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# iPLEDGE Weaknesses: Is It Time to Address the Flaws?

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## ABSTRACT

**Background:** The observance during acne follow-ups that information stored within iPLEDGE was discordant with medical charts prompted this study.

**Objective:** To evaluate the information acquired and stored within iPLEDGE as it compares to medical charts with a goal of assessing the efficacy of iPLEDGE as a database.

**Methods:** This is a multicenter retrospective chart review analyzing congruence and discrepancies between medical chart documentation and iPLEDGE data for all patients who received at least a single dose of isotretinoin from the primary investigators between January 2006 and November 2010.

**Results:** A total of 357 charts were analyzed. Overall congruence between medical chart documentation and iPLEDGE data was observed in only 73.1% of cases. The discrepancy (N=96) was due to a missed dose (prescription recorded in chart but not in iPLEDGE) in 81.4% of cases, or an addition (medication dispensed per iPLEDGE without corresponding chart documentation) in the remainder of cases. Of note, several charts had multiple discrepancies (N=249 total discrepancies).

**Limitations:** Retrospective chart review study.

**Conclusion:** Given the large percentage of discordant data, our findings question the efficacy of the iPLEDGE system, which is designed to monitor every dispensed isotretinoin dose.

*J Drugs Dermatol.* 2016;15(1):97-102.

## INTRODUCTION

Since its approval by the Food and Drug Administration (FDA) in 1982, Accutane (isotretinoin) has been contraindicated during pregnancy due to its known teratogenicity in animals.[1] Unfortunately, despite a designated "Category X" drug label, reports of fetal exposure and resulting birth defects ensued, forcing the FDA and Accutane's manufacturer, Hoffman La-Roche, to devise a series of risk management programs (RMP) to heighten awareness about fetal malformation and to minimize the number of pregnancies during treatment.[1,2] With each new RMP, including the Pregnancy Prevention Program (PPP) and System to Manage Accutane-Related Teratogenicity (SMART), additional requirements were placed on both the physician and patient, making the prescription of isotretinoin more rigorous and burdensome (Table 1).

In February 2004, the Drug Safety and Risk Management and Dermatologic and Ophthalmic Advisory Committees created iPLEDGE in order to reduce fetal exposure to isotretinoin and monitor the prescribing, dispensing, and distribution of all isotretinoin brands.[3] The main goals of iPLEDGE are to prevent pregnancies in females taking isotretinoin and to prevent pregnant females from taking isotretinoin.[4] Using a performance-linked access system, the responsibility for achieving these goals are distributed among patients, physicians, pharmacies, manufacturers, and wholesalers, all of whom are required to register with iPLEDGE online or by telephone.[1,2,5] As a result of the increasing demands placed on the physician, many dermatologists viewed iPLEDGE as an assault on their freedom to practice medicine, and believed that the isotretinoin registry would hinder their patients' access to this drug and breed select "isotretinologists."[5]

Despite these concerns, iPLEDGE became mandatory on March 1, 2006. Many greeted the web-based system with frustration as faulty program databases and glitches, coupled with inadequate telephone support, resulted in lengthy wait times and registration delays.[2,6] However, dermatologists continued to register with iPLEDGE despite these administrative burdens as there was no alternative way to legally prescribe isotretinoin in the United States.[5]

Successful use of iPLEDGE requires substantial coordination. Only after the web-based system verifies that physician and patient are compliant with all iPLEDGE requirements are pharmacists allowed to dispense the drug.[2,4]

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**TABLE 1.**

**History of Isotretinoin Risk Management Programs**

| Risk Management Programs (RMP) | Approach |
|---|---|
| Revised Warning<br>1983-1988 | Least aggressive RMP<br>"Dear Doctor" warning letters issued by Roche<br>Red warning stickers on drug bottles and package inserts |
| PPP[a]<br>1988-2001 | Comprehensive educational program directed at physicians and patients<br>Required patient consent form, pregnancy test 7 days prior to start of treatment, and selection of 2 forms of birth control unless abstinent<br>No mechanism in place to enforce compliance of required procedures |
| SMART[b]<br>2002-2006 | Strengthened educational aspects of PPP<br>Yellow qualification sticker<br>Issued only to prescribers enrolled in SMART<br>Confirmation that patient received contraceptive counseling, had chosen 2 forms of birth control, undergone 2 negative pregnancy tests<br>Pharmacists encouraged to fill only those prescriptions with qualification sticker <7 days old |
| iPLEDGE<br>2006 - present | Goals:<br>(1) Prevent pregnancies in females taking isotretinoin<br>(2) Prevent pregnant females from taking isotretinoin<br>Performance-linked access system requires registration by physicians, patients, pharmacies, manufacturers, and wholesalers.<br>Prior to starting treatment:<br>Physicians must register patients in iPLEDGE, and enter the results of 2 negative pregnancy tests, 2 forms of contraception that the patient agrees to use, and attest that pregnancy prevention counseling was provided.<br>After initial visit:<br>Physicians must verify results of a negative pregnancy test, re-enter contraceptive choices for female patients, and counsel female patients about contraception on a monthly basis.<br>Patients must continue to indicate contraceptive choices and answer questions demonstrating knowledge of the teratogenic effects of isotretinoin.<br>Pharmacists are only allowed to dispense drug once web-based system verifies that physician and patient complied with all iPLEDGE requirements. |

[a]Pregnancy Prevention Program; [b]System to Manage Accutane-Related Teratogenicity

During a recent study of isotretinoin usage,[7] we observed substantive discrepancies between patient charts and iPLEDGE documentation, leading us to formally examine congruence of these two entities. It is noteworthy that all published literature on iPLEDGE centers around its efficacy on pregnancy prevention or the obstacles providers face when attempting to use the system in clinical practice.[2,3,6,8,9] iPLEDGE has never been formally evaluated as an accurate information systems database.

## METHODS

### Study Design and Sample

A retrospective chart review of all patients registered in iPLEDGE by the primary investigators was completed between January 2006 and November 2010 (N=553). The study population was derived from a multi-dermatologist, multi-institution investigation, involving both academic tertiary care centers (Albert Einstein College of Medicine, Bronx, NY, and SUNY Downstate Medical Center, Brooklyn, NY) and a private practice dermatology office (Austin Dermatology Associates, Austin, TX). Patients who registered but never received a single dose of isotretinoin were excluded from the sample (N=161). An additional 35 patients were eliminated due to chart deficiencies, resulting in a final sample size of 357 patients.

Data collected from the chart review included: age, gender, ethnicity, history of prior isotretinoin treatment, presence of isotretinoin restart(s) [a period where a patient has become "lost to follow-up," locked out of the iPLEDGE system, and requires re-registration in order resume therapy], treatment length, and the number and dates of office visits during the course of treatment. Data collected from iPLEDGE included: number and dates of dispensed isotretinoin. Congruence between documentation in the chart and that recorded in iPLEDGE was evaluated. Discrepancies were stratified into iPLEDGE misses or additions based on data from the chart. A "miss" was defined as a documented patient visit and prescription for isotretinoin in the medical chart without a corresponding record in iPLEDGE. Moreover, the subsequent

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**TABLE 2.**

| Patient and Treatment Course Characteristics | | | | |
|---|---|---|---|---|
| **Patient Characteristics** | **Total** | **Einstein** | **Austin** | **Downstate** |
| Age, mean years (range) | 23.8 (11-63) | 24.0 (11-57) | 23.5 (12-63) | 24.1 (13-45) |
| Gender, % (N) | N=357 | N=172 | N=151 | N=34 |
| Female | 51.0% (182) | 64.5% (111) | 37.1% (56) | 44.1% (15) |
| Male | 49.0% (175) | 35.3% (61) | 62.9% (95) | 58.9% (19) |
| Ethnicity, % (N) | N=206 | N=172 | N/A | N=34 |
| Hispanic | 29.1% (60) | 34.9% (60) | N/A | 0% (0) |
| Caucasian | 34.5% (71) | 32.0% (55) | N/A | 47.1% (16) |
| African American | 19.4% (40) | 21.5% (37) | N/A | 8.8% (3) |
| Asian | 7.8% (16) | 8.7% (15) | N/A | 2.9% (1) |
| Other | 2.4% (5) | 2.9% (5) | N/A | 0% (0) |
| Unknown | 6.8% (14) | 0% (0) | N/A | 41.2% (14) |
| **Treatment Course Characteristics** | **Total** | **Einstein** | **Austin** | **Downstate** |
| Number of courses, % (N) | N=357 | N=172 | N=151 | N=34 |
| One | 82.1% (293) | 82.0% (141) | 84.8% (128) | 70.6% (24) |
| Two | 16.0% (57) | 16.9% (29) | 14.6% (22) | 17.6% (6) |
| Three | 1.1% (4) | 0.6% (1) | 0.7% (1) | 5.9% (2) |
| Four | 0.8% (3) | 0.6% (1) | 0% (0) | 5.9% (2) |
| Prior course information available, % (N) | N=64 | N=31 | N=23 | N=10 |
| Yes | 60.9% (39) | 74.2% (23) | 39.1% (9) | 70% (7) |
| No | 39.1% (25) | 25.8% (8) | 60.9% (14) | 30% (3) |
| Presence of restart, % (N) | N=357 | N=172 | N=151 | N=34 |
| Yes | 8.7% (31) | 7.0% (12) | 9.9% (15) | 11.8% (4) |
| No | 91.3% (326) | 93.0% (160) | 90.1% (136) | 88.2% (30) |
| Chart and iPLEDGE Congruence, % (N) | N=357 | N=172 | N=151 | N=34 |
| Yes | 73.1% (261) | 69.8% (120) | 82.8% (125) | 47.1% (16) |
| No | 26.9% (96) | 30.2% (52) | 17.2 (26) | 52.9% (18) |
| Reason for Discrepancy, % (N) | N=97* | N=52 | N=26 | N=19 |
| Missing doses on iPLEDGE | 81.4% (79) | 80.8% (42) | 84.6% (22) | 78.9% (15) |
| Added doses on iPLEDGE | 18.6% (18) | 19.2% (10) | 15.4% (4) | 21.1% (4) |
| Total Discrepancies, % (N) | N=249 | N=129 | N=54 | N=66 |
| Missing doses on iPLEDGE | 90.0% (224) | 86.8% (112) | 92.6% (50) | 93.9% (62) |
| Added doses on iPLEDGE | 10.0% (25) | 13.2% (17) | 7.4% (4) | 6.1% (4) |

*N=97 (note: though N=96 for discrepancies noted, 1 patient had both a miss and addition accounting for the extra dose)

patient visit documented that the patient, in fact, had taken the medication during the previous month. An "addition" occurred when isotretinoin was recorded as dispensed in iPLEDGE without a corresponding entry in the medical chart.

IRB approval was obtained for this study.

### Statistical Analysis

Data were summarized using descriptive characteristics for all variables.

## RESULTS

### Patient Characteristics

The mean age in this study was 23.8 years; 51.0% were female. At the two sites recording ethnicity (Einstein and Downstate), Caucasians and Hispanics comprised the largest treatment groups (34.5% and 29.1%, respectively). African Americans (19.4%), Asians (7.8%), and other (2.4%) were also represented, while 6.8% were unknown. Data stratified by site are presented in Table II.

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"Unfortunately, despite a designated "Category X" drug label, reports of fetal exposure and resulting birth defects ensued, forcing the FDA and Accutane's manufacturer, Hoffman La-Roche, to devise a series of risk management programs (RMP) to heighten awareness about fetal malformation and to minimize the number of pregnancies during treatment."

### Treatment Course Characteristics

A majority of patients had one documented course of isotretinoin treatment (82.1%, N=293), however, additional trials of isotretinoin therapy were documented in 17.9% (N=64). Of the patients who had previously received isotretinoin therapy, chart information regarding prior courses was available in 60.9% of cases (N=39). For known courses, four months of therapy was the most common prior course duration (15.4%, range: 1-14 months).

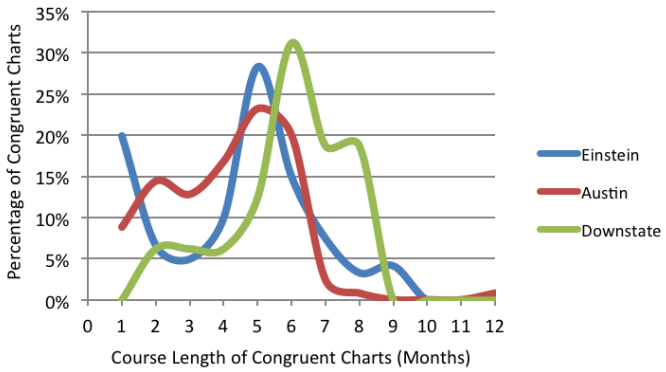
Regarding the primary treatment course, congruence between chart documentation and iPLEDGE data was observed in 73.1% of cases (N=261; Einstein=69.8%, Austin=82.8%, Downstate=47.1%; Table II). Average course duration for congruent charts was 4.3 months, range: 1-12 months (Figure 1). The number of discrepant doses between the chart and iPLEDGE is highlighted in Figure 2. Of the 96 discrepant charts, the majority (81.4%) was due to a missed dose(s), with an addition(s) in the remainder of cases. However, as many individual charts had multiple discrepancies, the total number of discrepant doses was 249, again with misses representing the majority (90%). An iPLEDGE restart was required for 8.7% (N=31) of patients. The number of isotretinoin doses administered before the restart is demonstrated in Figure 3.

## DISCUSSION

Per FDA Drug Safety and Risk Management and Dermatologic and Ophthalmic Drug Advisory Committee goals, iPLEDGE should monitor the prescribing, dispensing, and distribution of all isotretinoin brands. Given the large percentage of discordant data found in our study, we suggest that iPLEDGE is falling short of its goal to monitor every dose of isotretinoin. Nevertheless, several factors could potentially account for the discordance observed in this study.

A "restart," an easily modifiable error, accounted for 8.7% of all charts in this study. Restarts occur when a patient is "lost

**FIGURE 1.** Chart and iPLEDGE Congruence
Einstein N=120; Austin N=125; Downstate N=16.




to follow-up," and locked out of the iPLEDGE system until re-registration is complete. Per iPLEDGE rules, a patient may become lost to follow-up in four ways: 1) The patient has been in a "Registered" status for greater than 90 days and the prescriber/designee has not interacted with the patient's record; 2) Patient has been in a "Requires Confirmation" status for greater than 53 days and the prescriber/designee has not interacted with the patient's record; 3) Females of childbearing potential (FCBP) who are missing their pregnancy test at date of last dose; 4) FCBPs who are missing their final pregnancy test 30 days post treatment. Should a patient become "lost to follow-up" prior to the end of the planned treatment course, a physician may re-register that patient, but the practitioner is required to contact the iPLEDGE program and receive an "override code." Once patients are re-registered, they are eligible for isotretinoin according to the same rules as any other registered patient. However, in our experience, the online data readily available to the practitioner prior to the re-registration is lost. This phenomenon is coded in our study as a "restart." Though the data actually remains stored within the iPLEDGE system, it is not readily accessible to providers. Long-term maintenance and storage of information is not mentioned in any iPLEDGE supporting materials, and was discovered only when the primary investigators called to inquire about missing data. It is also interesting to note that while patients may be locked out of the system as soon as 30 days post treatment, three of our patients were found to have greater than 90 days between dispensed doses with no lost data.

An "addition" occurs when isotretinoin is noted to be dispensed through iPLEDGE without a corresponding office visit or other documented means of a patient obtaining an isotretinoin prescription. While revised iPLEDGE rules allow patients to receive more than one dispensed prescription of isotretinoin each month (exact dates and prescription window periods vary based on childbearing status of the patient), this requires a new prescription each time accompanied by corresponding chart documentation. Possible explanations for the observed additions

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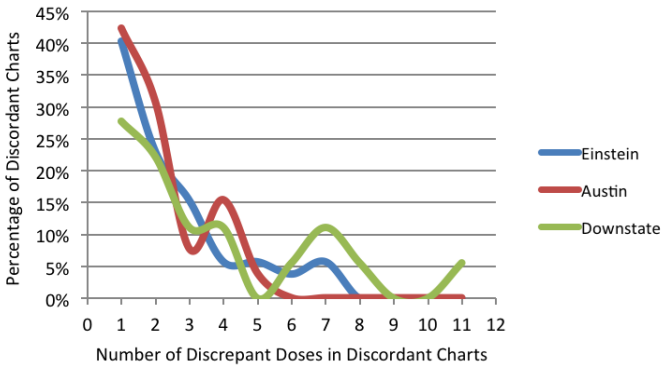
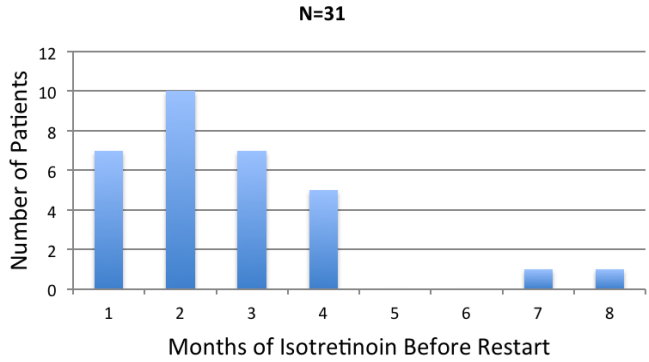
**FIGURE 2.** Chart and iPLEDGE Discrepancies
Einstein N=52; Austin N=26; Downstate N=18.




include: 1) Two prescriptions for isotretinoin were given during a single visit but only one prescription was documented; 2) Between office visits, a prescription was called in over the phone without documentation; 3) The pharmacy divides isotretinoin from a single prescription into two dates in order to satisfy insurance criteria; 4) The patient obtains an additional prescription by means other than above. Our personal experience is that certain insurance policies allow either a maximum number of isotretinoin tablets dispensed at one time (usually 90), or a certain number of days of medication (no more than 21 days per prescription); however, this alone should not result in additions, since any further dispensing of drug is ideally corroborated by an additional prescription in the medical chart.

We have termed the remainder of discrepancies, with restarts and additions discounted, as "true misses," and account for 13.4% of all charts. One explanation relies on patient compliance and accuracy of reporting (eg, patient reports that s/he is taking medication as prescribed but does not actually fill the prescription, this would result in a "miss"). Though patient non-compliance likely accounts for a portion of the discrepancy, there is no way to verify the data, and it seems unlikely that non-compliance alone accounts for all of the "true misses." Another possible explanation includes prescriptions obtained from online/out-of-country pharmacies. In this situation, a patient would be taking the medication as prescribed reflecting the corresponding chart documentation while there would be no similar record in iPLEDGE. It is important to note that while this situation is possible, in our study would be an unlikely scenario as patients required a minimum of one month medication dispensed through iPLEDGE to be included in our study. Additionally, if patients were receiving medication from a non-regulated source, one would expect documentation in the chart. In no instance was the latter observed. Other factors (eg, pharmacy dispensed medication without corresponding entry in iPLEDGE database) are thought to contribute as well.

**FIGURE 3.** Discordant Data Due to Restart.




## Electronic versus Paper Charts

This study compared data from three sites; two of the sites (Einstein and Downstate) used paper medical charts, while Austin used electronic medical records (EMR). Although all three sites were substantially discordant with iPLEDGE, Austin had fewer discrepancies than either of the two sites that utilized paper charts. Though we did not set out to study the difference between accuracy of electronic versus paper charts, this sizable difference in percentage of observed discrepancies (17.2% vs. 34.0%) is difficult to ignore.

EMR has potential benefits in areas of clinical, organizational, and societal outcomes.[10] In one study designed to evaluate completeness and uniformity of health record data entry for history and physical examination, electronic records were found to be superior to paper charts.[11] Another large multicenter study of 461 test results from 200 charts found that results managed with an EMR were more often in the right place in the chart, and had more clinician signatures, interpretations, and patient notifications documented.[12]

Our study reinforces the findings of improved accuracy for electronic charting, as the Austin site (ie, with EMR) had notably less discordance (16.8% lower rate), compared to the sites utilizing paper. A few noteworthy differences in electronic charting included the relative ease of data retrieval, as prescriptions were consistently located within a specific area of the chart, and records of telephone notes were captured in Austin charts but not in the paper charts. Since telephone notes frequently explained when a patient did not fill their prescription for isotretinoin, classification as a "miss" was avoided in the absence of a corresponding dispensed dose in iPLEDGE. Neither site utilizing paper charts had a reliable way to track additional correspondence outside of the standard office visit. Additionally, the Austin EMR was notable for having a cumulative dose tracker, which could help account for the lower number of additions at this site.

## Future Directions

From its inception, iPLEDGE was not specifically designed to function as an electronic database. Nonetheless, to "prevent

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pregnancies in females taking isotretinoin and to prevent pregnant females from taking isotretinoin," iPLEDGE "monitors all prescriptions and dispensed doses of the medication." As this monitoring requires significant effort by various parties (physician, office staff, patient, and pharmacist), simple improvements could be incorporated into the system design that would directly benefit patient care. Moreover, an important question still remains: why are men and post-menopausal women required to abide by the rules of iPLEDGE when the stated goal is to prevent teratogenic exposures in pregnancy? Perhaps excluding these patients from iPLEDGE would significantly decrease the burden on all involved parties and encourage more patients and providers to use isotretinoin.

In addition to removing the requirements on non-childbearing patients, we suggest when a patient is "lost to follow-up" and re-registered, or when a patient repeats a course of therapy, that all previous data of dispensed isotretinoin remain accessible to the provider and not hidden. Moreover, reporting the number of days for which isotretinoin is prescribed would have much greater utility if the actual dose of drug and number of pills dispensed were recorded and available. Since isotretinoin is generally prescribed with a cumulative dose target in mind, access to this extra data would create a built-in resource to corroborate information documented in the medical chart, should a question arise during a patient encounter. These changes would help not only to ensure medical record accuracy, but also would be especially useful for the patient who changes practitioners during or following a course of isotretinoin. The transfer of medical records between physicians is frequently suboptimal, and these enhancements would serve to minimize unnecessary challenges.

Another avenue of improved documentation likely rests on the complete transition from paper charts to an EMR. Though it stands to reason that the lower discrepancy rate at the Austin site is predominantly due to an electronic charting system, further studies are needed to assess the accuracy of electronic versus paper charts. It would be interesting to compare the health records of private practices utilizing paper charts versus those with EMR, as well as academic centers utilizing both types of health records.

Has iPLEDGE accomplished its ultimate goal of pregnancy prevention? Perhaps the most widely quoted study concluded neither the iPLEDGE program nor any of the previous RMPs have decreased the rate of fetal exposures to isotretinoin in females of childbearing potential.[8] Yet it seems a virtual certainty that iPLEDGE or a future RMP will be required for prescribing isotretinoin, and therefore its utility should be optimized. Notwithstanding its current flaws, iPLEDGE has the potential to improve patient outcomes by functioning as a complete database. This would undoubtedly enhance provider effectiveness in dealing with the challenges of both isotretinoin and iPLEDGE.

## DISCLOSURES

The authors have no conflict of interests to declare.

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