General Medical Council

GMC response to NHS England consultation to seek views on a proposed interim clinical policy on puberty suppressing hormones

October 2023

Our response

Sent via email

We're aware that you recently published a consultation setting out further details on the proposed interim clinical policy on puberty suppressing hormones for children/young people with gender incongruence/dysphoria. We appreciate the importance of research and data in medicine but are responding to seek clarity in several areas for clinicians to ensure they can continue to deliver good patient care, practising in line with both this interim clinical policy and following our professional standards.

As you're aware, we provide guidance on the professional standards expected of all doctors registered in the UK. These are not clinical standards, nor do we have a role in the design of service provision. As such, this response is limited to several specific areas including considerations around consent and the involvement of parents* when involving children and young people in research, as well as continuity of care.

Involving children and young people in research

Our guidance is clear that research involving children and young people can benefit all children; but they may be vulnerable because they cannot always recognise their best interests, express their needs or defend their rights (*0-18 years: guidance for all doctors*, paragraph 36). Doctors can involve children or young people in research as long as the research does not go against their best interests or involves only minimal or low risk of harm (paragraph 37a). We provide guidance on assessing best interests in paragraphs 12-13.

* References to 'parents' usually means those with parental responsibility for the child or young person in question. For further information see *Appendix 2, 0-18 years: guidance for all doctors*.

Consent

We note that the research study proposed as part of the updated clinical policy is subject to "usual ethical and scientific approval". We cover doctors' research responsibilities in *Consent to research* and set out the standards doctors must follow for *research involving children and young people*. We would expect doctors to comply with the statutory requirements in the UK research governance framework, including the standards around the design of the consent process for research projects and the quality of participant information provided to support the decisions of individuals considering whether to participate in the research.

You'll see the principles in our guidance rely on doctors communicating a range of information to children and young people and those close to them in making sure they have informed consent. As such, doctors require clear guidelines on who is eligible for the prescription of PSH in the context of research as well as clarity on the "exceptional, case by case basis" that would warrant a "clinical recommendation to prescribe PSH for the purpose of puberty suppression outside of research". Similarly, clinicians would need to be clear on the details of the "separate clinical policy", which is mentioned in your interim policy document, which covers "the use of PSH as a precursor to a moving onto gender affirming hormones".

In assessing whether a patient has the capacity to consent to participate in a research programme, see our *0-18 years: guidance for all doctors*.

Involving those close to the patient

Having highlighted the relevant areas of our professional standards around seeking consent, we feel it's also important that in implementing the proposed policy clinicians are provided with clear guidance around involving those close to their patient.

Children and young people that lack capacity to consent can be enrolled in research where there is consent from parents or other valid legal authority – such as the approval of the court (*Consent to research*, paragraphs 16-17). We say doctors should aim to reach a consensus with parents about a child or young person's participation in research. If disagreements arise it is usually possible to resolve them informally, and doctors should follow the advice in paragraphs 92-93 of *Decision making and consent*.

Therefore, in implementing the proposed policy, we feel that clinicians need clear guidance on what to do if disagreements or tensions arise with those close to the patient – particularly if these cannot be resolved through informal processes. This could be in instances where, for example, a patient is not eligible for participation in the research programme, or doctors do not assess it to be in the patient's best interest.

Continuity of care

The proposed policy states that "those already accessing PSH at the time the policy is implemented would need to reach a decision with their consultant endocrinologist about whether to continue this treatment."

We think clinicians would benefit from clear guidance about decision-making in this area at the point of implementation of this policy. We provide guidance for doctors on *prescribing* and, specifically, *prescribing unlicensed medicines*. If a doctor intends to prescribe unlicensed medicines where it's not routine or if there are other suitably licensed alternatives available, they should explain this to the patient, and give their reasons for doing so (paragraph 109). Without clear guidance on continuity of care for doctors at the implementation of this policy, clinicians may be challenged with regards to explaining to patients why the decision has been made for them to either continue or cease treatment.

Finally, we feel monitoring arrangements for patients that are enrolled in the PSH research programme should be made clear to ensure that doctors can continue to work in accordance with our professional standards on *prescribing*. This is particularly important for treating doctors who do not have substantial experience of supporting patients who receive treatment as part of a research programme. They are likely to need clear accessible guidance to understand how the patient's care will be managed between their team and the research team. In instances where doctors share responsibility for a patient's care with a colleague, they should make sure appropriate clinical monitoring arrangements are in place and that the patient and healthcare professionals involved understand them (paragraph 80c).