cross-sex hormones before 16, or earlier in individual cases, where such intervention is logical, and supported by best practice elsewhere.

The Bolam defence in these circumstances may fail because:

It can be demonstrated, in the articles referred to in the draft Policy, that a responsible body of medical men [sic] are providing cross-sex hormones in individually assessed cases, for young people under the age of 16, some of whom are under 14.

The reasoning has now been accepted in the UK that treating according to Tanner Stage rather than age is appropriate when providing hormone-blockers.

It is not logical to apply different reasoning in respect of cross-sex hormones.

This is especially the case where such treatment is acknowledged to be effective in treating gender dysphoria (which hormone-blockers are not).

Cross-sex hormones are partially reversible.

It is therefore irresponsible of clinicians to leave young people in limbo:

Hormone-blockers are indispensable, but they cause lack of energy, tiredness and menopausal symptoms;

Without oestrogen, trans girls will not have the physical pubertal changes that their classmates are experiencing, such as breast development. Their height is likely to be greater than is usually achieved by girls.

Without testosterone, trans boys will not begin to grow facial hair, their voices will remain feminine.

Social integration is therefore harder for both these groups.

Logically, the age criterion should be abandoned.

The young person should be assessed for Gillick competence using the Fraser guidelines; that is, they should have the capacity to understand the benefits and potential harms of both treatment with cross-sex hormones, and without.

“Therefore, psychological maturity and the capacity to give full informed consent may surface as the required criteria for puberty suppression and CSH in cases that meet other eligibility criteria.” Annelou De Vries 2014

Fertility can be preserved, and this should be discussed, if necessary with the specialist providers of gamete storage.

Further Considerations – Research

In Europe, the Council Directive 17/318/EEC states that all clinical trials ought to be in accordance with the Declaration of Helsinki. The Declaration reads at paras 7 and 8.

7. Medical research is subject to ethical standards that promote and ensure respect for all human subjects and protect their health and rights.

8. While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.

And the CIOMS guideline 11 states:

“Among the **essential features of ethically justified research** involving human subjects, including research with identifiable human tissue or data, **are that the research offers a means of developing information not otherwise obtainable**, that the design of the research is scientifically sound...”