

# Falsification of at-home isotretinoin pregnancy testing during the COVID-19 pandemic: A case series and proposal of mitigation strategies



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**Key words:** acne vulgaris; iPLEDGE; isotretinoin; REMS; solid facial edema.

## INTRODUCTION

In response to the COVID-19 pandemic, the US Food and Drug Administration changed the guidelines for existing Risk Evaluation and Mitigation Strategies on March 22, 2020, to reflect the increased need for self-isolation and social distancing. The update allowed for greater flexibility with laboratory testing and imaging requirements for drugs subject to a Risk Evaluation and Mitigation Strategies program.<sup>1</sup> As a result, adjustments were made to the iPLEDGE program, a Risk Evaluation and Mitigation Strategies program created to manage the risks of isotretinoin, a highly teratogenic medication used for severe nodulocystic acne. One such change allowed for the use of at-home urine pregnancy tests to fulfill the iPLEDGE requirement of monthly pregnancy testing.<sup>2</sup> Although this change may have eased the burden of having to present for an in-person urine or serum pregnancy test, it has also created the opportunity for patients to falsify their at-home pregnancy test results. In this case series, we aimed to identify methods by which patients taking isotretinoin falsify their at-home pregnancy test results.

## METHODS

This case series was approved by the University of Minnesota Institutional Review Board (STUDY#00 015820). All patients of the principal investigator

who were of childbearing potential and who were treated with isotretinoin for any dermatologic diagnosis from January 2021 to January 2022 were considered for the study. Research opt-outs were excluded. At-home urine pregnancy tests submitted by patients were verified for accuracy and originality by the principal investigator through close inspection of the photograph and by comparison to prior submissions. In each case, the principal investigator discussed the submitted photograph with the patient to ascertain its intentionality. If the photograph was deemed to be a repeat, outdated, or a stock image and the photograph was determined to have been submitted intentionally, the patient was included in this case series. The following parameters of the submitted pregnancy test were considered when making this assessment: background, pattern of lighting, color, shadowing, rotation, resolution, dimension, surrounding objects, time stamp, presence of brand names, and results of the pregnancy test.

## CASE SERIES

### Cases 1 and 2

A 25-year-old woman (Fig 1) and a 38-year-old transgender man assigned female sex at birth (Fig 2), both on isotretinoin for the treatment of acne vulgaris, resubmitted a previously uploaded photograph in a subsequent month.

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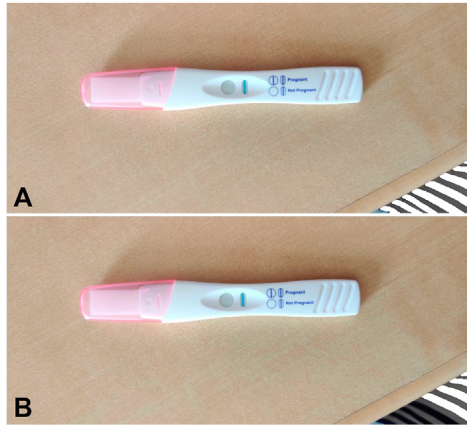
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**Fig 1.** Uploaded at-home urine pregnancy tests from case 1. **A**, The first uploaded photograph is identical to **(B)** the second uploaded photograph.

### Case 3

A 22-year-old woman on isotretinoin for the treatment of acne vulgaris submitted a screenshot of her urine pregnancy test. On close inspection of the photograph, the time stamp dated the picture to several months before the submission (Fig 3).

### Cases 4 to 6

A 20-year-old woman (Fig 4), a 24-year-old woman (Fig 5), and a 25-year-old woman (Fig 6), all on isotretinoin for acne vulgaris, resubmitted photographs identical to a prior upload; these photographs were digitally altered.

### Case 7

A 48-year-old woman on isotretinoin for solid facial edema submitted 2 different digital stock photographs of urine pregnancy tests (Fig 7). In 1 of the photographs, the image demonstrated positive pregnancy test results.

## DISCUSSION

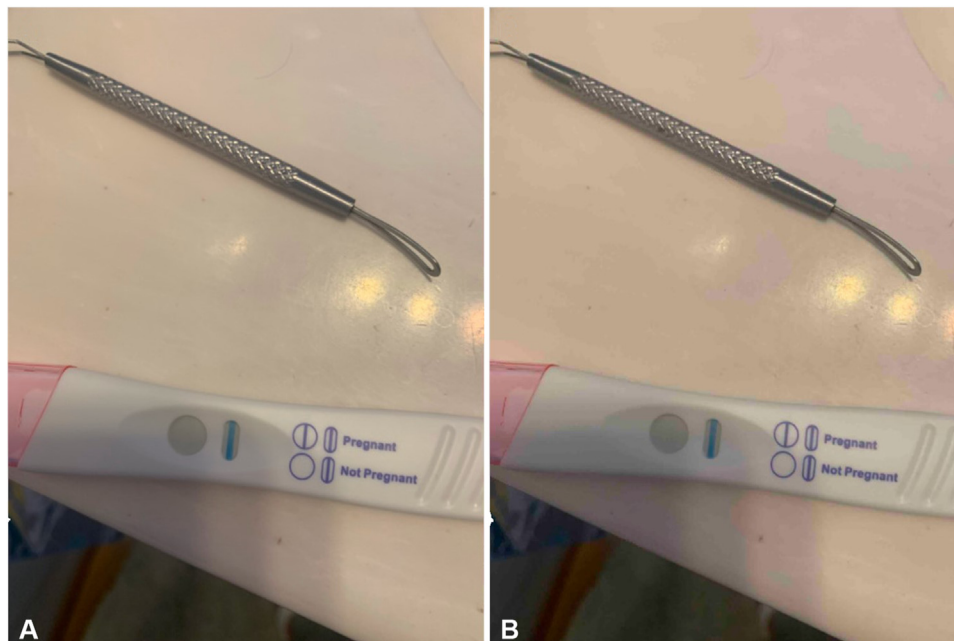
The adjustments made to iPLEDGE amidst the COVID-19 pandemic have increased accessibility to isotretinoin in several ways. For example, at-home testing has been shown to be more cost effective than in-person monitoring. At-home urine pregnancy tests can be found for as cheap as \$0.30 to \$6.99 per test.<sup>3</sup> Patients may also face fewer indirect costs with at-home testing because in-person monitoring may require that the patient arrange for childcare or take time off from work.<sup>3</sup> At-home testing may also be more time-convenient for those with other commitments, such as full-time employment, school, or parenting.

However, despite increased access to isotretinoin with at-home monitoring, in a recent study, a 15.7% rate of deliberate noncompliance with at-home pregnancy testing was reported.<sup>4</sup> Methods used by the patients in this study included the use of images from the internet or altered versions of previously uploaded photographs.<sup>4</sup> In our case series, these findings were validated through the identification of similar methods used by patients who were treated at a tertiary referral center based out of a populous Midwestern metropolitan area, and we propose a protocol to reduce the risk of deliberate noncompliance.

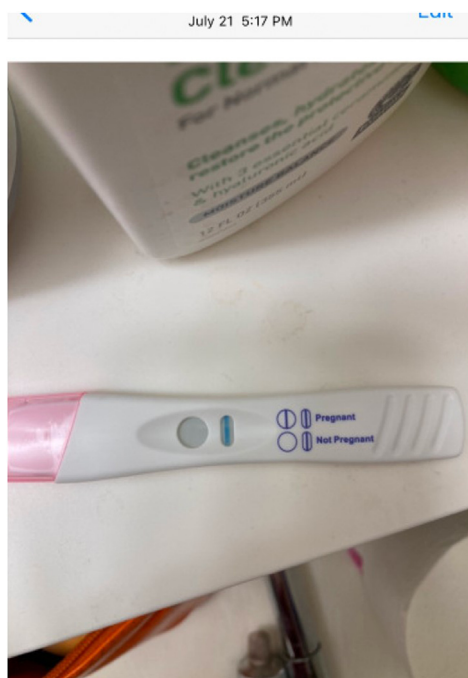
In light of this high noncompliance rate, barriers to the utilization of telehealth and remote monitoring must be considered. To use this form of monitoring, a patient must have a solid understanding of technology and have access to a technological device. Uploading a photograph and navigating the electronic medical record to do so may be challenging for some patients. Furthermore, home pregnancy tests can have variable sensitivity and often require patients to read the results, leading to potential interpretational errors.<sup>3</sup> Finally, ambiguous use of dates in the electronic medical record may make it hard for both the patient and the physician to accurately track when photographs were submitted. In particular, the Epic MyChart feature assigns a date on the basis of when the MyChart conversation was initiated, rather than the date on which the photograph was uploaded.

We propose that the iPLEDGE program consider establishing a best practices guideline to protect against the falsification of at-home isotretinoin pregnancy tests. At the University of Minnesota, patients are now advised to submit their pregnancy test with the interpretation instructions as well as their initials and the date handwritten on the test (Fig 8). Although similar methods have been established at other institutions in the United States, a single best practices guideline would ensure that each institution is following the same recommendations.<sup>4</sup> In addition, education should be provided to patients on the importance of compliance, including a thorough discussion of the risk of fetal birth defects and/or malformations. Potential barriers to at-home monitoring, such as those listed earlier in the article, should also be explored and addressed whenever possible. Finally, patients who falsify their results should be referred to a laboratory for in-person monitoring. If there are multiple instances of intentional falsification, discontinuation of isotretinoin should also be considered.

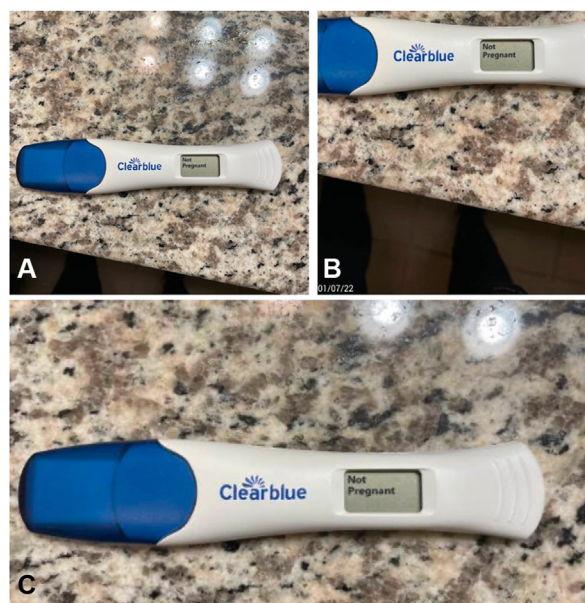
In conclusion, this case series reveals the various methods that patients may use to falsify their at-home urine pregnancy tests. Limitations to this study



**Fig 2.** Uploaded at-home urine pregnancy tests from case 2. **A**, The first uploaded photograph is identical to **(B)** the second uploaded photograph.



**Fig 3.** Uploaded screenshot of an at-home pregnancy test from case 3. The time stamp located at the top of the photograph dates it to several months before submission.



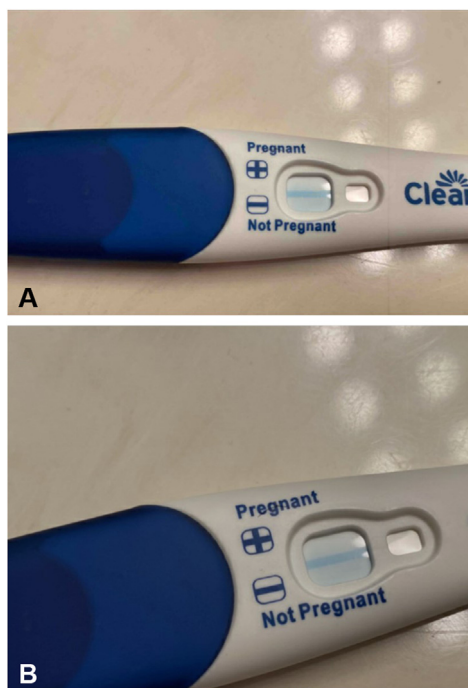
**Fig 4.** Uploaded at-home urine pregnancy tests from case 4. **A, C**, Two of the photographs were identical but cropped to different dimensions. **B**, When asked to resubmit, the patient digitally inserted the date to the same image.

include the potential for missed cases of falsification because only those determined to be intentional after discussion with the patient were included, and those determined to be accidental were not included. Given the wide scope of this issue, we

propose a 4-pronged approach: (1) establishing a best practices guideline, (2) continued education for patients on the importance of compliance, (3) continued exploration of barriers to at-home monitoring, and (4) additional steps to consider when falsified results are encountered. Further work must



**Fig 5.** Uploaded at-home urine pregnancy tests from case 5. **A**, The first uploaded photograph is identical to **(B)** the second uploaded photograph, albeit in different image resolution.



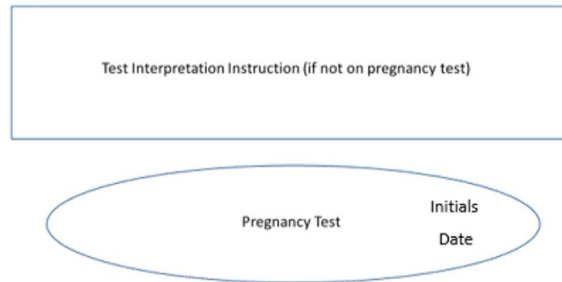
**Fig 6.** Uploaded at-home urine pregnancy tests from case 6. **A**, The first uploaded photograph is identical to **(B)** the second uploaded photograph, with a change in rotation and overlying color filter. These images were identified as duplicates on the basis of the overlying light fixture and the small eyelash located over the word “pregnant.”



**Fig 7.** Uploaded at-home urine pregnancy tests from case 7. **A**, The first uploaded image is a digital stock photograph. **B**, The second uploaded image is also a digital stock photograph and is positive for pregnancy.

Please, send in a photo of your home pregnancy test. The following must be present:

1. Test interpretation instructions
2. Your initials AND the date of the test handwritten on the pregnancy test



**Fig 8.** Example of a protocol used at the University of Minnesota to reduce deliberate noncompliance with at-home isotretinoin monitoring.

still be done to address the existing barriers to remote monitoring and to ensure that the new update to iPLEDGE is rolled out in a safe, effective, and equitable manner that balances increasing access to isotretinoin while ensuring appropriate pregnancy monitoring in any setting.

**Conflicts of interest**

None disclosed.

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