HOT CONTROVERSY

•The iPledge Program &

Should Pediatricians/NPs/PAs/FPs

Prescribe Accutane (aka Isotretinoin)??







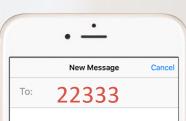
Participating with Poll Everywhere



Web voting



Text voting



NEMOURSCME <your response>



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NEMOURS CHILDREN'S HEALTH

- 17-year-old Deja presents with worsening nodular acne
- that has failed multiple topical treatments, antibiotics
- and spironolactone. She does have an IUD and she is
- not sexually active. Deja does not like seeing doctors but
- mom says she is very comfortable seeing YOU.

When poll is active, respond at pollev.com/nemourscme
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Would you consider treating her with Isotretinion? Your BEST Answer

NO I would not prescribe Isotretinion to anyone

NO I would only would consider it with male patients

MAYBE

YES I would prescribe Isotretinoin

Start the presentation to see live content. For screen share software, share the entire screen. Get help at pollev.com/app

HOT CONTROVERSY : Should pediatricians/NP/PA/FP prescribe Isotretinoin?

Rob (Ackroyd) Walter vs Kashie (Curtin) Oza



Hot Controversy : Should pediatricians prescribe Isotretinoin?



YES Rob Walter Northwestern University WILDCATS

NO Vikash Oza University of Chicago MAROONS

2016

S Editorials

SO ARE **PEDIATRIC** CAREGIVERS!!!!

Family Physicians Are Well Suited to Prescribe Isotretinoin

NATHAN HITZEMAN, MD, Sutter Health Family Medicine Residency Program, Sacramento, California

In a busy practice, physicians may be discouraged by the prospect of having to log onto yet another website or navigate more protocols to carry out patient care. However, a few extra minutes (and a few clicks on the computer) can open up rewarding therapeutic opportunities when registering with iPledge to prescribe isotretinoin. Isotretinoin was approved by the U.S. Food and Drug Administration (FDA) in 1982 for the treatment of severe, recalcitrant nodular acne and perfect; even with iPledge, there were 122 isotretinoin-exposed pregnancies during its first year.^{1,4}

Isotretinoin carries an FDA boxed warning for teratogenicity and may be associated with suicidal ideation and inflammatory bowel disease, although no causal relationship has been established.^{1,4,5} A patient receiving isotretinoin should discontinue other acne medications—especially tetracycline antibiotics—because of the risk of pseudotumor cerebri. Other drug-drug interactions exist. Vitamin A supplementation should be avoided in patients receiving isotretinoin. Heavy alcohol use may reduce its effectiveness (and that of contraception).¹

Navigating isotretinoin and the iPledge



OK, who CAN prescribe with iPledge??

- Dermatologists
- Family Practitioners
- •OB/GYN
- •Oncologists Isotretinoin can treat cancers too!
- PEDIATRICIANS (I registered last month)
- And YES Nurse Practitioners and Physician Assistants too in most states!

BACKGROUND: Isotretinion

- For severe recalcitrant nodular acne OR treatment resistant OR moderate acne which recurs when stop medications
- <u>Nothing works better for severe acne</u> 85% permanent cure (although in first month acne can worsen the Accutane purge)
- Dosing 0.5 mg/kg /day with food can go up to 1 -2 mg/kg/day . . TOTAL max 120 – 150 mg/kg over 4-6 mos : usually BID but can q day for compliance (often 20mg then gradually to 60 even 80 mg)
- Acne Can recur in 20% may repeat course after 2 mos



The BIG RISK - ISOTRETINOIN FETAL TERATOGENICITY

- 20% Spontaneous Abortion
- 20-30% Embryopathy/Birth Defects

- iPledge intro <u>2006</u> by FDA (SMART before that) to reduce fetal exposure to Isotretinoin
- Computer based Risk Evaluation and Mitigation Strategy (REMS)
- A Database for Prescibers & Patients & Pharmacies





• MUCH more onerous than the previous SMART!!!

- <u>Complaints/frustrations about iPledge</u>
- * repetitive intrusive confusing monthly attestations
- * strict prescribing windows for women which can block/delay treatment
- * glitches in labs, derm offices, pharmacies and iPledge database itself

•BUT DOES iPledge WORK????



2019 JAMA DERM Report Isotretinion and Pregnancy

JAMA Dermatology | Brief Report

US Food and Drug Administration Reports of Pregnancy and Pregnancy-Related Adverse Events Associated With Isotretinoin

Elizabeth Tkachenko, BS; Sean Singer, BS; Priyank Sharma, MD;

- Isotretinion pregnancies peaked 768 in 2006 when iPledge introduced then gradual decline until 2011 then steady 250/yr since
- Decline more due to LARCs, emergency contraception
- "Ipledge did not lower the RATE of fetal exposures compared to less onerous SMART and still too many pregnancies"



OTHER Possible Isotretinoin side effects

- Headaches: Pseudotumor with tetracyclines-papilledema vision tinnitus dizziness
- <u>Psychiatric: Depression Suicidality</u>? <u>Huang YC, Cheng YC. Isotretinoin treatment for acne</u> and risk of depression: A systematic review and meta-analysis. J Am Acad Dermatol 2017; 76:1068. – No causal relationship – YES increased depression if severe acne
 . (*new Brit J Derm 2/22 - it <u>reduces</u> psychiatric risk!*)
 - <u>Inflammatory Bowel Disease</u>? No causal relationship people with severe acne may be more prone to IBD independently
- Who better to monitor Headaches, mood, GI issues than the pediatric medical home????

MORE Potential Side Effects

- <u>Hyperlipidemia</u>: Triglyceride rise in 30%, Milder inc cholesterol/LDL in 20% . . IF TG 500-800 then reduce dose, rarely need to stop (TG > 800)
- <u>Liver inflammation</u>: NOT common. Alcohol not forbidden but avoid excessive

Lee et al. Jama Derm 2016: Get baseline LFTs and Lipids. repeat it ONCE 6-8 weeks later if all OK (monthly labs NOT required)

- Decreased Night Vision, night driving concerns
- Sun sensitivity
- Muscle aches : Rx stretch, occasional NSAID

AGAIN, WHO IS BETTER MONITORING THESE THAN US!!



•ACNE FULMINANS ok, scary

•(Help us Kashie)



The most common side effect....

•DRY EVERYTHING!!

- If not dry, then not compliant!
- Skin moisturizers non comedogenic
- Eyes: artificial tears/saline
- Lips: Lip Balm
- nose/nosebleeds: nasal saline/petroleum gel
- Avoid makeup



So....iPledge for those who cannot become pregnant: Short and sweet!!

- Enroll short enrollment form if cannot become pregnant
- •Access website
- Baseline labs LFTs/ lipids for all
- Give Precription max 30 day supply
- START <u>ANYTIME</u> IN NEXT 30 DAYS
- •See ya monthly!!



BUT...iPledge for those who CAN become pregnant OY!!!!

- 1st visit negative pregnancy test CLIA lab needs to be entered to enroll
- Enroll patient signed consent general plus detailed info of birth defects (thereafter patient monthly quiz on birth control/sexual activity on website)
- Counsel on mandatory TWO forms birth control OR refer to professional –
- 1) LARCs BCPs & 2)Condom/Sponge/Diaphragm
- Manufacturer will reimburse for 1 visit contraceptive counselling
- Baseline CBC Diff glu CPK , LFTs/Lipids
- STILL, Cannot get ANY prescription until SECOND visit in a month

CHILDREN'S HEALTH

MUST ALL those child bearing potential be on birth control?

• YOU MAY choose abstinence instead – commit to no sex for 1 month before starting until one month after ending Recommended only if lifestyle choice, NOT for just not having partner

• THE MOST COMMON REASON for Isotretinion pregnancy is intercourse when pledged to be abstinent – NOT birth control failure

• "Should ALL women of child bearing age be required to be on birth control?"

Second Visit in 1 month for those who CAN become pregnant

- Second preg test CLIA certified lab at least 30 days after enrollment and during 1st 5 days of menstrual cycle
- STRICT 7 day window from when second preg test done (NOT when prescription sent) to fill prescription for 30 days of isotretinoin –
- IF they miss 7 day window (computer glitch office busy pharmacy error patient busy at college) <u>MUST START OVER next month!</u>
- Pregnancy test every month with office visit (vs home preg test and text pic?) -Same 7 day window rules for pregnancy test – also need f/up LFTs/lipids too



My Worries about isotretinoin prescribing...

• The Hassle!! BUT we are allowed designate office personnel through iPledge to help online (it is all much easier with males!)

• ACNE FULMINANS esp males with severe acne trunk/face –

- Lack of experience But if Kashie can do it, so can we!
- Partner with derm?



YOUR TURN Dr Oza!







POST DEBATE HOT CONTROVERSY – <u>ISOTRETINOIN</u> `

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(POST DEBATE) Should every patient with child bearing ability on isotretinoin be on some form of birth control (declaring abstinence is not good enough?)

YES NO

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