Applying Risk Prevention Documentation to Everyday Practice

Satellite Conference
Wednesday, June 29, 2005
2:00-4:00 p.m. (Central Time)

Produced by the Alabama Department of Public Health
Video Communications Division

Faculty

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Objectives

- Explain the value of legally credible documentation.
- Identify effective documentation practices that can reduce the liability of staff in clinical practice.
- Discuss the importance of using an approved abbreviation list.
- Demonstrate, through case study, appropriate documentation techniques.
- Identify the primary purpose of an incident report.

If It's Not Written, It Did Not Happen!!!

Documentation

- Good medical care
- Minimizes chance for miscommunication
- Legal defense
  - Standard of care
  - Careful, thorough care
  - Poor documentation
    - Careless
    - Force settlement
    - Serious harm

Major Principles

- Accuracy
- Comprehensiveness
- Legibility
- Objectivity
- Timeliness

Accuracy

- Use standard method
- Special circumstances
- Consistent in word usage
- Accepted and agreed upon abbreviations
- Time, date and legible signature

Comprehensiveness

- Identification
- Current condition
- Past medical history
- Past surgical history
- Family history
- Social history
- Medications
- Physical examination

Comprehensiveness

- Initial assessment and reassessment
- Results
- Operative reports
- Procedure notes
- Consultant reports
- Informed consent

Comprehensiveness

- Counseling and education
- Disposition
- Patient correspondence
- Advanced directives

Quality Assurance

- Information evaluated
- Alternatives considered
- Recommended treatment
- Reasoning
  - Diagnosis
  - Choosing treatment
  - Deviating from the standard of care
  - Deviating from consultant's recommendations

Patient Response

- Compliance with recommendations
- Missed appointments
- Patient concerns
- Informed consent
- Informed refusal

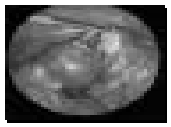
Informed Consent?

- Reasons why particular course of treatment
- Risks and benefits of treatment
- Alternatives to treatment
- Comprehension
- Update as circumstances change

Consent for Surgical and Medical Treatment

- Diagnosis
- Nature and purpose of procedure
- Likelihood of success
- Practical alternatives
- Prognosis if treatment rejected
- Material risks

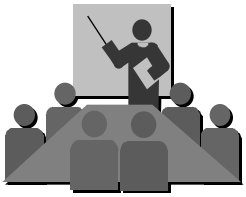
Material Risks



- Infection
- Allergic reaction
- Severe loss of blood
- Loss or loss of function of any limb or organ
- Paralysis or partial paralysis, paraplegia or quadriplegia

Material Risks

- Disfiguring scar
- Brain damage
- Cardiac arrest
- Death



Material Risks

- Generally recognized and accepted by reasonably prudent physicians
- . . . which if disclosed to a reasonably prudent person in the patient's position, could reasonably be expected to cause such person to decline such proposed surgical or diagnostic procedure . . .

Alabama Code

- ". . . reasonable medical practitioner under similar circumstances would have disclosed . . ."

What About Patient Responsibility?

- Listen to explanations
- Carefully read the consent form
- Ask questions

NO

Informed Refusal

- 27 Ca. 3d 285, 1980
- Repeatedly advised routine Pap smear
- No documentation of explanations/ potential risks
- Died from advanced cervical cancer

Helpful Hints

- Include family members/significant others
- Use words the patient can understand
- Make sure the patient understands
- Use printed materials
- Allow enough time for questions

Helpful Hints

- Give truthful answers
- Base discussion on current data/guidelines
- Never guarantee success or suggest specific outcomes
- Make notations about high-risk issues discussed

Telephone Conversations

- Telephone messages
- Detailed notes
  - Gathered all necessary information
  - Understands recommendation/follow-up
  - Medications given
  - When in doubt have patient come in
- Copies of e-mails

Legibility

- Wastes valuable time
- May reflect sloppy/inadequate care
- Misinterpretations

98,000 excess deaths

Medication/Test	Mistaken for
Dicloxicillan	Doxycycline
Rhogam	Depo-provera
Purinethol	Propylthiouracil
Do hepatitis profile	Prolactin level

Objectivity

- Relevant facts
- Do not criticize
- Do not resolve differences
- Avoid judgmental words

Why Health Care Practitioners Are Sued

"Jousting"

At all other institutions except yours!

Background Information

A female patient is admitted to the ER with complaints of left calf pain. She is quite uncooperative in that she won't allow a complete physical examination. As the physician you insist that she allow you to do a complete physical exam. She becomes verbally abusive and continues to refuse.

Timeliness

- Record events when occur
- Review results in timely fashion
- Develop policy

Background Information

You discover that a note you made in Ms. Herman's record does not clearly describe what was done to evaluate her respiratory status upon admission to the hospital. Her condition is rapidly deteriorating.

Lawsuit Prevention

Documentation
Documentation
Documentation

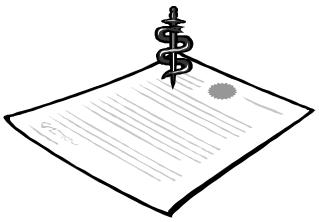
- **The chart, friend or foe?**
- **First checked**

The Quest
May Not Be to Seek
"the Truth"!

Not Necessarily About Truth or Fairness but

Winning

What Should Be Documented?



If It's Not Written, It Did Not Happen!!!

Documentation

- Events
- Decisions
  - Cesarean Section
  - Informed Consent Issues
- Problems
  - Non-compliance
  - Refusals

Events Involving Patient Care

Decisions: C-section or vaginal birth; patient's consent; all risks and benefits discussed with informed consent issues.

Problems

- Non-compliant patient
- Refusing Cesarean Section
- Refusing blood
- Refusing fetal monitoring

Best Practice Encounter Note

- Legible
- Timely
- Eliminate abbreviations and acronyms
- Decision Specific
  - Convey relevant, objective, accurate info
  - Subjective conjecture or opinion inappropriate

Best Practice Encounter Note

- Reasonable Treatment
- Planned Follow Up
- Identifiable Instructions

Abbreviation	Option 1	Option 2
SBE	Self Breast Exam	Subacute Bacterial Endocarditis
AV	Audiovisual	Arteriovenous
AB	Antibody	Abortion
AROM	Artificial Rupture of Membranes	Assisted Range of Motion
BPD	Biparietal Diameter	Broncho-Pulmonary Dysplasia
PDA	Personal Digital Assistant	Patent Ductus Arteriosis

Abbreviation	Option 1	Option 2
AMA	American Medical Association	Against Medical Advice
DNA	Deoxy-ribonucleic Acid	Did Not Answer

Prohibited Abbreviations

Prohibited Abbreviation	Replace With
Q.D. **	Daily, every day
Cc	mL
U	Units
Trailing/Leading Zero (X.0, .x mg)	X.0=x mg/.X=0.X
IU	International Units

Prohibited Abbreviations

Prohibited Abbreviation	Replace With
MgS04	Mag Sulfate
MS04, MS	Morphine
QOD**	Every other day
TIW	Specify days
Ug	Mcg or microgram

Did Medical Record Reflect Recognition?

- Comment on risk factors
- Record discussion with mother or parents
  - Record refusal and reason
  - Re-visit

Tips

- Do not leave blank lines
- Document N/A to indicate area was addressed
- Document your thought process
- Be careful with generic documentation
- Do not alter medical records
  - Destroy defense
  - Destroy credibility
  - Can be made to appear self-serving

Tips

- Make your issues clear
- Place check marks carefully
- Never leave clinically significant discrepancy unmentioned
- Document if chart/notes not available

Why Healthcare Practitioners Lose Malpractice Cases

- Bad Medicine - 10%
- Bad Records - 60%
- System Failures - 30%

Conclusion

- Importance of documentation
- Major principles
- Informed consent
- Misuse of abbreviations

Thanks to:
John Banja
Larry Wagner
Laura Dean
Department of Ethics in
the Health Professions
Emory Risk Management Department

IN THE COURT OF APPEALS OF TENNESSEE AT KNOXVILLE

February 3, 2004 Session

JULIE JILES, ET AL. V.
STATE OF TENNESSEE

Appeal from the Claims Commission of the Eastern Division No. 99000266
Vance W. Cheek, Jr., Commissioner

Facts of Case

- Patient and husband sued
- Order of judgment entered March 2003
  - Standard of care was not breached
  - Another provider proximate cause
- Appealed

Claims

- Negligently failed to recommend timely treatment
- Resulting in diagnosis of carcinoma in situ
- Resulting in unnecessary hysterectomy at age 27

Facts

- Dr A, primary care physician.
- Dr. B performed pap.
  - Abnormal pap with second pregnancy
  - Borderline atypical cells
  - Chart reflects colposcopy recommended at 6 week check-up
- Patient's insurance changed and thus she followed at the Health Department.

- Detailed history → abnormal pap with dysplasia.
- Pap at Health Department shows ASCUS → repeat 3 months.
- Patient returns 6 months later → next pap = ASCUS cannot r/o dysplasia → repeat 3 months per chart.
- Patient does not recall.
- Next pap 6 months later (after receiving letter) → LGSIL, mild-mod dysplasia. Recommend colposcopy, bx. Scheduled per HD nurse.

- Colpo bx = CIS.
- Patient states told needed repeat colpo.
- Visited nurse at HD to move appt earlier.
- Patient states called "irrational" and told "baby cancer". Nurse denies.

- Patient returns to Dr. A. Pap → referral to specialist (S).
- Dr. S performs colpo, repeat pap (3 paps in 2 months) → CIS schedules surgery for same day but unable.
- Surgical options cone bx and hysterectomy.
- Expert for π states breached standard of care.
  - Should have referred immediately based on history.
  - Should have referred after initial pap.

- Counters
  - Not in protocol.
  - Request for prior records not in protocol.
  - Told patient to return in 3 months.
  - Need current data to get referral appointment.
  - Expert agrees. Consistent with NIH protocols.

Court Held

- Protocol is the "established standard of care"
- Dr. S proximate cause of π damages

What Was Done Right?

- Obtained detailed history
- Followed algorithm in protocol
  - Repeat pap
  - Scheduled colposcopy
- Labs on chart

What Was Done Right?

- Updated protocol in place at time of discovery
- Letter sent once missed appointment/protocol
- Letter in chart/appointment vs. call
- Documented telephone messages

But . . . !!

- Nurse and NP had to go to court

Where Could a Lawyer Find Fault?

- "Irrational"
- "Baby cancer"
  - Babies are happy
- Was education documented?
  - Cone bx vs. hysterectomy
  - Risk of recurrence
  - Patient concerns – staying alive to raise children

Where Can We Make Improvements?

- Told to return at 6 week check up.
- If seen in FP are they aware of abnormal pap smears.
- Which protocol following.
- Letters, correspondence in chart.
- 2 letters and certified or . . .
- Did patient go to colpo appointment?
  - Are we still responsible?

Where Can We Make Improvements?

- Clinically – 3 paps in 2 months.
- What if protocol is wrong?
- What if patient is wrong or didn't indicate abnormal pap?
- Is protocol up-to-date?
- If appointment missed can patient get early follow-up?

Just do a good job and treat people nice

WEISS & SHOBER
Medical Malpractice

Cervical Cancer
Cancer of the cervix is recognized as a largely preventable disease. Here's what the U.S. Preventive Task Force had to say about problems that exist with accurately performing screening through Pap smear tests:

"... many women who are tested receive inaccurate results due to interpretative or reporting errors by cytopathology laboratories or specimen collection errors by clinicians. The failure of some physicians to provide adequate follow-up for abnormal Pap smears is another source of delay in the management of cervical dysplasia..." Page 111, Guide to Clinical Preventive Services, Second Edition (1996)

Cervical Cancer

Our firm is currently litigating several cases on behalf of women with improperly delayed diagnosis of cervical cancer. Michael L. Weiss, Esq., recently settled a claim stemming from an improperly delayed diagnosis of a cervical cancer for 1.8 million dollars.

LINDER•MYERS

After graduating in law at Leicester University, Julia studied for her Law Society Finals at the College of Law in York. She trained in a specialist claimant clinical negligence practice before qualifying in 1994. Once qualified, she attained a Diploma in Personal Injury Litigation from Manchester Metropolitan University.

LINDER•MYERS

She has practiced exclusively in claimant clinical negligence with a caseload including obstetric and gynaecological negligence such as birth trauma, wrongful birth, delayed diagnosis and treatment of cervical cancer.

Failure to Diagnose

Failure to diagnose cancer 49.5%

- Breast Cancer 61%
- Cervical Cancer 19.5%
- Ovarian Cancer 7.3%

Delayed Diagnosis

- Failure to perform a pap smear

Delayed Diagnosis

Failing to perform a pap smear

- Pap obtained elsewhere
- Cannot afford
- S/P hysterectomy
  - Supra cervical hysterectomy
  - For benign condition
  - No evidence of cervical dysplasia or cancer
  - DES exposure (ACS, ACOG)

Pap Testing after Removal of the Cervix

- Cost-effectiveness has not been demonstrated
- Vaginal cytologic screening based on risk factors
- ACOG Technical Bulletin 183, 1995

Pap Testing After Removal Of The Cervix

- Screening may not be necessary if:
  - Hysterectomy for benign condition
  - Cervix totally removed
  - Previously normal Pap smears

Delayed Diagnosis

Failing to perform a pap smear

- Age 18? Or 21? (AAFP, ACOG, AMA, AAP, ACPM)
- Age 65? Or 70? (USPSTF vs. ACS)
  - "..Provided women have had *adequate recent screening*.."
  - USPSTF – "Evidence is limited to define "adequate recent screening…"

Delayed Diagnosis

Failing to perform a pap smear

- ACS
  - ≥ 3 documented, consecutive, technically satisfactory… *AND*
  - Who have had no abnormal cytology tests within the last 10 years

Heart and Estrogen/Progestin Replacement (HERS)

- 2,561 patients annual cervical smears
- Mean age 66.7 years
- One year later
  - 78 (3%) had abnormal finding
- Two years later
  - 32 had abnormal findings
  - Sawaya Ann Intern Med 133(12):
  - 942 50,2000.

Heart and Estrogen/Progestin Replacement (HERS)

110 (78 + 32) women with abnormal findings

- 109 false positives
- 1 HGSIL

Delayed Diagnosis

Failing to perform a pap smear

- 3 year interval or yearly
  - "cytologically normal"
  - Liquid-based cytology vs. Conventional Pap screening
  - Before age 30 or after (USPSTF vs. ACS)
  - Risk factors (ACOG)
    - STDs
    - Cervical Neoplasia
    - HPV
    - High risk sexual behavior

High-Risk Factors

- Multiple sexual partners
- Male partner
  - Multiple partners
  - Other sexual partners with Cervical Cancer
- Sexual intercourse beginning at an early age
- History of HPV or HSV infection
- History of other STDs

High-Risk Factors

- Smokers
- Immunosuppressed
- HIV positive
- History of
  - cervical dysplasia
  - endometrial, vaginal, or vulvar cancer
- Lower socioeconomic status

Safety of 3 Year Screening

- False-negative results
- Failure of patients to return
- Extending screening intervals
- Women unknowingly at high-risk
  - Unaware of prior sexual contacts of partner

"System" Failures

- Insufficient procedures to assure follow up
  - Patient did not keep appointment
  - Patient did not follow for pap smear
  - Patient did not come back for results
  - Patient did not follow with referral
- Pap smear/biopsy report not reviewed
- Lack of communication amongst medical team

Delayed Diagnosis

Failing to

- Identify cancerous mass on cervix
- Test for cervical cancer when a patient exhibits symptoms
- Order/perform a biopsy when testing abnormal

Delayed Diagnosis

Failing to

- React to biopsy
- Recommend appropriate treatment options
- Follow-up with patient
- Misinterpreting the pap smear/biopsy result

Sources of Error with the Conventional Pap Smear

- Sampling/preparation errors
  - Cells not collected on sampling device
  - Collected cells not transferred to slide
  - Poorly preserved cells

Sources of Error With The Conventional Pap Smear

- Screening/interpretive errors
  - Abnormal cells missed by cytologist
  - Cells incorrectly classified

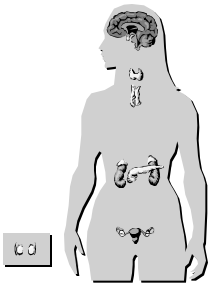
Limitations of the Conventional Pap Smear

- False negatives (1.5-55%)
  - Disease present on cervix but not detected on slide
- False positives (5%-10%)
  - Disease "found" on slide but not present on cervix
- Inconclusive (5-10%)
  - Results ambiguous

Liquid-Based Automated System

- Increased number of cells viewed
- Reduces obscuring elements
- Preservation of abnormal cells better
- Lower rate of unsatisfactory or "satisfactory but limited by . . ." pap smears
- Higher rate of diagnostic abnormalities
  - Lee KR. Obstet Gynecol 90:278, 1997

Obtaining The Papanicolaou Smear



Important Tips

- Perform testing <u>prior</u> to STD cultures or bimanual exam
- Hold spray fixative at least 10 inches away
- Apply sample uniformly to slide
- IMMEDIATE FIXATION

Important Tips

Avoid:

- Heavy bleeding
- Obvious inflammation
- Recent cervical manipulation
- Vaginal creams / lubricants / contraceptives
- Douching within 24 hours
- Intercourse within 24 hours

Case Analysis

"Pap smear was not performed in a timely fashion. Cone biopsy should not have been done. It is my opinion that the physician was negligent in his duties."

Key Points

- **Document the facts of the case**
- **"It is unethical for a physician to disparage another's professional competence....."**

  ACP Ethics Manual
- **"Jousting" inappropriate in the medical record**
- **Invites lawsuits**

What Is The Diagnosis?

- **Medical student note mentions "unusual vessels with inflammation".**
- **1st Year Resident indicates part of lesion "not visible".**
- **Attending describes lesion as "visible through all dimensions".**

Key Points

- **"Teach" documentation**
- **Always read every entry**
- **Correct entry appropriately**

Case Study

- **28 year old home health aide**
- **Pap smear by general practitioner → cervical dysplasia**
- **Recommendation to repeat test in three months**

Wynn v. Robson 11 (12) VST 421

- Patient seen by other providers for unrelated conditions during the next year
  - Irritation
  - Itching
  - Bleeding
- Repeat reported as "cell study negative"

- General Practitioner documents
  - "abnormal appearing cervix"
- Seen by gynecologist 30 months after the repeat pap

- Pap, colposcopy and cone biopsy → invasive cervical carcinoma.
- Suit filed against general practitioner, pathologist, hospital and interim physicians.

- Repeat → cytotechnologist – "containing dysplastic cells"
- Overruled by pathologist

$2 Million

Key Points

- Watch terminology.
- If suspicious, pursue.
- Consider pap smear discussion regardless of patient reason for visit.

Case Study

- 27 year old with abnormal pap smear
- Cryosurgery performed x 2
- Normal pap smears x 4 years → abnormal
- Gynecologist recommends vaginal hysterectomy
- Patient seeks second opinion from another gynecologist

»Haney v. Wade 16(2) VST 58

- Second gynecologist "Agree with Dr. ____ plan to perform vaginal hysterectomy"
- Did not obtain initial doctors records
- Refused patient's offer to obtain records
- Vaginal hysterectomy performed by second physician
- Invasive cervical cancer → death in 4 years
- First doctor settles within policy limits prior to trial

- Second doctor claims warned patient of need for cone biopsy
- States patient refused
- States surgery to be performed under same anesthesia as for vaginal hysterectomy

$ 3.48 million

Key Points

- Always document planned follow up and reasonable treatment plan.
- Document refusals and noncompliance with treatment.
- Maintain copy of request for records.

Case Studies

Polypharmacy

- A chart audit revealed this information
  - A 30-year-old family planning patient with past medical history of diabetes, hypertension, hypothyroidism, seizures and asthma is seen in the family planning clinic.

Polypharmacy

- Drug count included diabetes (three drugs), epilepsy (two drugs), asthma (two inhalers), hypertension (one drug) and hypothyroidism (one drug).
- Records indicated last family planning annual visit was 1 year ago to date, when the patient was started on a combined oral contraceptive with physician order.

Polypharmacy

- Patient denied any current concerns and all conditions are under fair control.
- The medication history was not updated. Patient was issued a one year supply of a combined oral contraceptive. No physician order was noted in the chart.

Review

- Patient presents with multiple medical problems
- Prior documented medication (9)
- Prior physician order for contraceptives
- Documentation approximately 3 lines, indicates patient provided with one year of COCs

Documentation Problems

- Medical History update noted in chart? NO
- Medication History update noted in chart? NO
- Annual physician order required to initiate or continue hormonal contraceptive in chart - NO

Best Practices

- Update information - medication history, medical history, allergies and any changes at every patient visit.

Patient Complaint - Breast

- A medical record revealed this documentation:
  - Patient complained of breast mass before menstruation. Patient counseled to return one week after beginning of next menstrual period for reexamination.
  - No other assessment or intervention was included in the documentation regarding this patient's status.

Best Practices

- Do not document a problem or patient symptom without also documenting your assessment and what you did about it.

Patient Complaint - Breast

- Another case involved an anxious patient who complained to her nurse of a tender lump in the breast. Not only did the nurse ignore the patient's positive family history of breast cancer, she also told her that tenderness meant the lump was benign, and that she could confidently palpate the process as fibrocystic.

Best Practices

- Be sure you are practicing and documenting within your scope of practice.

Patient Complaint - Breast

- The QA team reviewed another case in which a breast mass in a 40-year-old patient was clinically diagnosed by the nurse practitioner as "fibroadenoma."
- A mammogram was ordered, which was interpreted as showing no sign of cancer.

Patient Complaint - Breast

- An ultrasound of the breast revealed the mass to be solid but "consistent with fibroadenoma."
- Nine months later, the patient had a 3cm tumor removed, with 28 positive axillary lymph nodes.
- On review of patient chart, documentation in progress note was "breast mass" or "thickening" is noted.

Review

- Patient complains of breast mass
- Documentation indicates only patient to return in 4 weeks
- Breast mass diagnosed as fibroadenoma in 40 y.o. woman
- Mam and US c.w fibroadenoma
- Patient returns with metastatic carcinoma
- "Breast mass" or "thickening" is noted, a provider is at the mercy of interpretations by plaintiffs' attorneys and expert witnesses

Best Practices

- Documenting all concerns addressed demonstrates your thoroughness in obtaining a patient's history and avoids later charges that the patient brought an important symptom to your attention that you ignored or neglected.

Grammar and Spelling

- In clinic, the physician's progress notes were so poorly written, that it was difficult for the staff to identify instruction from a MD. The order was given for the patient to have a "hepatitis profile" prior to starting oral contraceptives. The progress notes were indiscernible. But a nurse recognized the physician's handwriting particular to the order written and in question. Her best interpretation was the physician, may have written an order for a "prolactin level ".

Best Practices

- Write legibly using correct grammar and spelling.

Abbreviations

- A progress note read, the AAFP patient in with mother for Depo Provera.

Review

- AAFP (African American Family Planning). This was not a recognized medical abbreviation nor was it approved for use according to the facility policy.

Best Practices

- Use medical terminology and only use abbreviations approved by your facility.

Abnormal Finding Not Covered in Protocol

- In one medical record, the nurse documented positive urine dipstick for nitrites and leukocyte esterase on a symptomatic patient and 2+ proteinuria. The progress notes stated "no treatment provided. Protocol does not allow for management of 2+ proteinuria".

Review

- Positive urine dipstick reveals 2+ proteinuria → "no treatment".

Best Practices

- Do not write excuses such as "treatment not provided due to…" in the medical record.

Pap Smear Management

A chart audit revealed this information

- 20-year-old woman who presented for a family planning complained of urinary frequency. Pelvic examination was performed, and a yeast infection, acute cervicitis, and vaginitis were found.
- Appropriate treatment was instituted, and the patient was told to return in two weeks for examination and a Pap smear.

Pap Smear Management

A chart audit revealed this information

- A Pap smear was taken, and a follow-up appointment was scheduled for two weeks later. The Pap smear was Class III, but the lab report was filed in the patient's chart before being seen by the nurse practitioner. A follow up letter was sent to the patient.

Pap Smear Management

A chart audit revealed this information

- The patient discarded the letter without reading it. A similar notice was sent by certified mail without response. It was not until one year later, when the patient's mother, also a patient of the same family planning clinic, inquired about the health of her daughter, that the abnormal test was readdressed.

Pap Smear Management

A chart audit revealed this information

- A review of the chart at that time revealed the Pap smear report. At re-examination, the patient was found to have a fungating carcinoma of the cervix.
- She died a little more than one year later.

Best Practices

- Test results should be reviewed by the provider before they are filed in the medical record. The provider's initials on test reports are an indication to the staff that the documents have been reviewed and can be filed.

Patient Education/Counseling

- A patient developed adverse effects from Metronidazole. The medical record review showed no evidence of verbal or written instructions on how to take the medication or what to do if problems.
- The patient denied receiving any specific instructions from the nursing staff nor had evidence of any instructions in writing to guide her.

Review

- The medical record review showed no evidence of verbal or written instructions on how to take the medication or what to do if problems.
- The patient denied receiving any specific instructions from the nursing staff nor had evidence of any instructions in writing to guide her.

Best Practices

- Chart precautions and preventive education.

Standardized Charting

- Charting is so standardized and routine for social work staff that they take little thought to what the words really mean.
- In a review of five medical records of patients seen the same day for case management by the county social worker, all entries were noted to be identical.

Best Practices

- Generic charting → generic treatment.

Incident Reporting

- Why is incident reporting important?
  - Know your facility's definition on "incident" and consistently follow the applicable incident reporting procedure.

Conclusion

- Professional Liability Crisis.
- Significance of preparation for malpractice litigation.
- Background of "Informed Consent".
- Strategies for Prevention.