Recognizing and Avoiding Adverse Drug Events

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OADs can be a matter of perspective.

30-year-old woman

Case Example

• 30-year-old woman

Evidence of impaired judgment, confusion seems normal
Temperature (100°), dizziness, sense of slowed time, no hallucinations, suicide thoughts elevated.

Self-admitted for suicidal ideation, taken off Prozac and placed on Cymbalta. Reassess after 5 days. Within 4 days, calls to complain of NO sleep for 4 days. Visual hallucinations, skin rash, elevated heart rate, elevated temperature. Skin rash, elevated heart rate.

Adverse Drug Events

May Cause:

- Death
- Depression
- Vomiting
- Sensitivity
- Anaphylaxis

Avoiding Adverse Drug Events

Only you can prevent ADEs!

ADEs are common and commonly missed. The more eyes are on a patient, the more likely an ADE is recognized.

Example: sedation can be an “unwanted, unpleasant” reaction to one drug in one case can be the desired reaction in one case.

an in jury resulting from medical drugs, including medication errors, ADRs, allergic reactions, overdoses

a drug effect that is unwanted, unpleasant, noxious.

Adverse Drug Reaction
Role for psychologists

- Many ADRs are unpreventable knowledge or forgetting
- APA Guidelines on Psychopharmacology (2011)
- Several medications are filled every year
- Approximately 1.6 million hospital stays involving ADEs occurred in 2014
- Psychotropics accounted for 8.1% of hospital ADE stays in 2014

Why are ADEs important?

- one of the leading causes of morbidity and mortality in health care—possibly the 4th leading cause of death
- over 4 billion prescriptions are filled every year
- the rate of ADRs increased significantly with 4 or more prescriptions
- Approximately 1.6 million hospital stays involving ADEs occurred in 2014
- Psychotropics accounted for 8.1% of hospital ADE stays in 2014

Adverse Drug Events account for what portion of ALL hospital adverse events?

<table>
<thead>
<tr>
<th>Medication Class</th>
<th>ADEs</th>
</tr>
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<tbody>
<tr>
<td>Analgesics</td>
<td>1 in 3</td>
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<tr>
<td>Antimicrobials</td>
<td>1 in 9</td>
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<tr>
<td>Antipsychotics</td>
<td>1 in 20</td>
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<tr>
<td>Diabetes Medications</td>
<td>1 in 50</td>
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<tr>
<td>Cancer Medications</td>
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</tr>
</tbody>
</table>

\# of ADR reports made to FDA

- Over 4 billion prescriptions are filled every year
- The odds of an ADR increase significantly with 4 or more prescriptions
- Approximately 1.6 million hospital stays involving ADEs occurred in 2014
- Psychotropics accounted for 8.1% of hospital ADE stays in 2014
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- One of the leading causes of morbidity and mortality in health care—possibly the 4th leading cause of death
- Over 4 billion prescriptions are filled every year
- The rate of ADRs increased significantly with 4 or more prescriptions
- Approximately 1.6 million hospital stays involving ADEs occurred in 2014
- Psychotropics accounted for 8.1% of hospital ADE stays in 2014

Adverse Drug Events account for what portion of ALL hospital adverse events?

| Medication Class | ADEs | 0-5% | 5-10% | 10-15% | 15-20% | 20-25% | 25-30% | 30-35% | 35-40% | 40-45% | 45-50% | 50-55% | 55-60% | 60-65% | 65-70% | 70-75% | 75-80% |
|------------------|------|------|------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| Analgesics       | 1 in 3 | 0.5% | 5.5% | 10.5% | 15.5% | 20.5% | 25.5% | 30.5% | 35.5% | 40.5% | 45.5% | 50.5% | 55.5% | 60.5% | 65.5% | 70.5% | 75.5% | 80.5% |
| Antimicrobials   | 1 in 9 | 0.5% | 5.5% | 10.5% | 15.5% | 20.5% | 25.5% | 30.5% | 35.5% | 40.5% | 45.5% | 50.5% | 55.5% | 60.5% | 65.5% | 70.5% | 75.5% | 80.5% |
| Antipsychotics   | 1 in 20 | 0.5% | 5.5% | 10.5% | 15.5% | 20.5% | 25.5% | 30.5% | 35.5% | 40.5% | 45.5% | 50.5% | 55.5% | 60.5% | 65.5% | 70.5% | 75.5% | 80.5% |
| Diabetes Medications | 1 in 50 | 0.5% | 5.5% | 10.5% | 15.5% | 20.5% | 25.5% | 30.5% | 35.5% | 40.5% | 45.5% | 50.5% | 55.5% | 60.5% | 65.5% | 70.5% | 75.5% | 80.5% |
| Cancer Medications |        | 0.5% | 5.5% | 10.5% | 15.5% | 20.5% | 25.5% | 30.5% | 35.5% | 40.5% | 45.5% | 50.5% | 55.5% | 60.5% | 65.5% | 70.5% | 75.5% | 80.5% |
Most common ADRs of top 200 drugs

1. dizziness
2. nausea
3. headache
4. vomiting
5. diarrhea
6. rash
7. constipation
8. fatigue
9. insomnia
10. pruritus
11. thrombocytopenia
12. abdominal pain
13. somnolence
14. allergic reactions
15. dyspepsia
16. urticaria
17. dyspnea
18. hypotension
19. depression
20. paresthesia
21. anxiety
22. palpitation
23. tremor
24. arthralgia
25. anorexia
26. nervousness
27. anaphylaxis
28. xerostomia
29. fever
30. taste disturbance


But most of all beware of...
1. allergic reactions,
rashes
2. altered consciousness
3. vomiting/eating problems
4. diarrhea, constipation
5. heartbeat changes
6. fainting or dizziness
7. muscle changes (rigidity, spasms, weakness, righting, etc.)
8. swallowing, breathing difficulties
9. unusual bruising or bleeding
10. feeling sick
11. sexual side effects

Acetylcholine (ACH)

Acetylcholine (ACh)
• Acetylcholine= central and peripheral nervous system neurotransmitter that controls voluntary muscle function, digestion, glands, and glands.
• Anticholinergics can treat dizziness, extrapyramidal symptoms, GI disorders, insomnia, incontinence, respiratory problems, etc.

Sexual Side Effects
• Very common among psychotropics.

Mouth
Yellowing of eyes, skin

Fun Fact: many of the first chemical weapons are acetylcholinesterases.

Kim Jong-nam

Acetylcholine (ACh)

Acetylcholine (ACh)
• Acetylcholine= central and peripheral nervous system neurotransmitter (motor neurons, GI tract, urinary tract, alertness, arousal, etc.)
• Anticholinergics can treat dizziness, extrapyramidal symptoms, GI disorders, insomnia, incontinence, respiratory problems, etc.

Sexual Side Effects
• Very common among psychotropics.

Mouth
Yellowing of eyes, skin

Fun Fact: many of the first chemical weapons are acetylcholinesterases.

Kim Jong-nam
Sergei Skripal almost killed with Novichok powder — another acetylcholinesterase inhibitor.

Anticholinergic drugs

- Donepezil (Aricept)
- Rivastigmine (Exelon)
- Galantamine (Razadyne)

- Paracelsus (1493-1541)
  "Poison is in everything, and no thing is without poison. The dosage makes it either a poison or a remedy."

Anticholinergic drugs

- American Geriatrics Society (2019) Beers criteria

- First-gen antihistamines
  - diphenhydramine, hydroxyzine, meclizine, promethazine
- Anti-Parkinson’s drugs
  - benztropine (Cogentin)
- Antidepressants
  - TCAs, Paxil
- Antipsychotics
  - Clozapine, olanzapine, thioridazine
- And many more!
Anticholinergic symptoms

- Sedation
- Dry mouth
- Blurred vision
- Dizziness
- Urinary retention
- Confusion/delirium
- Constipation
- Hallucinations
- Reduced sweating and higher body temp
- Tachycardia

Antidepressants

- SSRIs
- SNRIs
- NDRIs
- NaSSAs
- SARIs
- TCAs
- MAOIs
- Atypicals

**Anticholinergic symptoms**

- Blind as a bat (dilated pupils)
- Red as a beet (vasodilation)
- Hot as a hare (hyperthermia)
- Dry as a bone (dry skin)
- Mad as a hatter (hallucinations/agitation)
- Bloated as a toad (urinary retention)
- And the heart runs alone (tachycardia)

**Antidepressants**

- **SSRIs**
  - Celexa, Lexapro, Prozac, Paxil, Zoloft
- **SNRIs**
  - Pristiq, Cymbalta, Effexor, Fetzima
- **TCA**
- **SRIs**
- **NaSSAs**
- **SARIs**
- **TCAs**
- **MAOIs**
- **atypicals**
Anti-depressants

- *TCA’s*
  - Amitriptyline, Clomipramine, Desipramine, Imipramine, Nortriptyline

- *MAOI’s*
  - Marplan, Nardil, EMSAM, Parnate

- *NDRI’s*
  - Wellbutrin (bupropion)
  - Also amphetamine, methylphenidate

- *NaSSa’s*
  - Remeron (mirtazapine)
  - Weilbutrin (bupropion)
  - NDRI’s

- *SARI’s*
  - Trazodone

- *Atypicals*
  - Viibryd (SSRI, 5-HT2A and 5-HT2C antagonist)
  - Trintellix (5-HT1A agonist, 5-HT1B partial agonist, 5-HT3 & 5-HT7 antagonist)
  - Brexanolone (NEW) allopregnanolone
  - Esketamine (NEW) NMDA antagonist, opioid?
Anti-depressant ADE's

- GI related ADE's:
  - Nausea
  - Vomiting
  - Weight Gain
  - Insomnia
  - Sexual effects (more likely than benefits!)
  - Agitation/drowsiness
  - Restlessness/racing thoughts
  - Suicide…?
  - Tardive dysphoria (TDp)…?
  - Drug interactions
  - QT prolongation (esp TCAs)
  - PVCs (with the antihistamines)
  - Falls, hyponatremia, dementia in elderly?*
  - And more! (tremor, night-sweats, yawning…)


In: NIHR Health Technology Assessment programme: Executive Summaries. Southampton (UK)


QT prolongation

- drugs that cause it:
  - CNS stimulants, chlorpromazine, haloperidol, thioridazine, quetiapine, risperidone, ziprasidone, fluoxetine, paroxetine, sertraline, citalopram/escitalopram (over 40mg), venlafaxine, TCAs, antibiotics, anti-fungals, sodium channel blockers, serotonin channel blockers, dopamine channel blockers, benzodiazepines, barbiturates

- risk factors: women, older, family history, heart disease, renal or hepatic disease, drug interactions, bradycardia, extremely low or high weight

- www.qtdrugs.org

- Torsades de pointes

- What to do?
  - get an EKG before and after starting a drug with QT potential

Serotonin Syndrome

- caused by over activation of 5HT-1A and 5HT-2A

- Serotonin Syndrome
  - caused by overactivation of 5HT-1A and 5HT-2A
  - result of:
    - a single drug used appropriately
    - two serotonergic drugs
    - over dosage
    - an overdose
    - renal or hepatic disease
    - drug interactions, bradycardia, extremely low or high weight

- signs:
  - Yawning
  - Agitation/drowsiness
  - Seizures
  - Sexual effects (more likely than
  - DT’s
  - Gastrointestinal distress
  - Weight gain
  - Yawning
  - Nausea
  - QT prolongation

- OT probablist

- Anesthesia

OT probablist ADE's
Serotonin Syndrome


Serotonin Syndrome

- Agitation
- Hyperreflexia
- Diaphoresis (excessive sweating)
- Tremor
- Mental status changes
- Shivering
- Myoclonus (involuntary muscle twitching)
- Diarrhea
- Poor coordination
- Fever

Withdrawing antidepressants

- Not a topic that has had much attention until recently.
- Withdrawing SSRI's slowly
- Count capsule pellets
- Crush pill, mix in liquid, slowly reduce volume over time.
- Liquid formulations, reduce dose over weeks.
- Some SSRI's have liquid formulations but may be hard to get
- Some studies now suggesting SSRI's should be decreased over months to years, maybe to 1/40 dose before.


Slowly withdrawing SSRI’s

Multiple studies now suggesting SSRI’s should be decreased over months to years, maybe to 1/40 dose before.

Depression mood, labile, with eos” (transient) syndromes of withdrawal include insomnia, anxiety.

Symptoms of withdrawal include insomnia, anxiety.

Anxiolytics

- Benzodiazepines (GABA agonists)
  - Xanax, Valium, Ativan, Clonazepam, etc.
  - BuSpar
  - Prazosin
  - Propranolol

Anxiolytics ADE’s

- BuSpar (buspirone) 5HT1A partial agonist
  - dizziness
  - nervousness
  - nausea
  - headache
  - jitteriness

- Inderal (propranolol) (beta-1 and beta-2 adrenergic antagonists)
  - dizziness
  - fatigue
  - bradycardia
  - hypotension

- Prazosin (Alpha-1 adrenergic antagonist)
  - sleepiness, dizziness, headache, weakness
  - priapism rarely reported
  - caution when adding to other hypertensives

- Benzodiazepines (sedation)
  - memory impairment, slurred speech, grogginess, confusion
  - incoordination (risk of falls in elderly)
  - dependence
  - paradoxical agitation
  - respiratory depression (avoid with apnea, alcohol, other sedatives)

- Propranolol (beta-1 and beta-2 adrenergic antagonists)
  - dizziness
  - nervousness
  - nausea
  - headache
  - jitteriness

- Prazosin
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Stimulants

- The Amphetamines
  - amphetamine (Evekeo)
  - dextroamphetamine (Dexedrine)
  - lisdexamfetamine (Vyvanse)

- The Methylphenidates
  - methylphenidate (Ritalin)
  - dexmethylphenidate (Focalin)

All are NDRIs but have other effects as well.

Stimulant AdEs

- Dry mouth/thirst
- Decreased appetite
- Nausea/Vomiting
- Abdominal cramps
- Constipation or diarrhea
- Heart rhythm changes (QT prolongation)—probably not as risky as we used to think when taken as prescribed.
**Antipsychotic ADEs**

### Typical Antipsychotics
- Tardive dyskinesia
- Weight gain
- Metabolic syndrome
- ACh symptoms
- QTc prolongation
- Increased prolactin

### Atypical Antipsychotics
- Weight gain
- Dry mouth
- Increased prolactin
- QTc prolongation
- ACh symptoms
- Suicide ideation
- Priapism
- Jaundice

### Comparison of Side Effects for Atypical Antipsychotics

<table>
<thead>
<tr>
<th>Name</th>
<th>Generic Name</th>
<th>Metabolic Syndrome</th>
<th>Weight Gain</th>
<th>Dry Mouth</th>
<th>ACh Symptoms</th>
<th>QTc Prolongation</th>
<th>Dry Mouth</th>
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<tbody>
<tr>
<td>Clozaril</td>
<td>Clozapine</td>
<td>++/++</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>+/+</td>
<td>0-10%</td>
</tr>
<tr>
<td>Risperdal</td>
<td>Risperidone</td>
<td>+</td>
<td>10-20%</td>
<td>-</td>
<td>++/++</td>
<td>-</td>
<td>0-10%</td>
</tr>
<tr>
<td>Latuda</td>
<td>Sertindole</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>++/++</td>
<td>+/+</td>
<td>0-10%</td>
</tr>
<tr>
<td>Zyprexa</td>
<td>Quetiapine</td>
<td>+</td>
<td>+/++</td>
<td>+</td>
<td>-</td>
<td>0-10%</td>
<td>0-10%</td>
</tr>
<tr>
<td>Seroquel</td>
<td>Ziprasidon</td>
<td>+/++</td>
<td>++</td>
<td>+</td>
<td>++/++</td>
<td>+/+</td>
<td>++/++</td>
</tr>
<tr>
<td>Abilify</td>
<td>Aripiprazol</td>
<td>++</td>
<td>++</td>
<td>+</td>
<td>++/++</td>
<td>+/+</td>
<td>0-10%</td>
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<tr>
<td>Paliperdin</td>
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<td>+</td>
<td>++</td>
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<td>++/++</td>
<td>+/+</td>
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<td>++/++</td>
<td>+/+</td>
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<td>Aripiprazol</td>
<td>+/++</td>
<td>++</td>
<td>+</td>
<td>++/++</td>
<td>+/+</td>
<td>0-10%</td>
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<tr>
<td>Blonanserin</td>
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<td>+/++</td>
<td>++</td>
<td>+</td>
<td>++/++</td>
<td>+/+</td>
<td>0-10%</td>
</tr>
<tr>
<td>Perospiron</td>
<td>Paliperidone</td>
<td>+/++</td>
<td>++</td>
<td>+</td>
<td>++/++</td>
<td>+/+</td>
<td>0-10%</td>
</tr>
<tr>
<td>Melperone</td>
<td>Melperone</td>
<td>+/++</td>
<td>++</td>
<td>+</td>
<td>++/++</td>
<td>+/+</td>
<td>0-10%</td>
</tr>
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**Stimulant ADEs**

- Psychosis (.21% amphetamine vs. .1% methylphenidate ages 13-25)
- Tics
- Mood swings
- Irritability
- Agitation
- Tension

### Dopamine and Serotonin Antagonists
- Better to compare each drug on its own terms
- Clozaril, Risperdal, Latuda, Zyprexa, Seroquel, Abilify
- Atypicals
- Typical
Antipsychotic ADEs

- Metabolic syndrome
  - Cluster of metabolic risks
  - Increased triglycerides
  - Increased blood pressure
  - Insulin resistance
  - Obesity
  - Decreased high-density lipoprotein (HDL) cholesterol
  - Increased risk of CV disease and diabetes

- Metformin

Neuroleptic malignant syndrome

- Approximately 1% of people taking APS drugs
- High fever
- Confusion
- Rigid muscles
- Variable blood pressure
- Sweating
- Fast heart rate
- Seizures
- Risk of death 10-20%
- Onset usually in less than 3 days, at beginning of treatment
- First signs are muscle cramps, tremor, fever, unstable blood pressure, agitation, delirium
- Higher risk with high potency drugs, rapid increase in dose, long-acting forms

Mood stabilizers

- Antipsychotic ADEs
  - Dizziness (orthostatic hypotension)
  - Blurred vision
  - Motor restlessness
  - Mental restlessness
  - Apathy
  - Dementia in elderly
  - Increased mortality in elderly
  - Neuroleptic Malignant Syndrome

- Mood stabilizers
  - Monitor weight/lipids
  - Behavioral changes to reduce calorie intake
  - Mood stabilizers
Mood stabilizers

- AKA neuromodulators, ant-convulsants, anti-epileptics
- Lithium, Lamictal, Depakote, Trileptal, Tegretol, Dilantin
- Seroquel, Latuda, Abilify, Symbyax (fluoxetine/olanzapine)

Mood stabilizer ADE’s

- Suicide thoughts/behaviors (incidence rate of thoughts/behaviors: .43% vs. .24% anticonvulsants vs. placebo)
- Drug Rash with Eosinophilia and Systemic Symptoms (DRASS): fever, rash, and/or lymphadenopathy, signs of multiple organ systems affected on onset 2-8 weeks after exposure, chronic course
- Stevens-Johnson syndrome (10% of body) on onset 1-39 days post exposure, median 5 days
- Toxic Epidermal Necrosis (TEN) (>20% of body)
- Learning difficulties
- Mental fogginess (e.g., Topamax AKA “Dope”amax)
- Nausea/vomiting
- Indigestion
- Polydipsia (increased thirst) and Polyuria (more urine)
- Thyroid problems
- Increased weight gain
- Polygrapha (increased thirst and Polyuria (more urine))
- Nausea/vomiting
- Mental foginess (e.g., Topamax AKA “Dope”amax)
- Learning difficulties

Mood stabilizer ADE’s

- Lithium toxicity
- Increased weight gain
- Polygrapha (increased thirst and Polyuria (more urine))
- Nausea/vomiting
- Mental foginess (e.g., Topamax AKA “Dope”amax)
- Learning difficulties

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- Learning difficulties
Remember all that?

Have you noticed any physical or mental changes?

Don't overlook long-term patients especially as they enter their 60's.

How am I supposed to remember all that?

Mood stabilizer ADE's
1. allergic reactions, rashes
2. altered consciousness
3. vomiting/eating problems
4. diarrhea, constipation
5. heartbeat changes
6. fainting or dizziness
7. muscle changes (rigidity, spasms, weakness)
8. yellowing of eyes, skin, or mouth
9. unusual bruising or bleeding
10. fever, feeling sick
11. sexual side effects

What should I do?

Be informed

• Be aware of higher risk groups
  - Elderly
  - Trouble regulating blood pressure, temp (ACh)
  - Decreased liver, kidney functioning
  - Less weight, less water, more fat

• More drugs

Be informed

• Be aware of higher risk groups
  - Children
  - Drugs understudied in children
  - ADRs may be attributed to normal childhood
  - Be informed of higher risk groups

Be informed

• Be aware of higher risk groups
  - People taking multiple medications
  - Risk of interaction effect increases
  - Use an online interaction checker (but respond cautiously to results)

Once again…
Be Informed
• Be aware of higher risk groups
  • Poor CYP metabolizers and ultra-rapid metabolizers
  • History of chronic back pain
  • Depression
  • Meds: Oxycodone, Amitriptyline, Flexeril, Clonazepam (for sleep)

Educate
• Talk to patients about the meds they are taking or going to take—answer questions, look up information in session, inform them of risk and benefits the MD may not have covered

Case Example
45-year old man referred for psychotherapy for depression
• Known medical issues: High blood pressure, high cholesterol, seasonal allergies
• Meds: Oxycodone, amitriptyline, Flexeril, clonazepam (for sleep)

Case Example
A 65-year old man recently directed symptoms of severe depressed mood for at least six months. Reports anhedonia, fatigue, anorexia
• Known medical issues: High blood pressure, high cholesterol, seasonal allergies
• Medication include: Valium, PRN for agitation; fluoxetine, qam for depression; atorvastatin for cholesterol; clonidine, BID for hypertension; diphenhydramine OTC, daily, for allergies; drinks several cups of coffee throughout the day

Reporting Suspected ADEs
• Option 1: Consider reporting ADR to MedWatch Voluntary Reporting System
• Option 2: Contact the patient to discuss concern
• Option 3: Contact the patient’s PCP to discuss concern
• Option 4: Send the patient to the ER
• Option 5: Consider reporting ADR to MedWatch Voluntary Reporting System

Case Example
50-year old man, recently divorced, complains of severe depressed mood for at least six months. Reports anhedonia, lethargy, occasional agitation, frequent dizziness, substantial weight gain, excessive sleep, no suicidal ideation. No similar episodes prior to this. Attributes the symptoms to the divorce which has been very hard for him to cope with but suspects depression
• Known medical issues: High blood pressure, high cholesterol, seasonal allergies
• Medications include: Valium, PRN for agitation; fluoxetine, qam for depression; atorvastatin for cholesterol; clonidine, BID for hypertension; diphenhydramine OTC, daily, for allergies; drinks several cups of coffee throughout the day
Dr. Tony Ragusa

That's all, folks!

Additional Resources

• Stephen Stahl “Prescriber’s Guide” Sixth Edition
• Stephen Stahl “Essential Psychopharmacology”
• Medscape or Epocrates Interaction Checker
• The Psychopharmacology Institute
• The Carlat Report
• Evangelical Community Hospital