약물사용 안전성 확보를 위한 DUR제도 도입방안

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Implementation of DUR program for assuring medication safety in Korea

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Medication safety

Who has responsibility for this purpose?

US: FDA has the responsibility for assuring the safety and efficacy of all regulated marketed medical products.
MedWatch, The FDA Safety Information and Adverse Event Reporting Program,

Korea: KFDA (한국식품의약품 안전청)
what program?

Four levels for medication safety

in US..

1. Federal level
2. State level
3. PBM level
4. Patient level

1. Federal level:

MedWatch (US FDA)

1. serves both healthcare professionals and public
2. provides information about safety issues of medications including OTC drugs
3. disseminates safety alerts, recalls, withdrawals, and important labeling changes via web site
4. allows healthcare professionals and public to report serious events to FDA either by phone or on-line
5. Form FDA 3500, 3500A available by on-line

Why Medwatch?

- To ensure a safe use of medications

- To provide information about safety issues of medications to healthcare professionals and public

2. State level:

DUR Board (NY)

(Source→http://www.health.state.ny.us/nysdoh/mancare/omm/1198med.htm)

Board members:
- 5 physicians
- 5 pharmacists
- 2 persons with expertise in DUR
- 1 person assigned by Commissioner of DOH

Meets quarterly
Performs RetroDUR
Manages formulary control

2. State level:

DUR Board (CA)

(Source→ http://files.medi-cal.ca.gov/pubsdoco/dur/dur_bm.asp)

MDs

PharmDs

DUR staffs

Why DUR Board?

- To ensure a safe (proper) use of medications
- To reduce medical costs

Omnibus Budget Reconciliation Act of 1990 (OBRA 90)
√ enacted by Congress on November 5,1990
√ affected Medicaid pharmacy programs and providers
√ mandated pharmacists to perform DUR from 1/1/1993

3. PBM level:

DUR in Meadcohealth →

- √ Therapeutic duplication
- √ Drug-drug interaction
- √ Drug-disease interaction/contraindication
- √ Drug-age precaution
- √ Early refill (overuse)
- √ Late refill (underuse)
- √ Pregnancy alert
- √ Drug allergy allert
- √ Low dose/high dose

4. Patient level:

Labeling includes →

- √ patient name
- √ adress an phone nember
- √ prescriber and pharmacist name (phone nember)
- √ drug name and direction
- √ auxiliary labeling where applicable
- √ contraindication
- √ warning
- √ precaution
- √ side effects
- √ drug interaction
- √ overdose
- √ missed dose

What's going on in Korea?

√ Anything like Medwatch in KFDA?
√ Anything like DUR Board in Ministry of Health?
√ Anything like DUR processing center in National Health Insurance Corp.?

Now, we got to go for DUR...

1. Nationally...
   √ DUR processing center

2. Locally...
   √ on-site DUR processing system
   - at tertiary medical centers
   - at local hospitals/clinics
   - at local pharmacies

DUR Board in Korea: suggestion

Affiliation: Ministry of Health
Board members:

- **5 physicians→3 actively practicing, 2 specialized**
- **5 pharmacists→3 actively practicing, 2 specialized**
- **2 non-physician/non-pharmacist→with expertise in DUR**
- **1 person→assigned by Ministry of Health**

Meets quarterly
Discusses ProDUR guideline
Performs RetroDUR

2003 영남대학교 유봉규

한국임상약학회

Tools for DUR:

Drug Information Framework-Korea® : for POS and ProDUR (PharmVan, Korea)

First SX®: for POS and ProDUR (First Health Services, US)

First IQ® : for RetroDUR in US (First Health Services, US)

Other computer softwares available commercially…

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DUR system implementation: in Korea

1. Hardware
   - DUR center
   - real-time communication

2. Software
   - legislation (DUR bill?)
   - computer program (s/w)
     √ for ProDUR
     √ for RetroDUR
   - educational program
     √ for physicians
     √ for pharmacists

Three components of DUR

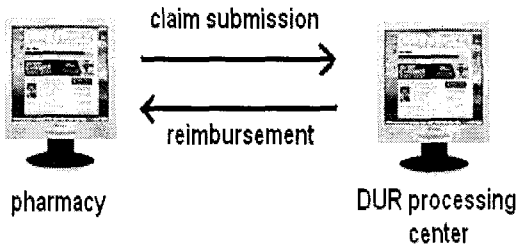
1. ProDUR program
2. RetroDUR program
3. Educational program
   - prescribers
   - dispensers

ProDUR alerts

1. Therapeutic duplication
2. Drug-drug interaction
3. Drug-disease interaction/contraindication
4. Drug-age precaution
5. Early refill (overuse)
6. Late refill (underuse)
7. Pregnancy alert
8. Drug allergy allert
9. Low dose/high dose
10. Other alerts...

ProDUR alerts

1. Within a scrip?
2. Within a patient's whole medication profile?



ProDUR alerts

1. TD (therapeutic duplication):
   - alerts when a patient receives two or more drugs from the same therapeutic or pharmacologic class
   - increases the risk of an adverse events
   - incurs medical costs without therapeutic benefit

2. DI (drug-drug interaction):
   - alerts only for significant (Severity Level 1) drug interactions between drugs in a new prescription and currently active on the patient's profile.

ProDUR alerts

3. DD (Drug-Disease interaction):
   - alerts when certain target drugs are prescribed for patients with existing medical conditions. ICD-9 diagnosis codes from medical and hospital claims data are used to detect diseases that may be aggravated or altered by the prescribed target drug.
   - diseases are classified as either short term (remain active in patient history for 3 months) or long term (remain active indefinitely).
   - disease durations are to be determined by consensus of the DUR Board.

ProDUR alerts

4. PG (Drug-age precaution, pediatric/geriatric):
   - alerts select target drugs for specific age ranges.
   - pediatric conflicts pertain to patients age <18
   - geriatric conflicts pertain to patients age ≥65

5. ER (Early Refill, overuse):
   - alerts early refills and/or potential abuse situations
   - alerts when a subsequent prescription submitted for the same target drug with greater than 25 % of the previously dispensed prescription remains.

ProDUR alerts

6. LR (Late Refill, Underuse):
   - alerts when patients fail to refill timely
   - alerts when subtherapeutic doses are detected

7. PG (pregnancy):
   - alerts when categories D or X are prescribed for a pregnant women
   - pregnancy is detected by ICD-9 codes from the patient medical claim history and claim history for prenatal vitamins.

ProDUR alerts

8. DA (Drug-Allergy):
   - alerts when a drug previously documented as allergic to the patient is prescribed

9. LD/HD (low dose/high dose):
   - alerts when doses for a drug falls outside the normal adult or pediatric dosage range
   - adult recipients are ≥ 18 years
   - pediatric recipients are < 18 years

Typical schedule for ProDUR: 6 months...

1. Software purchase (2 months)
   - RPh should contact program vendors
2. Initial testing phase (2 months)
   - RPh should learn how to use DUR program
3. Educational phase (2 months)
   - RPh will see Alerts but without rejection
4. Full implementation
   - RPh will see Alerts
   - RPh should contact prescriber for processing the scrip

RetroDUR: what's good for?

1. Identify unsafe drug use
2. Educate prescribers and pharmacists for safe drug use
1. Prevents future drug-related problems

RetroDUR: what duty?

1. Guidelines
   - √ Creates guidelines for safe drug use
2. Statistics
   - √ Creates statistics of drug use pattern by prescriber
   - √ Creates statistics of drug use pattern by pharmacists
   - √ Creates statistics of drug use pattern by recipients
3. Audits
   - √ Performs yearly audits for select prescribers, pharmacist, and recipients
4. Educational program
   - √ Creates educational programs for prescribers, pharmacists, and recipients

RetroDUR

by who?

- performed by DUR Board and staff
- nationally and/or locally

what to do?

- guidelines, statistics, audits, educational program
- random audits → 10 pharmacies yearly
  10 hospitals yearly
  10 local clinics yearly

for what period?

- a one-year period

RetroDUR: specifically what kind of audit?

√ Required information in prescription ordered
√ Required information in labeling of dispensed drug
√ License numbers on claim versus on script
√ Verification of drug ordered, dispensed, and billed

√ Review prescribing practice of physicians
√ Review dispensing practice of pharmacists
√ Review drug utilization of individual recipients

√ Dispensing log maintenance

RetroDUR: example in CT Medicaid DUR Board

Case #440: Therapeutic Duplication (TD)

DOS	pt name	Drug	Qty	DS	pharm ID
3/29/03		Skelaxin 400mg	180	30	411
3/29/03		cyclobenzaprine 10mg	90	30	411
3/29/03		Amerge 2.5mg	6	5	411
3/29/03		Maxalt MLT 10mg	6	3	411
3/31/03		oxycodone/APAP 5/325	15	5	411
3/31/03		butalbital/APAP/caffeine	15	5	411
4/7/03		Amerge 2.5mg	6	3	411
4/7/03		Maxalt MLT	6	3	411

RetroDUR: example in CT Medicaid DUR Board

Case #450: Early Refill (ER)

DOS	pt name	Drug	Qty	DS	pharm ID	prescriber ID
1/20/03	Mary Doe	protonix 40mg	30	30	403	7010
2/4/03	Mary Doe	protonix 40mg	60	15	403	7010
2/20/03	Mary Doe	protonix 40mg	30	30	403	7010
3/5/03	Mary Doe	protonix 40mg	60	15	403	7010
3/17/03	Mary Doe	protonix 40mg	30	30	403	7010
4/17/03	Mary Doe	protonix 40mg	90	30	403	7010
4/24/03	Mary Doe	protonix 40mg	90	30	403	7010

Educational program

DUR Board should work on it

Based on the results of...

- √ ProDUR and RetroDUR
- √ RetroDUR
- √ statistics
- √ audits

Patient level:

Labeling for patient should include...

- √ drug name and direction
- √ auxiliary labeling where applicable
- √ contraindication
- √ warning
- √ precaution
- √ side effects
- √ drug interaction
- √ overdose
- √ missed dose

Crucial component for medication safety

Also a part of patient's right

Conclusion

- Real time communication: btw Rx and DUR center
- We have a strong internet system nationwide
- We are one of the most highly wired countries

- Concerns over medication safety can never be overemphasized!
- It is time to go forward DUR!

Question?