Medication Errors in the Clinic: Adverse Drug Events: Can We Fill the Holes in the “Swiss Cheese Model”

February 15th, 2011
Andy Steele
CAUTION

THIS SIGN HAS
SHARP EDGES

DO NOT TOUCH THE EDGES OF THIS SIGN

ALSO, THE BRIDGE IS OUT AHEAD
Objectives: Things Learned

1. Lots of medication errors in clinic
2. We should document medication “side effects” and severity
3. NSAID’s cause ulcers, some bleed
4. We can reduce the chance of getting ulcers while on NSAID’s
5. Carbon Dioxide is important for Swiss Cheese
Case Report

• ME is a 52 year-old male s/p CVA, with HTN, Depression, and Seizures

• Med List
  - Aspirin 325 mg Every Day
  - Crestor 5 mg Every Day
  - Prozac 20 mg Every Day
  - Docusate 0.4 mg tablets Every Day
  - Metoprolol ER 50 mg Every Day
  - Naproxen 500 mg Twice Daily
  - Amolodipine 10 mg Every Day
  - Clonazepam 2 mg Am, 1 mg Noon, 2 mg PM
#1: Failure to address ASA/NSAID interaction
Case Report

• 10/08
  – Admitted with Hematemesis
  – EGD: PUD, GUD
  – Discharge Diagnosis: UGI Bleed
    • EGD in 1 month, given date at discharge
    • “Do Not Take Aspirin or Naprosyn” “Until you talk to a Doctor”
    • Call if “dizziness, dark bloody stools”
    • No mention of PCP FU
was then completely withdrawn from the patient and the procedure continued.

ATIONS: No complications were found.
Case Report

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    • No mention of PCP FU
DENVER HEALTH MEDICAL CENTER
DISCHARGE RECORD / INSTRUCTIONS

(All sections of this inter-disciplinary form must be completed)

Admission Date 10/27/08 Discharge Date 10/29/08

Discharge Diagnosis Upper GI bleed, gastrointestinal ulcers, Isc stroke

MD/NP/PA Nagesh Narayanan, Resident ___________________________ Intern ___________________________

Language: ☑ English ☐ Spanish ☐ Other ____________ ☐ Interpreter ____________ ☐ AT&T Language Line

☐ Anticoagulation: ☑ N/A Reason for therapy: ☐ DVT, ☐ PE, ☐ A.fib, ☐ other _______ Treatment length_____

Follow-up Plan:
In the next 2 days, call for the following appointment(s) listed below. See the reverse side of this sheet for Denver Health’s clinic phone numbers/locations.

* You have a Repeat EGD in the GI lab on Tuesday December 2nd at 9:30 AM. Please see attached paper for instructions.

* Do Not take Aspirin or NAPROXEN

* Make an appointment with your Primary Care Provider (PCP) within 1 week. If you need a PCP see reverse side for clinics.

Medications: Please see attached medication sheet for a list of current medications.

Patient Instructions/Counseling:
1. If these symptoms, dark/bloody stools, nausea, vomiting, bloody dizziness, develop or worsen please call your health care provider right away. You may also call the Denver Health Nurse Line at 303-739-1211 any time day or night.
#2: Failure to Enter NSAIDs as a Side Effect or Contraindication
Case Report

• 11/08
  – Eye Clinic: “no allergies”

• 12/08
  – No Repeat EGD

• 4/09
  – Clonazepam refill visit, no mention of PUD
  – Naprosyn on med list
#3 Failure to do “Problem List Reconciliation”
Case Report

• 5/09
  – No Show for EGD

• 2/2010
  – PUD noticed, “doing well off Naprosyn”
#4 Failure to Enter NSAIDs as a Side Effect or Contraindication
Case Report

• 5/10
  – Naprosyn refilled with 11 refills
<table>
<thead>
<tr>
<th>Item</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item number</td>
<td>6279820</td>
</tr>
<tr>
<td>Description</td>
<td>NAPROXEN 500 MG TABLET</td>
</tr>
<tr>
<td>Non-Controlled</td>
<td>1t po bid pp</td>
</tr>
<tr>
<td>Source</td>
<td>DENVER, CO 80204</td>
</tr>
<tr>
<td>Order Date</td>
<td>2010-05-03 09:01:47</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>WESTSIDE PHARMACY</td>
</tr>
<tr>
<td>Pick Up</td>
<td>5/6/2010 11:00:00 AM</td>
</tr>
<tr>
<td>Expired Date</td>
<td>10/24/2009</td>
</tr>
<tr>
<td>Qty</td>
<td>60.0 (30 day supply)</td>
</tr>
<tr>
<td>Status</td>
<td>Call Doc (expired)</td>
</tr>
</tbody>
</table>

**Unable to refill due to:**
- [x] Not on LCR med list
- [ ] Dosage Discrepancy
- [ ] No visit in 12 months
- [ ] Not per refill standard

Fax to: [Signature]

Central fill RN [Signature]
#5 Failure to check past use of NSAID’s
Case Report

• 6/2010
  – Admitted with hematemesis
  – PUD, Gastric Ulcers, Transfused
  – Naprosyn entered as a Contraindication with level of “Severe”
  – Discharge Diagnosis: UGI Bleed
    • FU PCP 1-2 weeks
    • “Do Not Take Aspirin”
    • Call if “Chest pain, shortness of breath, other concerns”
NSAIDS

Allergy Status: Active

Onset: October, 2008

Reported by: Patient

Reason for Revision:

Last Changed: 8/11/2010 11:54 by: TDMACK (THOMAS D MACKENZIE)

Created: 8/11/2010 11:53 by: TDMACK (THOMAS D MACKENZIE)

<table>
<thead>
<tr>
<th>Reaction</th>
<th>Severity</th>
<th>Classification</th>
<th>Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duodenal Ulcer with USIB</td>
<td>Severe</td>
<td>Contraindication</td>
<td></td>
</tr>
<tr>
<td>Stomach Ulcer</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Allergy Comments:

Ingredient Detail

Cancel
Case Report

• 9/20/2010
  – Refill requested for Naprosyn
Refill Authorization Request

Date: 9/20/2010
Time: 2:07:02 PM

MR#

953,

P is requesting a refill on this medication we have it

Inactive in our system
Is she still supposed to take it?

Original Qty: 60
Original date filled: 5/3/2010
Original number of refills: 6
Last date filled: 8/25/2010
Physician's Name: Kathryn Lieber
Phone: <Not specified>
Fax: <Not specified>

Refills Authorized: DENIED
<and/or> refill until date: 

DAW: N
Physician's Signature: __________________________

PT had B12 def bleed
No NSAIDS called ox
To notify

Thank you
<table>
<thead>
<tr>
<th>Name</th>
<th>Dose</th>
<th>UOM</th>
<th>Route</th>
<th>Frequency</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASPIRIN (ASPIRIN) (31 mg Tablet, Delayed Release (E.C.)</td>
<td>2 Tablet Oral</td>
<td>1 TIME DAILY</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>COLCATE (COUCATE) SODIUM (100 mg Capsule</td>
<td>1 Tablet Oral</td>
<td>EVERY DAY</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LISONOPRIL (5 mg Tablet)</td>
<td>3 Tablet Oral</td>
<td>EVERY DAY</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>METOPROLOL SUCCINATE (50 mg Tablet)</td>
<td>1 Tablet Oral</td>
<td>EVERY DAY</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NITROGLYCERIN (0.4 mg Tablet, Sublingual)</td>
<td>1 Tablet</td>
<td>EVERY DAY</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PLAVIX (CLOPIDOGREL) (75 mg Tablet)</td>
<td>1 Tablet Oral</td>
<td>EVERY DAY</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>PROTONIX (PANTOPRAZOLE) (40 mg Tablet)</td>
<td>1 Tablet</td>
<td>EVERY DAY</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PROZAC (FLUOXETINE HCL) (20 mg Capsule)</td>
<td>1 Capsule</td>
<td>EVERY DAY</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SIMVASTATIN (80 mg Tablet)</td>
<td>1 Tablet</td>
<td>EVERY DAY</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**End of MEDICATIONS**
## Discontinued Medications

<table>
<thead>
<tr>
<th>Medication</th>
<th>Reason for Discontinuation</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASPIRIN (81 mg Tablet, Delayed Release (E.C.))</td>
<td></td>
</tr>
<tr>
<td>ASPIRIN (325 mg Tablet)</td>
<td></td>
</tr>
<tr>
<td>CLONAZEPAM (1 mg Tablet)</td>
<td></td>
</tr>
<tr>
<td>CLONAZEPAM (2 mg Tablet)</td>
<td></td>
</tr>
<tr>
<td>COLACE (DOCU SATE SODIUM) [100 mg Capsule]</td>
<td></td>
</tr>
<tr>
<td>CRESTOR (ROSUVASTAT IN CALCIUM) [5 mg Tablet]</td>
<td></td>
</tr>
<tr>
<td>HYDROCORTISONE [1 % Cream]</td>
<td></td>
</tr>
<tr>
<td>KLONOPIN (CLONAZEPAM) [1 mg Tablet]</td>
<td></td>
</tr>
<tr>
<td>LISINOPRIL [2.5 mg Tablet]</td>
<td></td>
</tr>
<tr>
<td>METOPROLOL TARTRATE [25 mg Tablet]</td>
<td></td>
</tr>
<tr>
<td>METOPROLOL TARTRATE [50 mg Tablet]</td>
<td></td>
</tr>
<tr>
<td>NAPROSYN (NAPROXEN) [500 mg Tablet]</td>
<td>Adverse Reaction</td>
</tr>
<tr>
<td>NAPROSYN (NAPROXEN) [600 mg Tablet]</td>
<td></td>
</tr>
<tr>
<td>NORVASC (AMLODIPINE BESYLATE) [10 mg Tablet]</td>
<td></td>
</tr>
<tr>
<td>OMEPRAZOLE [20 mg Capsule]</td>
<td></td>
</tr>
<tr>
<td>PRILOSEC (OME PRA ZOLE) [40 mg Capsule, Delayed Release (E.C.)]</td>
<td>Therapeutic Substitution</td>
</tr>
<tr>
<td>SELENIUM SULFIDE [2.5 % Lotion]</td>
<td>Condition No Longer Warrants</td>
</tr>
<tr>
<td>SELENIUM SULFIDE [2.5 % Shampoo]</td>
<td></td>
</tr>
<tr>
<td>SIMVASTATIN [80 mg Tablet]</td>
<td></td>
</tr>
<tr>
<td>SIMVASTATIN [20 mg Tablet]</td>
<td></td>
</tr>
<tr>
<td>SIMVASTATIN [40 mg Tablet]</td>
<td></td>
</tr>
<tr>
<td>ZZ LIST REVIEWED BY DC PHARMACY (FREE TEXT)</td>
<td>SEE COMMENTS</td>
</tr>
</tbody>
</table>

---

## Medication Details

**Name:** NAPROSYN (NAPROXEN)

**Strength:** 500 mg

**Dose:** 1

**UOM:** Tablet

**Route:** Oral

**Frequency:** TWICE A DAY

**Form:** Tablet

**Indication:**

**Comment:**

**Last Dose:**

**Time:**

**Source:**

**Reason for Discontinuation:** Adverse Reaction

**Start Date:**

**Status:** Active

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## Latest Prescription Information

**Date:**

**Time:**

**Printed by:**

**1st Disp #:**

**Refills:**
Medication Errors in the Clinic: Adverse Drug Events: Can We Fill the Holes in the “Swiss Cheese Model”
Airline Crashes: 270 Die

By KAREN DeMASTERS

If there is nothing new under the sun, as philosophers say, don’t tell the eight members of the Boonton-based roots rock band Swampadelica. It might make them feel like switching occupations, and, judging by their debut self-produced album, also called “Swampadelica,” that would be a loss.

Swampadelica’s rich gumbo of sounds comes from so many different influences that is difficult to describe. But the one thing that can be said for the group, which appears at clubs from Boston to Washington, D.C., is that it swings.

The Swampadelica sound is not rock ‘n’ roll, jazz or blues, but lies somewhere in between with large doses of New Orleans swamp and zydeco and hints of psychedelic hip-hop and even classical thrown in.

“Our influences are everything from Bach to James Brown,” said Damian Calcagne, a founding member and one of the two lead singers and writers in the group. “That’s not your usual B’s you think of when you think of music, but it is part of where we come from.”

Some of the music’s eclectic mix derives from the diverse musical backgrounds of the members of the band, which practices in and sometimes performs concerts in a barn in Vernon Township.

Mr. Calcagne, originally from Denville, honed his talents on keyboards in a Grateful Dead-style band known as Old Joe Bones and has played with the New Jersey jam band From Good Homes. The other founding member and lead singer, Stevo Nelson,
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Airline Crashes: 270 Die
Burden of Medical Errors

Published in 2000

98,000 deaths a year attributed to medical errors

IOM (2000). To Err is Human: Building a Safer Health System
Annual Deaths

- Diseases of the Heart: 2,500,000
- Malignant neoplasms: 1,500,000
- Cerebrovascular diseases: 500,000
- Lower respiratory diseases: 2,000,000
- Accidents: 1,000,000
- Medical Errors: 0
- Diabetes mellitus: 0
STILL WAITING FOR CHANGE
Medical mistakes plague Medicare patients

By Daniel R. Levinson

Today's hospitals are modern-day marvels of healing, and we expect them to be models of patient safety as well. But a just-released report from my office shows that medical care is falling short for too many hospitalized Medicare patients. A decade after an Institute of Medicine study placed preventable medical errors among the leading causes of death in the United States, our latest study found that a disturbing number of hospitalized patients still endure harmful consequences from medical care. 44% of them preventable. These instances, which the report calls "adverse events," include infections, surgical complications and medication errors.

Such occurrences are not always preventable, particularly since many Medicare patients are elderly and have complicated health problems. But enough patient harm is avoidable to make a strong case for action. Hospitals must improve, but they need the help of lawmakers, medical professionals and patients to do so.

Errors prolonged hospital stays
Figure 2. Rates of All Harms per 1000 Patient-Days, Identified by Internal Reviewers, According to Year. N Engl J Med 2010; 363:2124-2134 November 25, 2010
Definitions

• Adverse Drug Event (ADE) - injury resulting from drug therapy
  – Preventable Adverse Drug Event (pADE)
    • Known allergy and patient prescribed the medication
  – Non-preventable Adverse Drug Events
    • New allergy to medication

• Adverse Drug Reaction (ADR) – a “response to a drug which is noxious and unintended and which occurs at doses normally used
ADE Is Not the Same as Medical Errors

pADE in Ambulatory Care

- ADE: 14.9 / 1,000 person months
- pADE: 5.6 / 1,000 person months
  - ~25-35% of ADE are preventable
- 86.5% of pADE's
  - cardiovascular drugs, analgesics, and hypoglycemic agents
- pADEs requiring hospital admission
  - 45% - inadequate monitoring
    - Failure to prescribe prophylaxis to patients taking nonsteroidal anti-inflammatory drugs
    - Lack of monitoring of diuretic, hypoglycemic, and anticoagulant

National Ambulatory Medical Care Survey

Percentage visits with adverse effect of care

- 2004: 0.8%
- 2006: 0.6%
- 2007: 1.2%
Burden of Ambulatory ADE’s

- Over 4 million clinic or ED visits
  - ~5% due to NSAID’s
- Over 100,000 admissions annually

Pharmacoepidemiology and Drug Safety, 2010; 19: 901–910
Thing Learned #1
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• There are a “butt load” of errors in medicine
Thing Learned #1

“Last year, I may have harmed nearly 1 patient out of 15 that I care for”
• 1500 patients
• 1500*12 = 18000 patient months
• 15*18 ADE
• 5*18 pADE 90 pADE/1500 patients = 10/150 = 1/15
Should NSAIDS’s have been entered as an allergy? as a side-effect? as a Contraindication?
• Allergy
  – hypersensitive disorder of the immune system
• Side Effect
  – harmful and undesired effect judged to be secondary to a main or therapeutic effect
• Contraindication
  – Absolute
    • there are no reasonable circumstances for giving the medication
  – Relative
    • patient is at higher risk of complications, but that these risks may be outweighed by other considerations
A. Unsafe Conditions

B1. The event did not reach the individual because of chance alone. ("Near-miss")

B2. The event did not reach the individual because of active recovery efforts by caregivers. ("Near-miss")

C. The event reached the individual but did not cause harm (an error of omission such as a missed medication dose does reach the patient.)

D. The event reached the individual and required additional monitoring or treatment to prevent harm.

E. The individual experienced temporary harm and required treatment or intervention.

F. The individual experienced temporary harm and required initial or prolonged hospitalization.

G. The individual experienced permanent harm.

H. The individual experienced harm and required intervention necessary to sustain life (e.g. transfer to ICU).

I. The individual died.
### Allergies

<table>
<thead>
<tr>
<th>Active Allergies</th>
<th>Reaction</th>
<th>Severity</th>
<th>Classification</th>
<th>Comments?</th>
<th>Onset</th>
</tr>
</thead>
<tbody>
<tr>
<td>NSAIDS</td>
<td>GI Bleed, PUD</td>
<td>Severe</td>
<td>Contraindication</td>
<td></td>
<td>10/2001</td>
</tr>
</tbody>
</table>

**Inactive Allergies**

- No Known Drug Allergies

**Change Date**: 11/1/2010

**Reason for Removal**: Inactivated by activation of NSAIDS

---

**Legend**: "!" means Allergy Checking will be performed during an ordering session.
WARNING: Potential allergic reactions exist for:

Drug Description

NAPROXEN

Current Allergies:

<table>
<thead>
<tr>
<th>Alert</th>
<th>Allergen</th>
<th>Severity</th>
<th>Reaction</th>
<th>Classification</th>
<th>Pt Allergy</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>NSAIDS</td>
<td>Severe</td>
<td>DM, Bleed, PVD</td>
<td>Contraindication</td>
<td>NSAIDS</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Flushing (Skin)</td>
<td></td>
<td>Allergy</td>
</tr>
</tbody>
</table>

Legend: Allergy, Cross Sensitivity
Do Alerts Help?

• 6 months in 2006
  – 2,321 Clinicians
  – 60,352 patients (1,833,254 prescriptions)
  – 279,476 drug interaction alerts (~15%)

• NNI= 331 alerts to prevent 1 ADE
• 10% of alerts led to ~60% of averted ADE
• 10% alerts accepted

ARCH INTERN MED/VOL 169 (NO. 16), SEP 14, 2009
Look Out For Too Many Alerts
Indicating Severity

Reaction: GI Bleed, PUD
Severity: • Mild • Severe
• Moderate • Unknown

*Classification:
Management: Allergy
• ADR
• Contraindication
• Intolerance
• Side Effect

Accept
Rating Severity
(modified from VA)

• **MILD** - Requires minimal therapeutic intervention such as discontinuation of drug(s)

• **MODERATE** - Requires active treatment of adverse reaction, or further testing or evaluation to assess extent of non-serious outcome (see below for definition of serious).

• **SEVERE** - Includes any serious outcome, resulting in life- or organ-threatening situation or death, significant or permanent disability, requiring intervention to prevent permanent impairment or damage, or requiring/prolonging hospitalization.
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(modified from VA)

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- **MODERATE** - Requires active treatment of adverse reaction, or further testing or evaluation to assess extent of non-serious outcome (see below for definition of serious).
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Thing Learned #2

“It is important to document and determine “severity” of allergies and side effects”.
NSAID’s and GI Issues

• Every 1 dollar spent on NSAIDs leads to $0.66 to $1.25 spent on GI side effects

• Arthritis Patients- 1/3 of care costs for GI adverse events

Aliment Pharmacol Ther 2010; 32: 1240–1248
NSAID’s and GI Issues

NSAID’s and GI Issues

• 4 years ending in 2006
• 1380 sites, 46 countries
• 34,071 OA or RA patients
• Randomized to etoricoxib or diclofenac
• Tracked for GI complications

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Pharmacoepidemiology and Drug Safety, 2010; 19: 901–910
Significant predictors of clinical events and complicated events

**Hazard Ratio**

- **Age > 65**: Hazard Ratio 4.5
- **Aspirin**: Hazard Ratio 3.5
- **Prior GI Event**: Hazard Ratio 3.0
- **Steroids**: Hazard Ratio 2.5

Aliment Pharmacol Ther 2010; 32: 1240–1248
“If I give NSAIDs to 100 of my patients, I expect 25 to get ulcers, and 1-2 will have a significant bleed”.

Thing Learned #3
Prevention of NSAID-induced gastroduodenal ulcers

- 970 references
  - 23 misoprostol (PA)
  - 9 standard dose H2RA
  - 3 double dose H2RA
  - 9 PPI
Prevention of NSAID-induced gastroduodenal ulcers

- Placebo
- Misoprostol
- PPI's
- 2 x H2RA
- H2RA

NNT = 6-7

Prevention of NSAID-induced gastroduodenal ulcers (Review) i
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“If I need to give NSAIDs to my patients, I will consider giving PPI’s or double dose H2RA to prevent ulcers”.
Swiss Cheese Holes

- Propionibacter shermani bacteria
- Carbon dioxide released during fermentation
- Size of the holes change with acidity, temperature, and curing time
- Does the USA or Swiss want bigger holes?
Bacterial flatulence make holes in Swiss cheese
Things Learned
Things Learned

1. Lots of medication errors in clinic
Things Learned 2

2. We should document medication “side effects” and severity
Things Learned 3

3. NSAID’s cause ulcers, some bleed
Things Learned 4

4. We can reduce the chance of getting ulcers while on NSAID’s
5. Carbon Dioxide is important for Swiss Cheese
Things Learned

1. Lots of medication errors in clinic
2. We should document medication “side effects” and severity
3. NSAID’s cause ulcers, some bleed
4. We can reduce the chance of getting ulcers while on NSAID’s
5. Carbon Dioxide is important for Swiss Cheese
Errors

Harm
Plug The Holes

- ME is a 52 year-old male s/p CVA, with HTN, Depression, and Seizures
  - #1: Recognize ASA/NSAID interaction: consider PPI or H2RA *(Drug-Drug Interaction with EBM Guidelines)*
  - #2: Enter NSAIDs as a Side Effect or Contraindication *(Reports to check for Drug:Condition:"Allergy” match)*
  - #3 Reconcile Problem List *(Comprehensive Up To Date Problem List and Checklists)*
  - #4 Enter NSAIDs as a Side Effect or Contraindication
  - #5 Failure check past use of NSAID’s *(More integrated electronic health record)*
IT in Health Care