

Direct-to-consumer fertility tests confuse and mislead consumers, study shows

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Direct-to-consumer hormone-based "fertility testing" for women is viewed by consumers as both an alternative, empowering tool for family planning, and a confusing and misleading one, according to the results of a new study from Penn Medicine. Findings from the small, first-of-its-kind ethnographic study reinforce the need for consumer education around the purpose and accuracy of the tests, which have seen increasing interest in recent years due to the low cost and widespread availability. The study was published in the journal of *Social Science and Medicine*.

Many DTC companies in the "FemTech" space offer a test for anti-Mullerian hormone (AMH), a marker that estimates the size of a woman's egg supply or "ovarian reserve," which have also been called the 'egg timer' or 'biological clock test.' Fertility products and testing is frequently marketed as an accessible, low-cost option for investigating fertility status, yet the tests are not predictive of natural conception. In fact, a 2019 policy statement by the American College of Obstetricians and Gynecologists discouraged testing in otherwise healthy women without a history of infertility.

Measuring AMH levels has primarily been used as a clinical diagnostic tool prior to ovarian stimulation for in vitro fertilization (IVF) in women with infertility, or before oocyte cryopreservation (i.e. egg freezing), in order to guide medication selection and anticipate success rates. However, recently more women have been engaging with DTC testing, due, in part, to barriers to care like strict guidelines for diagnosis of infertility, insurance coverage limitations, high costs, and rising concern about age-related fertility decline.

"Consumers continue to desire these tests, and they're attractive, but they don't deliver on their promise," said Moira Kyweluk, Ph.D., MPH, a fellow in the department of Medical Ethics and Health Policy in the Perelman School of Medicine at the University of Pennsylvania, and the author of the paper. "I view DTC testing as an entry point into what I term the 'new (in)fertility pipeline' for women today. Because it is low cost and widely available, it's reaching a larger demographic, people of diverse identities and backgrounds, and raising awareness of more advanced procedures and technologies like egg freezing."

To better understand the decisions and experiences around DTC fertility testing, Kyweluk closely followed 21 participants pursuing fertility testing recruited in Chicago in 2018. The participants represented different ethnicities, socioeconomic statuses, sexual orientations, gender identifies, and ages. Through an online company, the women visited an accredited laboratory to have their blood drawn for analyses; however, many companies offer at-home kits for women to collect a sample of their own blood, which is sent in for hormone analysis.

Four major themes emerged from participant interviews, surveys, and observation of follow up consultations with a nurse practitioner from the selected DTC fertility testing company including: knowledge, empowerment, DTC fertility services as



a viable alternative for family planning, and finally, participant feelings of varying degrees of uncertainty.

This last theme, Kyweluk says, is the most important, and reinforces the need for better education to consumers around the true purpose for these tests.

"Though there may be some benefits to consumers using DTC fertility testing, across the board participants were left with incorrect assumptions about the power of hormone testing to predict fertility," Kyweluk said. "No test or medical procedure guarantees future fertility—including egg freezing—and these startups directly target women who are concerned about their reproductive futures."

Overall, the findings suggest that DTC fertility testing may allow for a larger population of women to be exposed to a range of assisted reproductive technologies and other information around fertility to inform <u>family planning</u> at any age. Kyweluk calls for future, similar research to better understand consumer experiences and outcomes with these products, as the infertility care industry and DTC fertility market are expected to expand.

"This study offers one model that social scientists can use to investigate the impact of new medical technologies and online delivery systems as they emerge...and create a better understanding of the ethical, legal, and social impacts of these options," she wrote.

More information: Moira A. Kyweluk, Quantifying fertility? Direct-to-consumer ovarian reserve testing and the new (in)fertility pipeline, *Social Science & Medicine* (2019). DOI: 10.1016/j.socscimed.2019.112697

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