ENHANCING PATIENT SAFETY IN ALLERGY PRACTICE

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WHY THIS TOPIC

- Malpractice litigation not a problem for allergists
- Purpose of lecture
  - Make you aware of patient injury due to allergy care
  - Prevent medical errors in allergy practices
  - Prevent patient injury due to medical errors
Malpractice Case

- 70 y/o – asthma history
- Presents with respiratory distress in June
- Given Allergy Shot – Ragweed - pre-seasonal IT
- Anaphylaxis and Death
MEDICAL ERRORS

- Medical error – adverse event or near miss – preventable with today’s knowledge
- Near miss-event that did not reach a patient but that could have resulted in injury if it had. It did not reach patient either by chance or timely intervention
- Patient Safety – the actions all of us undertake to prevent patient injury due to medical care
Basic Tenets Of Error

- Everyone commits errors
- Almost all – unintentional and unconscious
- Most quickly recognized and corrected
- Many due to system error
- Human error is important as well
WHY ERROR PREVENTION

- IT’S THE RIGHT THING TO DO
- 44,000-98,000 preventable deaths due to error per year
- 100,000 nosocomial deaths per year
- 3.4 preventable IT deaths per year
- How many deaths per year is reasonable cost of doing business?
COMMON CAUSES OF PAST EVENTS

- Lack of Critical Thinking Skills
- Non-compliance with policy, procedure or expectations
- Poor/incomplete communication
- Inadequate attention to detail
- Inadequate knowledge and skills
Drug Reaction Litigation – Antibiotics

- Hospitalized patient – given Penicillin
- Office record showed allergy to penicillin
- Severe anaphylaxis
- $675,000 award
SCOPE OF PRESENTATION

- Immunotherapy related errors
- Handoffs
- Documentation
  - Legibility
  - Correction of medical records
- Practice Parameters
- Disclosure of medical errors
- Drug related errors
MALPRACTICE CASE

- Transfer to new Allergist
- Last dose – 5000 PNU
- Doctor’s belief – 5000 PNU = 1:20
- Actual 50,000 PNU = 1:20
- Patient received 10X expected dose
- Anaphylaxis and death
Insanity-doing the same thing over and over, and expecting a different result’

A. Einstein
IMMUNOTHERAPY RELATED ERRORS

- Past 5 years – 1998-2003
- Incorrect injections
  - Wrong patient
  - Wrong dose – concentration or volume
  - Severity of reaction
  - Responders
    - 1717 emails – 431 responses
WRONG INJECTIONS

- Wrong patient – 57.1% of responders
- Wrong concentration – 75%
- Local only – 679
- Systemic – no hospital – 285
- Systemic – ER – 33
- Systemic – admitted – 12
- Death – 1

- Aaronson and Gandhi JACI 2006
FATALITIES DUE TO ALLERGEN INJECTIONS

- 1945 to 1987 – 46 fatalities
  - Error accounted for 3 and possibly 6 fatalities
    - Lockey et al JACI 1987
  - 1985-1989 - 17 fatalities
  - Error involved in at least 5
    - Reid et al JACI 1993
Fatal and Near-fatal reactions due to IT

- Near Fatal (NFR) – Respiratory Compromise or Hypotension
  - 1990-2001 – 23/year (not all confirmed)
    - 4.7/year – confirmed
    - 1/1 million injections

- Amin et al JACI 2006
Fatal Reactions – summary

- 1 per 2.8 million injections – Lockey
- 1 per 2.0 million injections – Reid
- 1 per 2.5 million injections - Amin
NFR – Important Contributing Factors

- Administration of IT at height of allergy season (46%)
- Dosing errors (25%)
- Less than optimal asthma control (10%)
- History of previous systemic (9%)

- Amin et al
NFR – Important Contributing Factors – cont

- Administration in medically unsupervised setting (9%)
- Failure to administer epinephrine (9%)
- Concomitant medications (i.e. Beta Blockers) (3%)
- Premature clinic departure (3%)
RECOMMENDATIONS FOR SAFE IT

- Annual CME/CUE in safe administration of IT
- All vials patient specific – no off-the-board
- Standardized forms in IT parameter
- Triple identity checking

- Aaronson and Gandhi JACI 2006
RECOMMENDATIONS FOR SAFE IT

- Individual drawing up dose must be same one administering IT
- Do not draw up dose until patient in room
- Only one patient receiving IT allowed in room at time IT administered
- Advise all IT patient to wait 20-30 minutes after IT
- Office staff must report all incorrect injections immediately and all near misses as soon as possible
Reactions to Allergens – Immunotherapy

- Immunotherapy injection drawn up by nurse
- Patient put into room by different nurse
- Wrong patient placed in room
- Injection given by RN who put patient in room
- Anaphylaxis and death
HANDOFFS

- Handoff – Transfer of immediate responsibility for a patient/problem
  - Physician to Physician
  - Physician to other care giver
  - Care giver to physician

- You own it until you hand it off

- If you accept it – you own it until you hand it off

- Allergy issues – handoff to associate or covering physician
COMMUNICATE CLEARLY
- HANDOFF

- 17 y/o with sore throat
- Phone order for mono test – MD leaves for weekend – evaluation not offered
- Family call Friday PM for report – denied
- Patient goes to weekend sleepover
- Punched in stomach
- Presents to ED Mon AM with ruptured spleen in shock
- Mono test positive
DOCUMENTATION – LEGIBILITY

- Coverage problems if records reviewed
- Wrong drugs
- Wrong doses
- Wrong instructions
50 y/o male hospitalized for Status Asthmaticus
Discharge order – Prednisone 50mgm QD
Pharmacist Misread – QID
Result – 100 pound weight gain, mood swings, bruising
Settlement - $7500

Physician reported to Data Bank

Weintraub M Neuro Clin N Am 1998
Practice parameters are clinical guidelines for allergy care and are “designed to assist clinicians by providing a framework for the evaluation and treatment of patients and are not intended to replace the clinicians judgment or establish a protocol for all patients. Not all recommendations will be appropriate for all patients.”

- Allergy Immunotherapy: A Practice Parameter Ann of Allergy 2003
Similar disclaimers in all parameters
Consistent with AHRQ
Are evidence or consensus based
Require regular review
Written note necessary if parameters not followed
Informed consent necessary/documented
Used by payers to set standard of care and determine payment eligibility
**Immunotherapy Parameter Issues**

- **Indications for IT** – recommend use JCAAI form
- **Document informed consent** – warnings to include possibility of death
- **Relative contraindication**
  - B Blocker
  - FEV$_1$ <70% or poorly controlled asthma
  - During symptom exacerbation or height of season
  - Significant CVS disease
Immunotherapy Parameters Issues cont

- Systemic occurring after patient leaves office may require longer wait
- No home IT – “administer in setting where anaphylaxis will be recognized by physician or other health care professional”
- Follow vaccine expiration dates
- Patients who transfer allergists
  - Any vaccine change may require reevaluation and start over
- No Off-The-Board IT
Patients want broad disclosure – physicians want narrow definition

Patients want all errors disclosed – physicians disclose only error causing harm

Patients want near miss disclosure – not doctors

Patients want apology – liability concerns doctors

- Gallagher T JAMA 2003
DISCLOSING MEDICAL ERRORS TO PATIENTS

- Disclose known facts – explain error and how it occurred
- Expression of genuine regrets and apology
- Answer patients questions
- Explanation of what happens next
- Information on what to expect-if known
- Describe actions to be taken to prevent recurrences

Australian council for safety and quality in health care
MEDICATION ERRORS

- Overview
- Black Box Warnings
- Informed Consent
- Pregnancy and medications
- Off label medication use
- Do not use abbreviations
- Easily confused names
- Telephone prescribing
MEDICATION SAFETY

- 247,000 annual injuries due to drug therapy
- 34,200 annual deaths due to drug therapy
- 9423 annual deaths due to negligently administered drugs

Leape – AM J Health Syst Pharm 1995
PHYSICIAN MEDICATION ERRORS

- Dosing errors
- Errors in decimal points
- Lack of knowledge about drug prescribed
- Lack of Knowledge of patients
  - Condition
  - Characteristics
- Medications with similar names
Drug Reaction Litigation – Antibiotics

- Sinusitis
- Treatment – Clindamycin
- Pseudomembraneous Enterocolitis
- Colectomy
- Award – basis – failure to warn
DRUG REACTION LITIGATION - ANTIBIOTICS

- Bronchitis in Pregnant Woman
- Treatment – Tetracycline
- Child sued mother – tooth damage
MALPRACTICE CASE - ANTIHISTAMINES

- Bus driver falls asleep at wheel
- Crash
- Passenger injured-sues
  - Bus company
  - Doctor who prescribed PBZ
- Doctor found liable for failure to warn
  PBZ causes sleepiness
  - Kaiser v Suburban Transit 1965
“BOXED WARNINGS”

“Special problems, particularly those that may lead to death or serious injury, may be required by the Food and Drug Administration to be placed in a prominently displayed box.”

(§201.57(e) Warnings)

Warnings limited to 20 lines – if longer must be summarized – could result in loss of information
DRUGS WITH BLACK BOX WARNINGS

- FDA does not have a complied list
- Access private compiled list at
  - www.formularyproduction.com
- No assurance this list is complete
ALLERGY DRUGS WITH BLACK BOX WARNINGS

- Long Acting Beta Agonists
  - Salmeterol
  - Formotorol

- Topical calcineurin inhibitors
  - Tacrolimus
  - Pimecrolimus

- Omalizumab
  - Xolair
INFORMED CONSENT FOR DRUGS WITH BLACK BOX

- No different than for drugs without black box warning
- Must inform of Black Box and reasons as well as other risks
- Alternative treatment/no treatment discussion particularly important
- Inform of “all material risks of treatment that are not remote or merely theoretical”
  - Bianco in Legal Medicine 4th Edition
OBTAINING AND DOCUMENTING CONSENT

- Oral consent only – acceptable but not recommended
- Written physician note – acceptable
- Written consent signed by patient – probably best – legally
Medication Reconciliation

- National Patient Safety Goal 8
- Accurately and completely reconcile medications across the continuum of care
  - Need to know every med patient taking
  - Rule applies anytime a patient enters a new health care organization – including your office
- Must have process to compare current medication list with a changed med list
  - Includes anything that could be a med
- Complete list of meds is communicated to next provider and to the patient
# PREGNANCY AND PRESCRIBING

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category A</td>
<td>Safe – adequate studies in humans</td>
</tr>
<tr>
<td>Category B</td>
<td>Animal studies OK- no human studies or animal studies not OK and human studies OK</td>
</tr>
<tr>
<td>Category C</td>
<td>Animal studies show AE + No Human studies – no studies in animals or no studies in pregnant women</td>
</tr>
</tbody>
</table>
Avoid if Possible

- Flunisolide
- Fluticasone
- Mometasone
- Loratadine*
- Fexofenadine

- Hydroxyxine-1 trimester*
- Cetirizine-1 trimester *
- Diphenhydramine
- Doxepin
- *use OK if Benefit outweighs risk

Aaronson DW
Nov 2000
Avoid if possible

- Azithromycin
- Clarithromycin
- Most Antifungals (nystatin OK)
- Cefaclor (ceclor)
- Ceftriaxone (Rocephin)
- Cephalexin (Keflex)
- Most Cephalosporins - No Data
- Antisecretory agents - Proton pump inhibitors - lansoprazole and omeprazole

- Aaronson DW nov
Unsafe Drugs in Pregnancy

Alpha Adrenergics
Epinephrine – especially in first trimester
Iodides
Tetracyclines
Quinalonones
ACE Inhibitors—especially 2 and 3 trimester

Aaronson DW  Nov 2000
Off Label Use

- FDA act 1962 - FDA has no control over the manner in which a physician may use an approved drug. Once marketed a product may be prescribed in a different treatment regimen or for medical disorders that are not in approved labeling. The FDA has repeatedly pointed out that such off label use is not experimental and may be rational and appropriate. The PDR does not set the standard of care.
Guidelines for Off Label Use

- Know the data
  - Indications – PDR Plus
  - Side Effects and AE warnings
- Have scientific basis for off label use
  - Dose
  - Indication
- Informed Consent Necessary
  - Drug injured patient without consent = negligence or battery
**DO NOT USE ABBREVIATIONS**

<table>
<thead>
<tr>
<th>Do not use</th>
<th>Problem – mistaken for</th>
<th>Use instead</th>
</tr>
</thead>
<tbody>
<tr>
<td>U (unit)</td>
<td>Zero, 4, or cc</td>
<td>Write “unit”</td>
</tr>
<tr>
<td>IU (international unit)</td>
<td>IV or the number 10</td>
<td>Write out entire words</td>
</tr>
<tr>
<td>QD or QOD</td>
<td>Each other</td>
<td>“daily” or every other day</td>
</tr>
</tbody>
</table>
**DO NOT USE ABBREVIATIONS**

<table>
<thead>
<tr>
<th>Do Not Use</th>
<th>Problem</th>
<th>Use Instead</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trailing zero (X.0)</td>
<td>Decimal missed</td>
<td>Write (X) mg</td>
</tr>
<tr>
<td>Lack of leading Zero</td>
<td>Decimal missed</td>
<td>Write (0.X)</td>
</tr>
<tr>
<td>MS, MSO(_4)  MgSO(_4)</td>
<td>Meaning unclear</td>
<td>Write morphine or magnesium</td>
</tr>
<tr>
<td>Potential do not use</td>
<td>Problem</td>
<td>Use Instead</td>
</tr>
<tr>
<td>----------------------</td>
<td>--------------------</td>
<td>--------------------</td>
</tr>
<tr>
<td>@</td>
<td>Mistaken for “2”</td>
<td>Write “at”</td>
</tr>
<tr>
<td>CC</td>
<td>Mistaken for “U”</td>
<td>ML or milliliters</td>
</tr>
<tr>
<td>Ug</td>
<td>Mistaken for “mg”</td>
<td>Write “mcg” or micrograms</td>
</tr>
</tbody>
</table>
## EASILY CONFUSED NAMES

<table>
<thead>
<tr>
<th>Benylin</th>
<th>Ventolin</th>
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<tbody>
<tr>
<td>Hydrocodone</td>
<td>Hydrocortisone</td>
</tr>
<tr>
<td>Nicoderm</td>
<td>Nitroderm</td>
</tr>
<tr>
<td>Ocufen</td>
<td>Ocuflox</td>
</tr>
<tr>
<td>Vantin</td>
<td>Ventolin</td>
</tr>
<tr>
<td>Xanax</td>
<td>Zantac</td>
</tr>
<tr>
<td>Dicloxacillin</td>
<td>Doxycycline</td>
</tr>
</tbody>
</table>

US Pharmacopial Convention
TELEPHONE PRESCRIBING

- High injury risk area
- Need Written Phone Management System
  - Who designates triage responsibility
  - Criteria for privilege – record training
  - Standard protocols/guidelines for assessment
  - Documentation – forms
  - Physician participation-MANDATORY
  - Cannot triage everything
  - When should patient be seen
Prescribing for Another Physicians Patients

OK for routine drugs
Not OK for addicting drugs
Need full current drug history – documented
Do not Prescribe Unfamiliar Drugs
No staff OK for these refills
Limit amounts of drugs to what is necessary until regular MD available
When should we do STAR?

When you are in a high-risk situation?

- Desire to Achieve
- Peer Pressure To Work Fast
- Time Constraints
- Distractions or performing Multiple Tasks
- Desire to Avoid an Uncomfortable Situation
- Uncomfortable Situation
Attention To Detail

- **Stop:** Pause for 1 to 2 seconds
- **Think:** Focus on the act to be performed
- **Act:** Perform the act
- **Review:** Check for desired results
**Verbal Orders.**

**Sender initiates** communication using Receivers Name. Sender provides an order, request, or information to Receiver in a clear & concise format. Receiver writes it down.

**Receiver acknowledges** receipt by a read-back of the order, request, or information.

**Sender acknowledges the accuracy** of the read-back – “That’s Correct”. If not correct, repeats the communication.
Situational Awareness

- Shared understanding of situation at hand – remember we work in teams
- Everyone knows what is likely to happen next
- Everyone knows what to do if “expected” does not occur
- A common mental model
Losing Situational Awareness

- Things don’t feel right
- Ambiguity – plan less clear
- Confusion
- Decrease in communication
- Trying something new under pressure
- Deviating from established norms
- Verbal Violence
Are You at Risk of *Loosing* Situational Awareness?

- Poor communication
- Weak handoffs
- Distractions
- Too much workload
- Too little workload
- Pressure to meet a deadline
- "The technology will catch it"
- "I’ll take care of it later"
- Group-think
- Work stress
- Home stress
- Fatigue
- Doing something new
  ...especially when under pressure
MALPRACTICE CASE

- 40 y/o with rash on hands due to work materials
- Rash cleared with Aristocort tabs
- 7 years of intermittent treatment
- Cushings Syndrome
- $500,000 award
- Reported to data bank
MALPRACTICE CASE

- 40 y/o with rash on hands due to work materials
- Rash cleared with Kenalog shots/oral/topical
- 6 years intermittent treatment
- Cataracts and osteoporosis
- Malpractice suit
- Lost – documented informed consent and urging to eliminate contact
CONCLUSION

- 44,000+ premature deaths per year due to medical error
- Most deaths are preventable
- Human error is a serious contributor
- WE CANNOT KEEP DOING THE SAME THING AND EXPECT A DIFFERENT RESULT