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12th May 2020

Deputy Mattie McGrath, Leinster House, Dublin 2

PQ Number 2972/20** To ask the Minister for Health if it will be made mandatory for clinics and services providing non-invasive prenatal tests to ensure that websites belonging to such clinics and services properly inform persons of the positive predictive values of the tests they offer (details supplied); and if he will make a statement on the matter.

Dear Deputy McGrath,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question, which you submitted to the Minister for Health for response. I have examined the matter and the following outlines the position.

In May 2019 advice was issued by the Clinical Director of the National Women and Infants Health Programme (NWIHP) to the Clinical Directors and Masters with a request to bring to the attention of relevant clinicians and healthcare workers.

The advice stressed the importance of providing accurate information in relation to antenatal testing for fetal abnormalities, particularly in relation to 'non-invasive prenatal testing'. An article by the Assistant Director of Nuffield Council on Bioethics (February 2019) was shared to emphasise that the positive predictive value of the non-invasive prenatal testing is dependent on context and patient profile. This needs to be conveyed clearly to patients in a way that communicates the limited specificity of this particular test. This is a complicated and sensitive area and informed consent is paramount. The advice further stated that this can only be facilitated when the information is correct, full, individualised and documented. This is general advice and in line with the HSE's Nation Consent Policy (2017).

I trust this clarifies the matter.

Yours faithfully,

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Mary-Jo Biggs

General Manager, National Women and Infants Health Programme