Initial Testing of Instruments to Discern Adverse Drug Reactions and Adverse Drug Experiences in an Ambulatory Patient Population: Preliminary Results

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BACKGROUND

Adverse Drug Reactions (ADRs)/Adverse Drug Experiences (ADEs)

- Increasing number of medications dispensed[1,2]
- Increase in adverse drug events (ADEs) and adverse drug reactions (ADRs)[3]
- Serious and fatal ADE/ADRs doubled from 1998 to 2005[3]
- ADE/ADRs underreported by as much as 94 percent[4-6]

Community Pharmacy

- Pharmacists can reduce the incidence of ADEs in both hospital and community settings[7-8]
- Community pharmacists:
  - Are highly-trained
  - Are very accessible and see chronic patients very frequently
  - Can address the issue of ongoing ADE/ADRs in ambulatory patients

OBJECTIVE

Primary Objectives

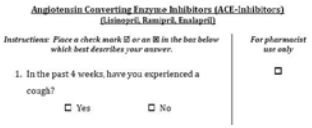
1. To estimate the prevalence of patient-reported ADE/ADRs in the community pharmacy setting
2. To determine the prevalence of ADE/ADRs relative to pharmacist expert judgment

METHODS

Instrument Development

- Used *Pharmacy Times* Top 200 Drugs of 2008 list to identify the top 200 dispensed medications[9]
- ADE/ADRs for each medication obtained from *Drug Facts and Comparisons*, *Lexi-Comp*, and *Micromedex*[9]
- Brief 5 item modules developed for each pharmacologic class within the top 200 medications (n=51)
  - Determined the most common ADE/ADRs experienced for each class
  - Created questions related to the top 5 ADE/ADRs from the existing literature with a yes or no response
  - Check box next to the symptom for a pharmacist to indicate whether they believe the ADE/ADR is due to the medication

Example Question:



Angiotensin Converting Enzyme Inhibitors (ACE-Inhibitors)
(Lisinopril, Ramipril, Enalapril)

Instructions: Place a check mark ☑ or an ☒ in the box below which best describes your answer.

For pharmacist use only

1. In the past 4 weeks, have you experienced a cough?

☐ Yes ☐ No

☐

Instrument Testing

- 10 community pharmacy sites across Indiana
- Administering 20 instruments for each of the 51 pharmacologic classes
  - Each site n = 1,020 instruments
  - Overall N = 10,200 instruments
- Procedure:
  - Patients requesting a prescription refill for a top 200 medication asked to participate
  - Patients instructed to check "yes" or "no" for each ADR they've experienced in the past 4 weeks
  - Pharmacists will:
    - Review the completed instrument prior to counseling
    - Proceed with routine counseling procedures
    - Discuss indicated ADE/ADRs
    - Indicate on the instrument if they believe, based on their expert clinical judgment, the ADE/ADR is related to the medication

Data Analysis

- Double-entry of data
- Analyzed using SPSS v. 18.0
- Frequencies calculated

Data Collection

- Ongoing
- Current N = 1914 at 7 months

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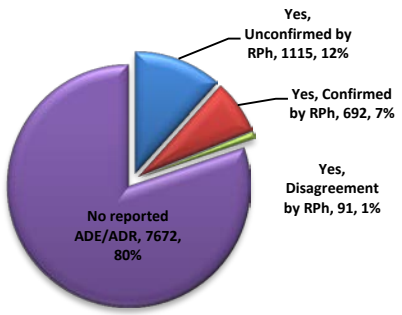
RESULTS

Raw Incidence of ADE/ADRs by Pharmacological Class

Pharmacological Class	N	%
Agents for Gout	13	7.9
Bisphosphonates	15	8.8
Anti-Fungals	13	10.0
Estrogens	20	11.4
Leukotriene Receptor Antagonists	20	11.4
Impotence Agents (Phosphodiesterase Type 5 Inhibitor)	18	12.0
Selective Estrogen Receptor Modulator	3	12.0
Serotonin 5-HT1 Receptor Agonists	3	12.0
Gastrointestinal Agents (H2 Antagonists)	15	12.5
Opioid Analgesic Combinations	38	13.1
Respiratory Agents	23	13.5
Electrolytes (K+ Replacement)	28	14.0
Aminopenicillins	19	14.1
Anti-Histamines	26	14.4
Anti-Hypertensive Combinations	37	14.8
Bronchodilators (Sympathomimetic)	17	15.5
Narcotic Analgesics	17	15.5
Non-Steroidal Anti-Inflammatory Agents (NSAIDs)	27	15.9
ARBs	41	16.4
ACE-Inhibitors	65	16.7
Dermatological Agents (Topical Local Amide Anesthetic)	6	17.1
Sedatives and Hypnotics	37	17.6
Diuretics	61	17.7
Vasodilators (Nitrate)	18	18.0
Anti-Coagulants	38	18.5
Anti-Hyperlipidemic Agents	87	18.7
Thyroid Hormones	64	19.1
Contraceptive Hormones	55	19.6
Prostaglandin Antagonists	14	20.0
Smoking Deterrents	19	20.0
Nutrient and Nutritional Agents (Fat Soluble Vitamin)	35	20.6
Skeletal Muscle Relaxants (Centrally-Acting)	26	20.8
Proton Pump Inhibitors (PPIs)	65	22.0
Anti-Diabetic Agents	83	22.7
Calcium Channel Blockers	49	22.8
Cholinesterase Inhibitors	8	22.9
NMDA Receptor Antagonists	8	22.9
Benzodiazepines	70	23.0
Anti-Infective Agents	48	23.4
Intranasal Steroids	34	23.4
Anti-Cholinergics	44	23.8
CNS Stimulants	50	23.8
Anti-Platelet Agents (Aggregation Inhibitor)	49	25.1
Opioid Analgesics	39	25.2
Anti-Psychotic Agents	37	25.5
Anti-Adrenergic Agents (Centrally-Acting)	41	27.3
Anti-Dopaminergics	34	28.3
Adrenal Corticosteroids	47	31.3
Anti-Convulsants	55	31.4
Anti-Depressants	109	32.5
Cardiovascular Agents	110	33.8
Total Completed	**1914**	**18.8**

Overall Raw Incidence of Reported ADE/ADRs



10 Pharmacologic Classes with the Most Patient-Reported ADE/ADRs

Rank	Pharmacologic Class	N	%
1	Cardiovascular Agents	110	33.9
2	Anti-Depressants	109	32.5
3	Anti-Convulsants	55	31.4
4	Adrenocorticosteroids	47	31.3
5	Anti-Dopaminergics	34	28.3
6	Anti-Adrenergic Agents (Centrally-Acting)	41	27.3
7	Anti-Psychotic Agents	37	25.5
8	Opioid Analgesics	39	25.2
9	Anti-Platelet Agents (Aggregation Inhibitor)	49	25.1
10	CNS Stimulants	50	23.8

5 Pharmacologic Classes with Highest Level of Patient-Pharmacist Congruence

Rank	Pharmacologic Class	N	%
1	Selective Estrogen Receptor Modulator	28	80
2	Nutrient and Nutritional Agents	28	80
3	Agents for Gout	36	76.6
4	Anti-Dopaminergics	26	76.5
4	Narcotic Analgesics	13	76.5

5 Pharmacologic Classes with the Least Patient-Reported ADE/ADRs

Rank	Pharmacologic Class	N	%
1	Agents for Gout	13	7.9
2	Bisphosphonates	15	8.8
3	Anti-Fungals	13	10
4	Impotence Agents	18	12
4	Sedatives and Hypnotics	3	12
4	Serotonin 5-HT1 Receptor Agonists	3	12

IMPLICATIONS

Implications

- Full system will enhance pharmacists ability to discern ADE/ADRs their patients may be experiencing
- Use of the module system may lead to earlier identification of patients experiencing ADE/ADRs and positively impact patient safety and medication outcomes

Limitations

- Current format is unable to differentiate between pharmacist no comment and pharmacist failure to complete module
- Current estimates of congruence may therefore provide only the lower bound of validated incidence of ADE/ADRs in the community setting

Future Directions

- Complete pilot testing
- Automate system
- Develop sufficient evidence of benefit in order to justify inclusion of module system in community pharmacy work flow

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