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LETTERS

GENDER DYSPHORIA

Gender dysphoria: scientific oversight falling between responsible institutions should worry us all

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The troubles around the Gender Identity Development Service's study^{1,2} seem to be symptomatic of our wider collective failure to determine whether, and when, we should prescribe puberty blockers, or cross sex hormones, to children and young people identifying as transgender.

The ethics of research conduct belongs to the Health Research Authority (HRA), and the quality of science is an important consideration when determining ethics. Some procedural issues might not be serious, but the HRA did not try to determine if its first research ethics committee (which advocated the need for a trial) was right, and yet defended a resubmission without tackling the first committee's concerns.³ Effectively, the HRA absolved itself from responsibility for judging the science in deliberations about ethics, leaving it wholly to the academic institution (as investigator and sponsor).

Although many paediatricians prescribe off-label drugs,⁴ halting natural puberty in gender dysphoria could have far reaching consequences, so a stringent research design is required. By gaining permission to study individuals without controls or piloting procedures for a (no doubt complex) randomised trial, an opportunity to determine harms and benefits was missed. The changing and growing demographic—mainly natal females with high rates of trauma—make the need for proper studies more urgent.

Instead, we have now moved from a small, uncontrolled study with unpromising, unpublished results to the scaled up commissioning by NHS England of interventions that are of

unproven benefit.⁵ The new study funded by the National Institute for Health Research is again designed only to observe, not test, effects.⁶ This illuminates the greater issue of how commissioners, service providers, and research institutions have failed this vulnerable group of people who deserve equitable standards of research. The UK has the potential to create the best service for young people questioning their gender. To do so, key institutions will need to embrace equipoise and work together effectively.

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Full response at: <https://www.bmj.com/content/366/bmj.l5647/rr-7>.

- 1 Cohen D, Barnes H. Gender dysphoria in children: puberty blockers study draws further criticism. *BMJ* 2019;366:l5647. doi:10.1136/bmj.l5647.31540909
- 2 Gender Identity Development Service. An evaluation of early pubertal suppression in a carefully selected group of adolescents with "gender identity disorder." <https://gids.nhs.uk/our-early-intervention-study>
- 3 Health Research Authority. Investigation into the study "Early pubertal suppression in a carefully selected group of adolescents with gender identity disorders." <https://www.hra.nhs.uk/about-us/governance/feedback-raising-concerns/investigation-study-early-pubertal-suppression-carefully-selected-group-adolescents-gender-identity-disorders/>
- 4 Scott S, Ford T. Puberty blockers study: much ado about nothing? [electronic response to Cohen D, Barnes H. Gender dysphoria in children: puberty blockers study draws further criticism]. *BMJ* 2019. <https://www.bmj.com/content/366/bmj.l5647/rr-1>
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- 6 Kennedy E. Longitudinal outcomes of gender identity in children. ISRCTN registry. <http://www.isrctn.com/ISRCTN98564473>

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