

Avoiding Medication-related Malpractice

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Lawsuit Categories

Delays in Diagnosis (45-50%)

Procedures (40-45%)

Medications (10-15%)

Most Common Medications

Anticoagulants 24%

Opioids 18%

Corticosteroids 10%

Aminoglycosides 9%

Nature of Lawsuit Allegation

Monitoring Error 45%

Wrong Medication 19%

Wrong Dose 15%

Allergic Reaction 4%

The Standard of Care

The standard of care is what a reasonable physician would do under the circumstances.

The standard of care is the best available combination of risk and benefit.

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Availability

Financial
Formulary

Patient Preference

The standard of care is the best available combination of risk and benefit.

Case #1

Elderly man
Admitted with sepsis
Broad-spectrum Abx (Gent)
Levels monitored & therapeutic
Patient recovered
c/o Hearing loss left ear
Audiometry – 80% hearing loss

Files lawsuit

Accused of Malpractice

“mal” means “bad”

Accused of “Bad Practice”

Elderly man
Admitted with sepsis
Broad-spectrum Abx (Gent)
Levels monitored & therapeutic

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“Did you order the gentamicin
for this patient?”

“Is it true that gentamicin is known to cause hearing loss?”

“So, you ordered a medication that you knew placed this man at risk for hearing loss?”

“And that hearing loss, in fact,
occurred didn't it?”

“So, would you agree then that your actions directly caused this man’s hearing loss?”

Any drug of choice, properly dosed, appropriately monitored and discontinued as soon as feasible is always within the standard of care.

Case #2

Patient with elevated BP

Numerous pharmacologic options

Treat with ACE inhibitor

Develops kidney failure

Files lawsuit

ACE caused kidney failure

A Beta-blocker would not have
caused kidney failure

“Did you prescribe the
ACE inhibitor?”

“Did the ACE inhibitor cause
this man to suffer
kidney failure?”

“Do Beta blockers cause kidney failure?”

“Could you have prescribed a
Beta blocker?”

“Is it fair to say that if you had prescribed a Beta blocker this man would probably not have kidney failure?”

Any drug of choice, properly dosed, appropriately monitored and discontinued as soon as feasible is always within the standard of care.

Informed Consent

Patient with elevated BP

Numerous pharmacologic options

Treat with ACE inhibitor

Develops kidney failure

Is a legal doctrine

Separate from the Standard of Care

Applies primarily to procedures

Almost never applies to medications

(Ex: Clinical Trials, Pa. chemo)

Patient with elevated BP

Numerous pharmacologic options

Informed Consent not required

The Standard of Care is required

How & When
Restrictions (activity, other meds)
Precautions
Monitoring
Follow-up

Documentation

“Elevated BP
Start ACE inhibitor 10 mg/d.”

“Elevated BP
Start ACE inhibitor 10 mg/d.”

“Proper Use Discussed”

“Elevated BP
Start ACE inhibitor 10 mg/d.”

“Risks, benefits, alternatives
 (“RBA”) discussed”

Common Malpractice Traps

Telephone Refills

Co-management

Patient Non-compliance

Package Insert

New Version (2006 - present)

Old Version (pre – 2006)

Indications and Usage

“Off-label” Use

“Off-label” Use

Food Drug and Cosmetic Act

Foreword to the PDR

The marketing of a medication is governed by the label.

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The use of a medication is governed by the standard of care.

“Off-label” Use

Food Drug and Cosmetic Act

Foreword to the PDR

Klein v. Biscup, 109 Ohio App. 855 (1995)

Indications and Usage

indications and dosage

Dosage and Administration

indications and dosage

Dosage and Administration

Contraindications

Warnings and Precautions

Adverse Reactions

Contraindications

Most serious safety issues

Memorize Contraindications,
not Indications

indications and dosage

Dosage and Administration

Contraindications

Warnings and Precautions

Adverse Reactions

“Boxed” warning

U.S.C. 21 § 201.57(c)(1)

The box is a highlight.

Warning: Celebrex increases
the risk of GI bleeding.

Warning: Celebrex increases
the risk of GI bleeding.



It's not the color of the box,
but rather what's written
inside that matters.

indications and dosage

Dosage and Administration

Contraindications

Warnings and Precautions

Adverse Reactions

Drug Interactions

indications and dosage

Dosage and Administration

Contraindications

Warnings and Precautions

Adverse Reactions

Drug Interactions

Use in Pregnancy

Avoiding Medication-related Malpractice (Current Model)

Allergies

Nature of Lawsuit Allegation

Monitoring Error 45%

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Avoiding Medication-related Malpractice (Current Model)

Allergies

Correct Patient, Abbreviations,
Decimal Points, Sound Alike

Most Common Medications

Anticoagulants 24%

Opioids 18%

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Aminoglycosides 9%

Avoiding Medication-related Malpractice (Proposed Model)

Anticoagulants (Coumadin)

Allegation: Monitoring Error

Patient Education

Organized Monitoring

Standardized Titration

Refill/Missed Appointment Policy

Documentation

Newer Anticoagulants

Less Monitoring

Fewer Drug Interactions

Limited Indications

Avoiding Medication-related Malpractice (Proposed Model)

Newer Anticoagulants

Coumadin Clinic

Opioids

Allegation: Overdose/Dependence

Chronic, non-cancerous pain

FSMB Guidelines (fsmb.org)

Treatment agreement

Meticulous documentation

Corticosteroids/Aminoglycosides

Allegation: Organ Damage

Avoid if possible

Use lowest effective dose

Discontinue as soon as feasible

Any drug of choice, properly dosed, appropriately monitored and discontinued as soon as feasible is always within the standard of care.