The Tavistock's Experiment with Puberty Blockers*

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In 1994 a 16-year-old girl who wished to be a boy, known to us as B, entered the Amsterdam Gender Clinic. She was unique for having her sexual development halted at the age of 13, after an adventurous paediatric endocrinologist gave her a Gonadotropin-Releasing Hormone agonist (GnRHa). Originally developed to treat prostate cancer, these drugs are also used to delay puberty when it develops abnormally early: in girls younger than 8, and boys younger than 9. The endocrinologist's innovation was to use the drug to stop normal puberty altogether, in order to prevent the development of unwanted secondary sexual characteristics—with the aim of administering cross-sex hormones in later adolescence. Dutch clinicians used B's case to create a new protocol for transgendering children, which enabled physical intervention at an age far below the normal age of consent (Cohen-Kettenis and Goozen 1998).

The Dutch protocol promised to create a more passable simulacrum of the opposite sex than could be achieved by physical intervention in adulthood. It was therefore embraced by trans-identified children and their parents, by older transgender activists, and by some clinicians specializing in gender dysphoria. The Gender Identity Development Service (GIDS), part of the Tavistock and Portman NHS Foundation Trust, treats children with gender dysphoria from England, Wales, and Northern Ireland. It launched an experimental study of "puberty blockers"—the more friendly term for GnRHa when administered to children with gender dysphoria—in 2011. The experiment gave triptorelin to 44 children, which in all or almost all cases led eventually to cross-sex hormones. This paper describes the origins and conduct of this study and scrutinizes the evidence on its outcomes. It draws on information obtained by requests under the Freedom of Information Act to the Tavistock, to the NHS Health Research Authority, and to University College London (UCL). I will argue that the experimental study did not properly inform children and their parents of the risks of triptorelin. I will also demonstrate that the study's preliminary results were more negative than positive, and that the single published scientific article using data from the study is fatally flawed by a statistical fallacy. My conclusion is that GIDS and their collaborators at UCL have either ignored or suppressed negative evidence. Therefore the NHS had no justification for introducing the Dutch protocol as general policy in 2014.

* Some of this material was first posted on Transgender Trend (Biggs 2019a, 2019b); most will appear in an edited volume (Moore and Brunskell-Evans 2019). Earlier drafts were shared with reporters at *The Times* (including Lucy Bannerman) and BBC Newsnight (including Deborah Cohen). Special thanks are due to Stephanie Davies-Arai, Elin Lewis, Susan Matthews, and an anonymous former clinician at GIDS for sharing their extensive knowledge, and to Sherena Kranat for her steadfast support. Credit is due also to three woke students taking the Sociology MSc who exhorted me to educate myself on the subject of transgendered children.

Origins

GnRHa drugs have never been licensed for treating children suffering from gender dysphoria. The particular drug used in Britain, as in the Netherlands, is triptorelin, which is licensed to treat advanced prostate cancer and sexual deviance in men; endometriosis and uterine fibroids in women (for no longer than six months); and precocious puberty in children (Electronic Medicines Compendium 2019). Using GnRHa to treat gender dysphoria is "a momentous step in the dark", for it is "presumptuous to extrapolate observations from an intervention that suppresses pathologically premature puberty to one that suppresses normal puberty" (Richards et al. 2018). Therefore the origins of the Tavistock's experiment needs some explanation.

The Dutch protocol became well known in Britain before the first scientific article was published. A television documentary showed girls who wished to be boys travelling to meet their peers in the Netherlands, who were taking GnRHa as young as 13 (Channel 4 1996). This inspired Stephen Whittle—who led the transgender campaigning organization Press for Change—to argue for a legal right to access "pubertal suppression"; doctors who failed to provide drugs could be vulnerable to litigation (Downs and Whittle 2000; Wren 2000: 224). This argument was first advanced at a conference at Oxford in 1998, whose keynote speaker was the head of the Amsterdam Gender Clinic. There was little movement, however, over the next few years. Guidelines issued by the British Society for Paediatric Endocrinology and Diabetes (BSPED) in 2005 still insisted that children had to reach full sexual development (known as Tanner Stage 5)—around the age of 15—before being prescribed GnRHa drugs.

A crucial role was played by organizations that campaign for the transgendering of children: the Gender Identity Research and Education Society (GIRES) and Mermaids. GIRES organized a symposium in London in 2005 to develop "guidelines for endocrinological intervention". Additional funding came from Mermaids, two medical charities—Nuffield Foundation and King's Fund—and the Servite Sisters Charitable Trust Fund. This brought together the creators of the Dutch protocol, American clinicians like Norman Spack in Boston, and key British figures such as Domenico Di Ceglie, the Director of GIDS, and Polly Carmichael and Russell Viner, both at Great Ormond Street Hospital. (The latter two would lead the 2011 experiment.) Some of the participants vigorously lobbied for the Dutch protocol. Veronica Sharp from Mermaids "described users' and parents' views of the available treatments, and the anguish they may experience when hormone blocking is delayed" (GIRES 2005). The symposium ended with agreement to push for amendments to guidance from bodies like BSPED, and to conduct collaborative research between London, Amsterdam, and Boston. There was another meeting in Amsterdam in the following year, but the collaboration did not eventuate.

International developments did enable parents to circumvent the NHS. GIRES (2006) warned that "those who can in any way afford to do so have to consider taking their children to the USA". The first was Susie Green, who later became the chief executive of Mermaids. In 2007 she took her son Jackie, aged 12, to Boston, to purchase a prescription for GnRHa from Spack; the drug was supplied by an online Canadian pharmacy (*Sun*, 19 October 2011). A presentation at Mermaids, presumably by Green, instructed parents in this medical tourism (Mermaids 2007). Spack treated a further seven British children over the next few years (*Times*, 22 January 2012).

By 2008, GIRES was more strident in criticizing British clinicians. One of its founders, Terry Reed, denounced them as "transphobic":

> They are hoping that during puberty the natural hormones themselves will act on the brain to 'cure' these trans teenagers. What we do know is what happens if you don't offer hormone blockers. You are stuck with unwanted secondary sex characteristics in

> the long term and in the short term these teenagers end up suicidal. (*Guardian*, 14 August 2008)

Reed was clearly drawing on the experience of her own child, who transitioned two decades before. This feature article in the *Guardian* signalled that the controversy was becoming newsworthy. GIRES objected to the fact that the Royal Society of Medicine had not invited many advocates for the Dutch protocol to its conference on gender dysphoria in adolescents. The conference was noteworthy as the occasion for a rare public protest by transgender activists (Brown 2018: 311). They targeted Kenneth Zucker from Toronto, a leading psychologist, who was denounced as a "transphobic doctor who supports repression and torture of gender-variant children" (Kennedy 2008). Criticism was not confined to activists. The psychiatrist Richard Green, formerly head of Britain's Gender Identity Clinic for adults, arranged a rival conference:

> Medical experts from the US, Canada and the Netherlands who treat young teenage transsexuals with puberty-blocking medications at the first signs of body change will discuss their programmes. Teenage Dutch transsexuals and their parents will discuss their positive experiences with blocking puberty. A UK family will report how their desperation led to them travelling to the US for treatment. (*Guardian*, 28 August 2008)

Contributors included a medical ethicist at the University of Manchester who denounced Viner's caution about the risks of GnRHa, on the grounds that "anything is better than life in an alien body" (Giordano 2008: 583). As the decade drew to a close, the demand for puberty blockers was irresistible.

Experiment

Shortly after Carmichael became Director of GIDS in 2009, she decided to offer GnRHa to younger children as part of a research project (BBC News 2009). The chief investigator was Viner at UCL; co-investigators included Carmichael and Di Ceglie, who had moved to Director of Training, Development, and Research. The proposal—"Early pubertal suppression in a carefully selected group of adolescents with gender identity disorder" —was rejected by the NHS Research Ethics Committee, on the grounds that it was not a proper randomized trial and therefore could not yield valid results (GIDS 2019b). The revised proposal (Viner 2010) argued that a randomized trial was not practical. Just as importantly, perhaps, it was submitted to a different Research Ethics Committee. This Committee approved the experiment in February 2011. Aside from the absence of any control group, what is surprising is how the proposal failed to maximize information on the effects of GnRHa. Children were asked to consent to completing questionnaires only until they were 16. If they had been asked to give consent for the researchers to access their medical records in perpetuity, then GIDS would have been able to analyze effects of the drugs over the long term. Although the proposal called this a "study", I prefer the word "experiment" (following Davies-Arai 2018) to underline the fact that it involved a drug regime that has never been licensed for this condition anywhere in the world.

The research proposal provided a comprehensive review of the potential benefits and risks of GnRHa. "It is not clear what the long term effects of early suppression may be on bone development, height, sex organ development, and body shape and their reversibility if treatment is stopped during pubertal development" (Viner 2010). Viner spoke frankly in a later newspaper interview:

> If you suppress puberty for three years the bones do not get any stronger at a time when they should be, and we really don't know what suppressing puberty does to your brain development. We are dealing with unknowns. (*Daily Mail*, 25 February 2012)

This caution echoed previous comments by Carmichael: "the debate revolves around the reversibility of this intervention—physical and also psychological, in terms of the possible influence of sex hormones on brain and identity development" (Carmichael and Davidson 2009: 917).

When the Tavistock announced the study, however, it claimed that GnRHa treatment "is deemed reversible" (Tavistock 2011). More disturbing is the fact that the Patient Information Sheet provided to children when they gave consent also minimized the risks acknowledged in the research proposal.[1] Although the sheet ran to four pages, it omitted the fact that GnRHa has never been certified as safe and effective for treating gender dysphoria. The words "experiment" or "trial" did not appear. Under "the possible benefits of taking part" came this astonishing statement:

> If you decide to stop the hormone blockers early your physical development will return as usual in your biological gender [sic]. The hormone blockers will not harm your physical or psychological development.

This directly contradicted the chief investigator's own statements.

As for side effects, there was a vague warning that the drug "could affect your memory, concentration and the way you feel". The triptorelin formulations used by GIDS—Gonapeptyl® Depot and Decapeptyl® SR—carry detailed warnings of side effects. Depression is common, affecting between 1% and 10% of patients (Ferring Pharmaceuticals 2016), and "may be severe" (Ipsen 2017). Other side effects affecting up to 10% of children treated for precocious puberty include "pain in abdomen, pain bruising [sic], redness and swelling at injection site, headache, hot flushes, weight gain, acne, hypersensitivity reactions" (Ipsen 2017). None are mentioned in the Patient Information Sheet.

One further absence deserves emphasis. The 2005 Symposium had noted the paradox that blocking a boy's puberty left him with stunted genitalia, which were then not sufficient to transform into a pseudo-vagina. "Although there are surgical means to deal this difficulty, the patient and her parents or guardians should be fully informed about its implications" (GIRES 2005). The Patient Information Sheet failed to mention this.

All these omissions might be explained by the input of parents who saw GnRHa as an elixir that would enable their child to change sex. "The wording … was agreed with a number of families with whom the draft had been discussed" (Di Ceglie 2019: 149). Whatever the cause, GIDS and UCL gave children and parents incomplete and misleading information, which contradicted the research proposal. Whether they could provide informed consent, in such circumstances, is open to serious question.

The basic parameters of the experiment are not entirely clear. It is known that GnRHa was administered to 44 children, starting from June 2011 (Tavistock 2019b). A conference presentation and published abstract described "baseline characteristics of a UK cohort beginning early intervention" but rather confusingly these numbered 50 subjects (Gunn et al. 2015a; Gunn et al. 2015b). The additional six, "included to improve the sample size", "were not eligible for this study due to being further developed in puberty and were treated at 15 years" (GIDS 2019b). Apparently the last child to enter the experiment was recruited in April 2014 (GIDS 2019b) and presumably some months elapsed before he or she was actually prescribed GnRHa.

There is contradictory information on the age of the subjects. GIDS recently stated that the youngest gave consent at the age of 12 years and one month (Tavistock 2019b). According to the initial presentation, however, the youngest child was 10.3 years "at hormone blockers" (Gunn et. al. 2015a: slide 17). The proposal approved by the Ethics Committee explicitly

[1] Version 1.0, 4 November 2010, obtained from UCL under the Freedom of Information Act. One portion is reproduced by Di Ceglie (2019: 149).

specified "age 12 and above" in the inclusion criteria (Viner 2010), and so the administration of drugs below this age would be a serious breach. Possibly the figure in the presentation was a typographical error, but another slide gives the age range at referral to the endocrine clinic as "10–15 years" (slide 14). A subsequent report gives the mean age at "start GnRHa" as 13.16, with a standard deviation of 1.06 (GIDS, 2015: 50). A Normal distribution with these parameters would have 14% of observations below 12; if you drew 44 observations from this distribution, the probability that none fell below 12 is only 0.2%. This is conjectural, of course, but it is difficult to reconcile these parameters with a minimum age of 12.

Results

Three years after the experiment began, Carmichael announced success to the tabloid press. "Now we've done the study and the results thus far have been positive we've decided to continue with it" (*Mail on Sunday*, 17 May 2014). Her statement was at best misleading. Six months earlier, she had already planned to continue the experiment indefinitely (*Sunday Times*, 17 November 2013). Then the sole justification was the large number of parents demanding drugs. At that point, the experiment had started only 23 children on triptorelin. These pronouncements make a mockery of Carmichael's earlier bromide: "as professionals we need to be looking at the long term and making sure this treatment is safe" (*Daily Telegraph*, 15 April 2011). Given the uncertainty surrounding the minimum age, it is telling that when she announced the experiment's success, she envisaged recruiting younger children. "Twelve is an arbitrary age. If they started puberty aged nine or ten instead of 12, as long as they're monitored and the bone density doesn't suffer, then it is right that the aim is to stop the development of secondary sex characteristics" (*Mail on Sunday*, 17 May 2014).

Where are these "positive" results described by Carmichael in 2014?[2] The current GIDS webpage on the evidence for puberty blockers states that "research evidence for the effectiveness of any particular treatment offered is still limited" (GIDS 2019a). There is no mention of its own experiment; it cites only research from the Netherlands. This is curious seeing that Carmichael told the World Professional Association for Transgender Health (WPATH) that "our results have been different to the Dutch" (Carmichael 2016). Di Ceglie stated last year that the "project is ongoing and the results are yet to be published" (Di Ceglie 2018: 14).

After my own investigation (Biggs 2019a; *Daily Telegraph*, 8 March 2019) pointed out the absence of published results, GIDS (2019b) posted a belated update on the experiment. It lists a total of two scientific publications; both are one-page abstracts on the physical effects of GnRHa. One describes the height of 14 of the subjects after they continued to cross-sex hormones (Catanzano and Butler 2018). Another reports bone density for children on GnRHa, some of whom were subjects in the experiment (Tobin, Ting, and Butler 2018). Density was measured over three years for 31 children.[3] The authors state reassuringly that bone density did not decline in absolute terms. This is misleading, because growing children need density to *increase* (Laidlaw 2018). The abstract acknowledges that the children experienced a decline relative to the norm for their age group, and this decline was especially marked for girls. By year three, the average girl on GnRHa had lower bone density than 97.7% of the population in her age group. Surely this raises serious concerns?

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[2] I emailed the address listed on the webpage announcing the study (communications@tavi-port.nhs.uk) on 1 February 2018, inquiring after the results. There was no reply.

[3] It is not clear whether "year 1" refers to the baseline before GnRHa or to one year after GnRHa. My email of 11 July to the authors requesting clarification has not yet been answered.

Diligent searching has uncovered unpublished results on the psychological effects. Most revealing is an appendix to Carmichael's report to the Tavistock's Board of Directors (GIDS 2015).[4] It tracks 30 of the children on triptorelin, measuring changes after one year of the drug regime; presumably the remaining 14 subjects had not completed their first year on the drug.[5] The text is sometimes internally inconsistent and occasionally contradicts the tabulated figures, suggesting that the appendix was prepared in haste. But we can summarize those changes that were reported as statistically significant (p-value < .05). Only one change was positive: "according to their parents, the young people experience less internalizing behavioural problems" (as measured by the Child Behavior Checklist). There were three negative changes. "Natal girls showed a significant increase in behavioural and emotional problems", according to their parents (also from the Child Behavior Checklist, contradicting the only positive result). One dimension of the Health Related Quality of Life scale, completed by parents, "showed a significant decrease in Physical well-being of their child". What is most disturbing is that "a significant increase was found in the first item 'I deliberately try to hurt or kill self'" (in the Youth Self Report questionnaire). Astonishingly, the increased risk of self-harm attracted no comment in Carmichael's report. Given that puberty blockers are prescribed to treat gender dysphoria, it is paradoxical that "the suppression of puberty does not impact positively on the experience of gender dysphoria" (measured by the Body Image Scale). When differentiated by sex, the impact was positive for boys on one aspect of body image, but negative for girls on two aspects.

Results for the 44 children after one year on triptorelin were given in two presentations to WPATH in 2016. Unfortunately only the abstracts are obtainable.

> For the children who commenced the blocker, feeling happier and more confident with their gender identity was a dominant theme that emerged during the semi-structured interviews at 6 months. However, the quantitative outcomes for these children at 1 years time suggest that they also continue to report an *increase in internalising problems and body dissatisfaction*, especially natal girls. (Carmichael et al. 2016, my emphasis)
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> Expectations of improvement in functioning and relief of the dysphoria are *not* as extensive as anticipated, and psychometric indices do *not* always improve *nor* does the prevalence of measures of disturbance such as deliberate self harm improve. (Butler 2016, my emphasis)

Where are the positive results announced by Carmichael in 2014? Curiously, both presentations are omitted from the recent list of publications on the experiment (GIDS 2019b).

In evaluating the psychometric evidence, we should remember that children and parents alike had a clear bias towards reporting favourable outcomes; after all, they had enrolled in the experiment because they wanted to take GnRHa. This positive bias increases the probative value of negative evidence. Why were these negative results never published?

There is one article on the outcome of puberty blockers, coauthored by Carmichael, which apparently includes some data from the experiment (Costa et al. 2015). The article discusses 101 children given GnRHa at GIDS, starting at ages ranging from 13 to 17. Given the date of publication, most or all of those children who started at ages 13 and 14 (and perhaps 15?) must have been part of the 2011 experiment. But the age range also indicates the exclusion of

[4] My annotated version is available at http://users.ox.ac.uk/~sfos0060/Annotated_GIDS_results.pdf.

[5] As the final subject was recruited in April 2014, it is surprising that so many had not completed a year on triptorelin by the time the report was issued in June 2015. I previously (Biggs 2019a) erred badly in describing these results as pertaining to 44 subjects, which is the number given on the first page (GIDS 2015: 50).

the experimental subjects who commenced GnRHa before the age of 13. Excluding some subjects without justification is poor practice, and raises suspicion of cherry picking. Nevertheless, we should consider this article as having some bearing on the 2011 experiment.

The abstract proclaims that "adolescents receiving also puberty suppression had significantly better psychosocial functioning after 12 months of GnRHa … compared with when they had received only psychological support" (Costa et al. 2015: 2206). The literature treats this article as providing evidence in favour of puberty blockers (e.g. Butler et al. 2018; Heneghan and Jefferson 2019). But the abstract is misleading: the analysis actually *failed to detect any difference* between children who were given GnRHa and those who were not. To understand this, we need to scrutinize the article in detail. (Statistically minded readers will recognize the fallacy described by Gelman and Stern 2006.)

The analysis starts with 201 adolescents diagnosed with gender dysphoria. The children were divided into two groups: those deemed eligible for puberty blockers immediately, and those who needed more time due to "comorbid psychiatric problems and/or psychological difficulties". This second group did not receive any physical intervention during the time of analysis, and so serves as a comparison group. Both groups received psychological support. The article chooses one outcome, psychosocial functioning as measured by the Children's Global Assessment Scale (CGAS). This scale was administered at the outset, and then after six, twelve, and eighteen months. It is suspicious that the article omits all the outcomes that were negative in the preliminary results of the 2011 experiment (GIDS 2015): the Child Behavior Checklist, the Youth Self Report Questionnaire, the Health Related Quality of Life scale, and the Body Image Scale.

The authors graph the CGAS results, but without confidence intervals—which indicate the extent of random statistical variation or noise. (The graph is redrawn with confidence intervals in Biggs 2019a.) The smaller the sample, the greater this noise. These samples shrank over time: after eighteen months, the group getting drugs numbered only 35, and the comparison group 36. The article does not explain why two thirds of the subjects disappeared. Presumably they did not stop the medication, because none of the children in the 2011 experiment quit GnRHa in the first two years (Gunn et al. 2015b).

The group given puberty blockers from six months onwards showed improvement at eighteenth months: the average CGAS score had increased from 61 to 67. This improvement is statistically significant, and it is the one that the authors chose to highlight. However, these children also received psychological support, and so attributing this improvement to medical intervention is unjustified. The crucial comparison is between the group receiving GnRHa and the comparison group. The latter's average CGAS score after eighteen months was lower, 63 compared to 67. This is hardly surprising because the comparison group was composed of children with more serious psychological problems. Anyway, this difference is *not statistically significant*: a two-tailed *t*-test for the difference between group means yields a *p*-value of .14, far beyond the conventional .05 threshold. In other words, the samples were so small, and there was such wide variation in scores within each group, that we can draw no conclusions. There is no evidence that puberty blockers improve psychosocial functioning. No wonder that GIDS' own webpage on the evidence for medical intervention does not cite this article, nor does the recent update on the experiment (GIDS 2019a, 2019b).

The failure to fully publish the results of the experiment—for all 44 children given triptorelin, on all the outcomes that the study measured—suggests that it was a pretext to administer unlicensed drugs rather than an attempt to acquire scientific knowledge.

Consequences

The absence of comprehensive publications would be serious enough if the unlicensed use of triptorelin had been confined to the 44 experimental subjects. Sometime around 2013, however, the Director of GIDS transitioned from scientific caution to enthusiastic advocacy. Her new attitude was manifested in a BBC television documentary—aimed at children aged 6 to 12—broadcast in November 2014. It followed a 13-year-old girl who wished to be a boy, Leo, who was one of the experimental subjects. Carmichael appears on camera to reassure Leo:

> The blocker is an injection that someone has every month which pauses the body and stops it from carrying on to grow up into a man or a woman. … And the good thing about it is, if you stop the injections, it's like pressing a start button and the body just carries on developing as it would if you hadn't taken the injection. (BBC 2014)

To emphasize this point for the juvenile audience, the film superimposes a pause button on the screen. The clearest indictment of her statement to children comes from her own words a year later:

> The blocker is said to be completely reversible, which is disingenuous because nothing's completely reversible. It might be that the introduction of natal hormones [those you are born with] at puberty has an impact on the trajectory of gender dysphoria. (*Guardian*, 12 September 2015)

By 2015, however, GIDS had embraced the Dutch protocol with enthusiasm. "The Early Intervention Clinic will continue to follow the Service's 2011 research protocol, which *following evaluation*, has now become established practice, with the exception that hormone blockers will now be considered for any children under the age of 12 if they are in established puberty" (NHS England 2015: 26, my emphasis). By 2017, GIDS (including its satellite operation in Leeds) had prescribed GnRHa for a total of 800 adolescents under 18, including 230 children under 14 (*Mail on Sunday*, 30 July 2017). New prescriptions were running at 300 per year (BBC News, 2018). Freedom of Information requests submitted at the end of 2018 revealed that neither GIDS nor University College London Hospitals NHS Foundation Trust (which provides endocrinology services) kept precise records of the number of children given GnRHa; "work is currently in progress to manually enter all hormone blocker prescription data onto a database, pending future meetings with UCLH and LGI [Leeds General Infirmary] to ascertain who is collecting this info and how it is to be reported."[6] A subsequent request, however, revealed that 267 children under 15 were referred to the endocrine clinic and consented to puberty blockers from the beginning of 2012 to the end of 2018 (Tavistock 2019a). This figure includes most of the 44 experimental subjects, excepting perhaps half a dozen who started in 2011.

The abstract describing the baseline characteristics of the children in the experiment concluded: "Assessment of growth, bone health and psychological outcomes will be important to assess the medium and *long-term safety and effectiveness* of early intervention" (Gunn et al. 2015b: A198, my emphasis). This aspiration was never implemented. GIDS recently acknowledged that it loses track of its patients after they turn 18, blaming "the frequent change in nominal and legal identity, including NHS number in those referred on to adult services"—"to date they have not been able to be followed up" (Butler et al. 2018: 635).[7] By contrast, the Amsterdam clinic does attempt to trace its patients over time. The

[6] Internal Review (18-19312) of Susan Matthews' Freedom of Information request to the Tavistock (18-19230), 24 February 2019.

[7] Transgender activists successfully lobbied the NHS to provide new numbers to patients as well as to change the sex on their medical records (Birch 2014).

pioneer, B, has been followed to the age of 35. He did not regret transition, but scored high on the measure for depression. Owing to "shame about his genital appearance and his feelings of inadequacy in sexual matters", he could not sustain a romantic relationship (Cohen-Kettenis et al. 2011: 845). To the clinicians, however, this case exemplifies the success of the Dutch protocol.

Conclusion

GIDS and UCL launched an experiment in 2011 to use GnRHa to stop puberty in children suffering from gender dysphoria. The impetus for this unlicensed treatment came from children and parents, along with transgender activists and some clinicians, who seized on the notion that blocking puberty was akin to alchemy—it would enable a child to change sex, as long as he or she started young. Given unrelenting pressure from Mermaids and GIRES, supported by the climate of opinion among the *Guardian*-reading classes, the Tavistock arguably had to concede to the demand for GnRHa below the age of 16. From the outset, however, the experiment was flawed. The Patient Information Sheet understated the risks of this unlicensed treatment, despite those risks being acknowledged explicitly in the research proposal. Worse was to come. Before the experiment had run its course, Carmichael claimed "that the results thus far have been positive" in order to justify what must have been a premeditated decision to incorporate the Dutch protocol into the policy of GIDS. She even appeared on children's television to disingenuously promote GnRHa.

In fact, the initial results showed predominantly negative outcomes. The only tabulated data available, for 30 of the subjects after a year on triptorelin, showed that children reported greater self-harm; girls experienced more behavioural and emotional problems and expressed greater dissatisfaction with their body—so drugs exacerbated gender dysphoria (GIDS 2015). The fact that these outcomes have never been published is a serious indictment of Carmichael, Viner (now President of the Royal College of Paediatrics and Child Health), Di Ceglie, and the other scientists who proposed the research.[8] The failure can be highlighted by comparing another use of triptorelin: the treatment of hypersexuality in men, for which it is licensed. The chemical castration of seven dangerous sex offenders in Broadmoor Hospital resulted in a report spanning two pages, which detailed the adverse side effects experienced by three patients (Ho et al. 2012). The use of triptorelin on 44 adolescents—off license—has produced only two single-page abstracts reporting outcomes for subsets of the subjects (Catanzano and Butler 2018; Tobin, Ting, and Butler 2018).

Some of the experimental subjects were apparently included with older adolescents from GIDS in one published article (Costa et al. 2015). It examines a single outcome measure—notably not one of the measures that yielded negative effects in the preliminary results. This article misrepresents its finding. Properly analyzed, it shows no evidence for the effectiveness of drugs: there was no statistically significant difference in psychosocial functioning between the group given triptorelin and the comparison group given only psychological support.

My critique has evaluated the Tavistock's experiment in accord with its own aims, as laid out in the 2010 research proposal. For reasons of space, this paper has not discussed three additional serious problems attending the use of GnRHa to block puberty. The Dutch protocol was originally touted as diagnostic aid as well as treatment; it would give the child time to ponder her or his gender identity (Cohen-Kettenis and van Goozen 1998). In fact, however, children given GnRHa almost invariably progress to cross-sex hormones. The 2011 experiment was typical insofar as none of the children is known to have stopped the drug regime after one or two years (Gunn et al. 2015; Carmichael et. al 2016). (GIDS has never

[8] Names were redacted in the copy obtained from the Health Research Authority.

revealed the proportion who went on to cross-sex hormones.) Before the introduction of puberty blockers, around four fifths of young children with gender dysphoria would grow out of it naturally, typically becoming gay, lesbian, or bisexual adults (e.g. Zucker 2019). Using GnRHa to block puberty does not mean pressing a pause button, as Carmichael asserted—it is more like pressing fast forward into cross-sex hormones and ultimately surgery.

The second problem is obvious. Blocking puberty effectively destroys the individual's ability to have children. If the adolescent stops taking GnRHa, fertility should recover, but as we have seen, stopping is exceptional. The third problem is rarely admitted. Blocking puberty impedes the development of sexual functioning; some children given GnRHa never develop the capacity for orgasm (Jontry 2018). There is a strong taboo against mentioning this. The word 'orgasm' did not appear in the proposal for the 2011 experiment, and never appears on the GIDS website. When the endocrinologist at GIDS, Gary Butler, was asked about the effect of GnRHa on the ability to orgasm, he refused to answer.[9]

Since my critique was initially posted in March (Biggs 2019a), GIDS has responded with prevarication and obfuscation. When a parliamentary question was asked on my behalf, the House of Lords was told on 22 May that the Tavistock "plans to publish the data once all of the young people in the study have reached the stage when a clinical decision is made about moving from pubertal suppressants to cross-sex hormones, which the Trust expects to occur in the next 12 months" (Blackwood 2019). Just over a month later, GIDS belatedly posted a webpage providing an update on the experiment. "The study concluded in February 2019 when the last cohort member began the next stage of therapy (cross-sex hormones) at age 17 years" (GIDS 2019b). How can these two statements be reconciled? If the study had really finished in February, coincidentally just before my critique appeared, why was Parliament told in May that it would finish in the next twelve months?

"Analysing and extrapolating from different data sets out of context can be misleading" states the Tavistock (*Daily Telegraph*, 8 March 2019), downplaying my revelation of negative results. My analysis was dictated by the fact that GIDS and UCL produced a congeries of inconsistent data. The number of subjects varies from 30 (GIDS 2015) to 31 (Tobin, Ting, and Butler 2018) to 44 (e.g. Carmichael et al. 2016) to 50 (e.g. Gunn et al. 2015a) to 101 (Costa et al. 2015). It has taken me—along with Elin Lewis, Susan Matthews, and two others who must remain anonymous—many months of painstaking effort to reconstruct the course and results of the experiment. To dispel this confusion, Viner and Carmichael could simply tabulate *all* the various outcomes for *all* 44 children given GnRHa in this experiment. If the results were really positive, why the secrecy? Even after the experiment has come under scrutiny, GIDS still seems to be concealing negative findings. "Outcomes and outputs from the study" (GIDS 2019b) notably omits unpublished sources that showed psychological outcomes to be disappointing (Butler 2016) or negative (GIDS 2015; Carmichael et al. 2016). The conference presentation disclosing that the youngest child given GnRHa was 10 (Gunn et al. 2015a) has now vanished from the website.

By now the experiment has been running for eight years. According to the original research proposal, "At the end of the *first three years* the data will be analysed and an interim report will be produced giving a provisional evaluation in line with the objectives of the study" (Viner 2010, my emphasis). That commitment to produce a report with evaluation in 2014 has never been met. Subsequently, Carmichael's keynote address to WPATH in 2016 promised that "we're about to publish" results of the early intervention research (Carmichael 2016). That was three years ago. The first child consented to GnRHa in June 2011; the final subject must have started on the drug by late 2014. Therefore the entire cohort must have

[9] The question was posed by Susan Matthews after Butler's talk to the European Society for Paediatric Endocrinology's symposium on the Science of Gender, London, 19 October 2018.

completed three years of the drug regime by the end of 2017. The results should have been closely monitored and the outcomes published in scientific journals. The Tavistock has failed not just the scientific community, but more importantly the children in its care.

The Health Research Authority also emerges as negligent. After approving the research in 2011 (and an amendment in 2012 to enable children with very low bone density to take part), the Research Ethics Committee did nothing to ensure that the experimental findings were reported. From 2013 onwards, Viner as chief investigator did not submit the requisite annual progress report. The Committee posted occasional reminders, the final one in August 2015. It then seems to have forgotten the study.[10]

The Tavistock Trust now boasts of winning £1.3 million to conduct research (with UCL and two other universities) into the long-term outcomes for young children who use the service, "including both those who go on to use physical interventions such as hormone blockers and those who do not" (Tavistock 2019c). Given the failure of GIDS and UCL to publish the comprehensive data they have been gathering for eight years, why fund them to collect more? There is also a more insidious problem. Carmichael pronounced the results of the experiment to be "positive" back in 2014, and used this to justify a general policy of blocking puberty. Since then, GnRHa has been administered to more than 200 children under 15. How can GIDS and UCL now objectively analyze data from the experiment, when they naturally have a vested interest in justifying their longstanding policy of treating gender dysphoria with GnRHa?

What, then, is to be done? Richard Byng (2019) recently demanded a moratorium on the use of GnRHa for children suffering from gender dysphoria until there is robust evidence that this drug regime is safe and effective. A team of independent researchers must be given access to all the data from the 2011 experiment. They will need expertise in statistics, psychiatry, and endocrinology; most importantly, they must have no vested interests in the promotion of GnRHa. Given that this experiment has been used since 2014 to justify the provision of these drugs to children under the NHS, the outcomes of this experiment—on all the physical and psychological measures that were collected—must be published urgently.

[10] I wrote to the Chair of the London-Bloomsbury Research Ethics Committee, James Linthicum, on 11 April 2019 to convey my serious concerns; he never replied.

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