
Restricted Drug Programs

Restricted Drug Programs

- List medications with special dispensing requirements
 - Identify the medication associated with the **iPledge** program
 - Understand the regulations surrounding **Thalomid**
 - Understand the regulations surrounding **Clozapine**
 - State and be able to apply the restrictions on the sale of **Pseudoephedrine**
 - State and be able to apply the restrictions on the sale of **Emergency Contraception**
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Restricted Drug Programs

- **Restricted Drug Programs**

- List medications with special dispensing requirements.
 - These drugs generally are very useful for a small population or have a unique role in health care.
 - They also may have some very serious drawbacks to their use.
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iPledge Program - Isotretinoin

- Isotretinoin is sold as:
 - Accutane*
 - Amnesteem
 - Claravis
 - Myorisan
 - Sotret
-

iPledge Program

- Isotretinoin:
 - Uses: Severe recalcitrant nodular acne
 - Contraindications:
 - Pregnancy, breast feeding (Category X)
 - Hypersensitivity to soy oil
 - Dosing: 0.5 - 1 mg/kg/day
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Recalcitrant Nodular Acne



iPledge Program

- Isotretinoin:
 - AEs: dry, itchy skin, dry mucus membranes, liver abnormalities, depression, elevated cholesterol
 - Cautions
 - Do not donate blood!
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Pregnancy Categories

A: Generally acceptable. Controlled studies in pregnant women show no evidence of fetal risk.
e.g. folic acid, vitamins, magnesium

B: May be acceptable. Either animal studies show no risk, but human studies are not available, or animal studies showed minor risks and human studies done showed no risk.
e.g. Thyroid, Singular, Benadryl

Pregnancy Categories

C: Use with caution if benefits outweigh risks. Animal studies show risk and human studies not available or neither animal nor human studies done.

e.g. Prozac, Zoloft

D: Use in LIFE-THREATNING emergencies when no safer drug available. There is evidence of human fetal risk.

e.g. Cytoxan, Tetracycline

X: Do not use in pregnancy. Risks outweigh potential benefits. Safer alternative exist.

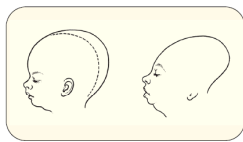
e.g. Accutane, Thalidomide

iPledge Program

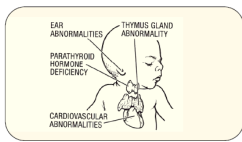
- The goals of the iPLEDGE program are:
 - To prevent fetal exposure to Isotretinoin.
 - To inform prescribers, pharmacists, and patients about Isotretinoin's serious risks and safe-use conditions.
 - Ensure that no female patient starts if pregnant and no female patient becomes pregnant while taking the drug.
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iPledge Program

Fetal exposure carries with it an extremely high risk of severe birth defects



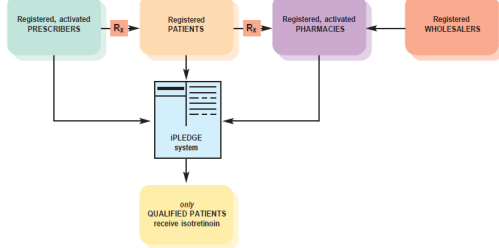
Line drawing represents the possible abnormalities of the low set, deformed, or absent ears; wide-set eyes; depressed bridge of nose; enlarged head; and small chin.



Line drawing represents the possible abnormalities of the brain, heart, and thyroid gland that may occur.

iPledge Program - Isotretinoin

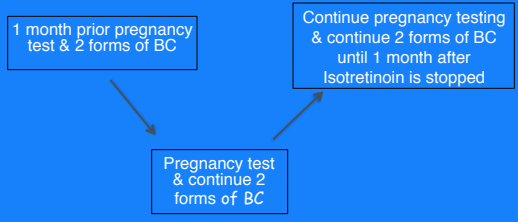
The trackable links of the iPLEDGE program



iPledge Program

- Women of childbearing potential must have negative pregnancy tests prior to starting and use 2 forms of contraception while on the drugs and for 1 month after stopping.
 - They must pick up their drug within 7 days of being seen by the prescriber.
 - They may only get a 30 day supply.
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iPledge Program



iPledge Program

- Men and women not of childbearing potential have fewer restrictions.
 - They must pick up their drug within 30 days of being seen by the prescriber.
 - They may only get a 30 day supply.
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iPledge Program - Pharmacy

- Must be registered
 - Must obtain authorization prior to dispensing
 - Must record authorization on prescription
 - Cannot refill a prescription
 - Cannot break a package
 - Cannot allow pick up after the time window
-

STEPS Program - Thalomid

- In the early 60s the drug was found to be a potent **teratogen**.
 - Severe abnormalities with as little as one dose!
 - 40% mortality at birth, or shortly afterwards.
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STEPS Program - Thalomid

- It is now recognized to be effective for some very selective diseases.
 - Erythema Nodosum Leprosum
 - Multiple Myeloma
 - GVHD.....
 - **Today it is no less dangerous!**
 - Pregnancy Category - X
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STEPS Program

- Goal of the STEPS program:
 - To prevent the risk of fetal exposure to Thalomid.
 - To inform prescribers, patients and pharmacists of the serious risk and safe-use conditions for Thalomid.
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STEPS Program - Childbearing Potential

- A woman should have 2 negative pregnancy tests, 10 – 14 days and 24 hours, before starting.
 - She must use 2 forms of contraception beginning 4 weeks before starting, during and for 4 weeks after stopping Thalomid.
 - Treatment must be stopped immediately if she become pregnant.
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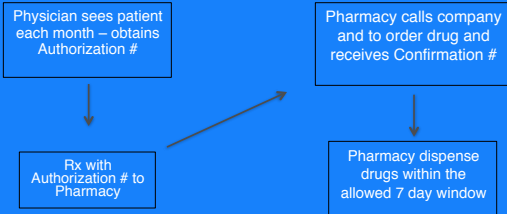
STEPS Program - Misc.

- Women 24 months post-menopausal or post-hysterectomy have fewer restrictions.
 - Men must always use a latex condom if engaging in intercourse.
 - Patients cannot donate blood while receiving Thalomid.
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STEPS Program

- This is again a closed distribution program.
 - Physician, Patient and Pharmacy must be registered and authorized to participate.
 - The product is shipped directly from the manufacturer.
 - There is only one brand on the market.
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STEPS Program



STEPS Program - Pharmacy

- Must be registered.
- Prescription must have Authorization #.
- Must obtain Confirmation # prior to dispensing.
- Must record Confirmation # on prescription.
- Cannot refill a prescription.
- Cannot break a package.
- Cannot allow pick up after the time window.
- Any returned drugs must be sent to company.
- Cannot transfer drug to another pharmacy.

Clozaril / Clozapine - Patient Registry

- Marketed as Clozaril
 - Now available generically from several manufacturers
 - Teva
 - Sandoz
 - Mylan
 - Others?
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Clozapine Patient Registry

- An effective drug for refractory schizophrenia, but...
 - Problem – impact on White Blood Cell counts.
 - Wide range in dosage. Patient dose titrated to reach benefit without blood count problem.
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Clozapine Patient Registry

- Prescriber, Patient and Pharmacy must be registered.
 - Each company making Clozapine has their own registry.
 - Patient's WBC counts must be reported to registry BEFORE the drug is dispensed.
 - Registry records counts and gives Okay to dispense drug.
 - Record this in the Rx database.
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Clozapine Patient Registry

- Frequency of WBC monitoring
 - 1st 6 months weekly
 - If okay, 2nd 6 months bi-weekly
 - If okay, every 4 weeks thereafter
 - If counts drop, there is a schedule for stopping and restarting the treatment.
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Pseudoephedrine Restrictions

- Daily sales limit of PSE
 - ???? per day, not per sale
- Monthly sales limit –
 - ???? mg per 30 days, but not on the same day
- This for the BASE drug.
- Mail order or mobil pharmacy ???? per month

CMEA – Limits on Daily Sale

| Ingredient | Number of tablets = 3,600 mg |
|--------------------------------|------------------------------|
| 25 mg. Ephedrine HCl | 175 tablets |
| 25 mg. Ephedrine Sulfate | 186 tablets |
| 30 mg Pseudoephedrine HCl | 146 tablets |
| 60 mg Pseudoephedrine HCl | 73 tablets |
| 120 mg Pseudoephedrine HCl | 36 tablets |
| 30 mg Pseudoephedrine Sulfate | 155 tablets |
| 60 mg Pseudoephedrine Sulfate | 77 tablets |
| 120 mg Pseudoephedrine Sulfate | 38 tablets |
| 240 mg Pseudoephedrine Sulfate | 19 tablets |

Emergency Contraceptives

- Purpose is to reduce the chance of pregnancy occurring in women who have had unprotected sex.
 - It is more effective when taken closer to the event.
 - Best taken within 72 hours of unprotected sex.
 - How effective is it?
 - Impact of weight on efficacy....
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Emergency Contraceptives

- Contains one of the hormones in normal OCs, but in a larger dose.
 - One tablet, taken once.
 - Primary AEs, nausea and vomiting.
 - Should not be substituted for normal birth control.
 - Should not be used if pregnant, but not harmful to the fetus.
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Emergency Contraceptives

- Has dual marketing status (both Rx and behind the counter OTC)
- Prescription drugs for < 17 years old
- Can be sold OTC for ≥ 17 years old
- Female only or males also?
- Hot political issue has kept it in this status.

Emergency Contraceptives

- Exceptions:
 - In Massachusetts if a pharmacist has additional training and a protocol in place with a licensed physician, the pharmacist may dispense Plan B to patients younger than 17 without an Rx.
 - The pharmacist must report on an annual basis to the department of public health the number of times they dispensed such EC.

Sale/Dispensing of Syringes

- Syringes are usually sold on prescription and paid by insurance.
 - In Massachusetts syringes MAY be sold without a prescription to individuals who are 18 ≥ years old.
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Sale/Dispensing of Syringes

- Why do we sell syringes without a prescription?
 - These are generally being sold to individuals with drug abuse issues.
 - Is this a good idea? Why?
 - The goal is to reduce needle/syringe sharing and reduce the spread of HIV/AIDS and Hepatitis.
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