

Bias and inaccuracy in marketing noninvasive prenatal tests

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Bias and inaccuracy are pervasive in the marketing of noninvasive prenatal tests (NIPTs), concludes an early-view study in the *Hastings Center Report*. The tests are marketed to consumers around the world

without regulatory oversight.

NIPTs are screening tests that assess the chance that a fetus is affected by various chromosomal and other conditions by analyzing fetal DNA in a maternal blood sample. In the absence of regulation, the responsibility to ensure that NIPTs are represented accurately and ethically falls to manufacturers.

The study examined whether manufacturers live up to this responsibility by evaluating English-language consumer brochures for NIPTs marketed globally. For a benchmark, the study used a guidance document produced by the Nuffield Council on Bioethics in the United Kingdom. Among the major findings:

- None of the brochures complied with all of the Council's criteria.
- Fifty-two percent of the brochures misrepresented NIPTs as diagnostic rather than screening tests. Patients who do not understand that follow-up [diagnostic testing](#) is required to confirm a positive NIPT result may make decisions about their pregnancy, such as having an abortion, based solely on the NIPT result.
- Companies failed to offer evidence to support their claims about their tests' performance.
- The brochures invoked the patient's own health care provider as an authority on NIPT. This is concerning for two reasons. 1) Several studies indicate that physicians have limited understanding of NIPTs. 2) There is evidence that physician-researchers have been engaged by NIPT manufacturers to conduct studies validating the tests, raising the possibility of a conflict of interest in evidence supporting a test.

The authors conclude that their study raises questions about the ability to access material on NIPTs that is "accurate, trustworthy, and ethically

responsible." They call for regulation of NIPTs and the claims made about them.

More information: Kelly Holloway et al, The Market in Noninvasive Prenatal Tests and the Message to Consumers: Exploring Responsibility, *Hastings Center Report* (2022). [DOI: 10.1002/hast.1329](https://doi.org/10.1002/hast.1329)

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