

Home pregnancy tests for iPLEDGE: ethically dealing with potential falsifications

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Isotretinoin is regulated through iPLEDGE due to its teratogenicity risk. In response to the coronavirus pandemic, the United States Food and Drug Administration modified the guidelines for Risk Evaluation and Mitigation Strategy to reflect the need for social distancing, telemedicine,^{1,2} and allowing reduced laboratory monitoring for drugs subject to Risk Evaluation and Mitigation Strategy programs such as iPLEDGE.^{1,2} Patients are permitted to submit photographs of at-home pregnancy tests to meet monthly test requirements instead of office testing,^{3,4} significantly expanding access to testing options for child-bearing potential patients on isotretinoin,³ but also affording patients opportunities to falsify pregnancy test results.

A recent study showed a 15.7% rate of deliberate circumvention of the iPLEDGE pregnancy testing regulations using falsified images of at-home tests;⁴ images included photographs downloaded from the internet or edited copies of previously uploaded photos.⁴ Reasons for falsification include convenience and avoiding further costs rather than patient's desire to conceal pregnancy.⁵ Falsification is unacceptable and reflects lack of understanding of potential consequences to an unborn fetus exposure to isotretinoin.

To guarantee a safe and equitable access to isotretinoin, provide convenience of teledermatology, and follow-up with the use of home pregnancy tests, the dermatology community must ensure safe use of at-home pregnancy tests as an authentic form of verification in iPLEDGE. If a physician suspects a falsified image has been submitted, we recommend the following to address and rectify the situation; confrontational conversation should be avoided, as it may undermine the patient's autonomy and erode the physician-patient relationship. However, accepting a potentially falsified test could result in serious medical and even legal consequences and violates the ethical principle of nonmaleficence. A nonjudgmental and nonpaternalistic discussion aimed at evaluating the patient's comprehension, motives and underlying challenges, is recommended. Discussion and re-education on potentially harmful consequences of isotretinoin would then be introduced. The medication cannot be prescribed until a verified pregnancy test has been submitted. If a patient refuses to co-operate, providers must then request the patient present for in-person testing. If circumstances force to require an in-person test and withdraw the patient's right to a telemedicine visit, this might be viewed as a breach of justice as telemedicine aids in reducing

health disparities.⁵ However, the safety and health of a potential fetus take precedence.

Routine establishment of preventative practices to mitigate reuse of old, falsified, or publicly available photographs of test results is needed. An effective strategy would be to require photographs be submitted with the date and patient's name written on the test itself.^{2,4,5} Physicians may request in-office testing or laboratory testing in patients in whom falsification is a concern.⁵

Testing requirements of iPLEDGE have previously placed financial and logistical burdens on patients, leading to potential inequities in care. Utilization of telemedicine has positively impacted access to isotretinoin, while also raising new patient safety issues. The potential to falsify pregnancy test results highlights our ethical responsibility to establish best practice guidelines to prevent submission of falsified pregnancy tests, to assure continued safe and equitable access to isotretinoin through telemedicine, and to ensure that physicians first do no harm.

Conflicts of interest

None.

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None.

Study approval

N/A

What is known about this subject in regard to women and their families?

- Verification of pregnancy tests for telemedicine visits for child-bearing aged women on isotretinoin has been associated with some women trying to falsify their pregnancy tests. Our submission discusses this issue, how to address the patient ethically and sensitively, and how best to achieve a successful outcome for both the patient and the potential unborn fetus.

What is new from this article as messages for women and their families?

- Some women obviously do not understand the teratogenic risk of isotretinoin. To maintain the ability of women to continue with teledermatology follow-up visits and maintain safety for the woman and her potential fetus, it is not acceptable to continue therapy unless a pregnancy test is verified as accurate and up to date.

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