Strategic Risk Management & Clinical Quality Improvement

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Learning objectives

- Explain principles and practice of risk management, patient safety, and relationship to quality improvement.
- Identify core factors that affect patient-related risk in community health centers, and approaches to reduce or eliminate those risks.

RISK & PATIENT SAFETY = QUALITY

Quality Improvement = ***Prevention***

Risk Management = ***identify – respond – refer to QI***

QUALITY GOALS

- Regulatory standards
- Satisfaction
- Clinical Effectiveness
- Patient Safety
  - *Risk response*
  - *Risk prevention*

National Pt Safety Goals - TJC

- Patient identification
- Verbal orders; Critical lab value reporting
- Hand off @ transition
- Infection control
- Medication safeguards:
  - Reconciliation, high alert meds
- Patient involvement in care
- Suicide assessment

RISK MANAGEMENT GOALS

- STOP Patient Harm
- PROTECT Facility
- SUPPORT Providers & Staff

Risk Identification

- **Incident reporting**
- Delays, omissions, errors: Dx & Tx
- Medication events
- Equipment failure
- Patient \ family \ staff complaints
- Communication gaps & barriers
- 'Risk Focus Groups'

Definition of 'Adverse Event'

- **Injury or harm** *(temporary or permanent)* **caused by healthcare interventions**
  – as opposed to patient's health condition
- **Error detected?**
- **If** event is result of error, delay, omission, then '**preventable**'

R Jackson, *Communication & Teamwork for Patient Safety The Magellan Group*

Causes of ‘Adverse Event’

- Majority of ‘adverse events’ = result of **errors – delays – omissions** during healthcare delivery.
- **Continuum of care** issue =62% claims
- Not all errors cause adverse events
  - Near miss

Terminology of 'Liability'

DUTY

Provider – Patient relationship
Reasonable & competent provider
Act under same /similar circumstances

BREACH OF DUTY

Adherence to clinical standards
Failed to exercise 'reasonable' care

INJURY **Proximately *CAUSED* by breach**

Case

- Walter S. was a 62-year-old patient with CHF. He **smoked** despite advice from his medical provider.
- One **Saturday evening**, Mr. S. arrived at the hospital emergency room in respiratory distress. He was admitted, then discharged on day 3.
- A chest X-ray was taken before discharge, but the **report was not available** until the day **after** discharge. It was filed in patient's hospital records.
- The report read: "a suspicious opacity in right upper lobe; immediate **CT evaluation recommended.**"

Case

- **Copy** of X-ray report was sent to health clinic and **filed;** however, **the medical provider never saw it.**
- **One year later**, Mr. D. developed hemoptysis & saw his medical provider who ordered hospital records.
- Records contained the X-ray report but **no follow up.**
- **Only now** did Provider realize that the **X-ray report** had been mistakenly **filed without his review.**
- Medical work-up of Mr. S. indicated he had advanced lung cancer. He died **2 years from date of original, mishandled X-ray report.**

Delay in Notification discovered

- **Medical record review**
- ***Flow charting*** missed abnormal X-Ray
- **Provider interview (s)**
- **Risk investigation report**
- **Follow up with patient** re: clinical care
- **Disclosure,** as appropriate

Delay in Notification – Follow Up

- **Update Protocol:**
  - Logging & tracking, diagnostic orders
- **Educate** staff & providers
- Monitor **provider sign-off** on **all** reports
- Monitor **verified patient notification**
- Certified letter sent **if no patient reply**

Diagnostic Accuracy & Reliability
Clinical Root Causes *(expert witness)*

- **Atypical** presentation & co-morbidities
- Inaccurate **medical history**
- Insufficient **physical examination**
- Inappropriate **diagnostics**
- Inadequate **treatment plan & follow up**
- Incorrect **interpretation of dx tests**
- Lost or delayed **diagnostic reports**

- Ann Intern Med 2006, Oct 3: 145(7):488-96

THE FISHBONE DIAGRAM
Critical Diagnostic reporting

I. Critical diagnostic **tests determined**

II. **Urgency** of critical values defined
1 hr \ 6-8 hrs \ 3 days

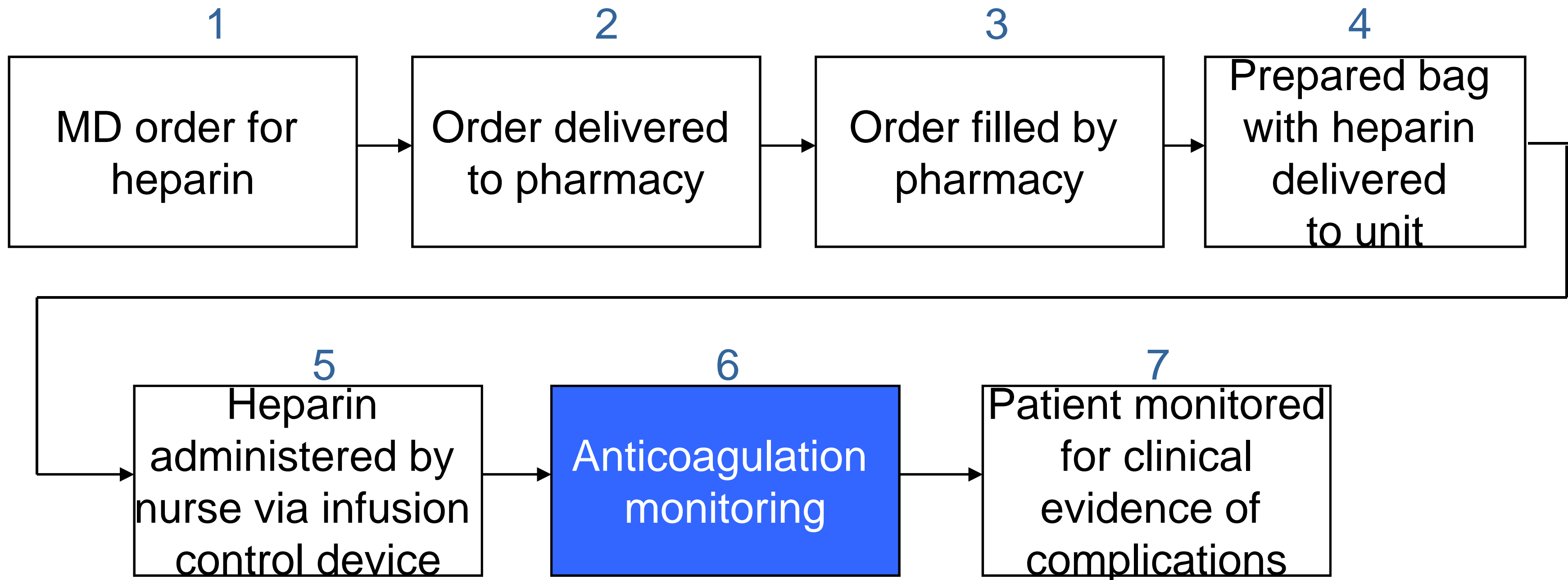
III. **Responsible practitioner** identified

IV. **Notification process** – electronic/PDA

V. Protocols and roles **standardized**

VI. Process **reliability monitored**

Sample Process Flow Charting: *Heparin Monitoring*



6A Physician writes order
6B Unit clerk processes order in computer
6C Nurse signs off on order & enters on Kardex
6D Lab draws patient every 6 hours as ordered
6E Lab calls Patient unit with abnormal results

Which tests may be 'critical' Local Patient population

- Cardiac & pulmonary tests – EKG
- Laboratory tests
  - hematology, coagulation
  - Chemistry /electrolytes
  - therapeutic drug levels
  - microbiology results
- Radiology studies

Notification of Critical Dx Results

Deliver Critical results per phone or person to assure **verified timely receipt**

- **Avoid faxing, phone messages, sticky notes in MR record,** or **standard filing**
- **Receipt** to be **verified by responsible medical provider**
- **Transmittal of report documented,** incl. mode, time, date, sender & receiver

Heparin Safety
FMEA & Corrective Action Plan

Step in Process	Failure Modes	Causes	Effect(s) of Failure	Risk Reduction Strategies
Anti-coagulation Monitoring	Delay or failure to order PTT	Omission. Lack of Communication	Unknown anticoagulation status	CPOE. Standardized order sets. Checklists.
	Delay or failure to transmit order	Staffing issue Orientation / training of unit clerks	Unknown anticoagulation status	Simplify process. Reinforce training. Checklist; Quality audit
	Specimen not labeled correctly	Inconsistent procedure, collection and labeling. Duplicate pt. name	Improper and unsafe treatment	Frequent quality control checks & reports; Safeguard labeling process; Redundancy
	Lab equipment not properly calibrated	Lack supervision Variation in carrying out procedures	Incorrect anticoagulation status reported	Frequent quality control checks & reports; built in redundancy
	Delay or failure to track results	Staffing issue; poor system design; failed Communication	Delay in treatment	Clear procedure; Automatic Reminders, tickler system; Audit

Resources

- February 2005, *Joint Commission Journal on Quality and Patient Safety* - Communicating Critical Test Results: Safe Practice Recommendations. The Massachusetts Coalition for the Prevention of Medical Errors: http://www.macoalition.org/initiatives.shtml
- http://www.jcrinc.com/fpdf/GPD/Critical_Test_Values.pdf
  - Scottsdale HC, P & P including value ranges
- http://www.jcrinc.com/fpdf/GPD/Critical%20Test.pdf
  - No name, value ranges & recording form
- http://www.jcrinc.com/fpdf/GPD/comp_npsg-07.pdf
  - UNM hospitals, value definitions, recording form

Resources

http://www.macoalition.org/Initiatives/docs/CTRstarterSet.xls

Red-orange-yellow classification, all dx tests: microbiology, Radiology, cardiology

http://www.macoalition.org/Initiatives/CCTRToolkit.shtml

Sample FMEA, P&P, audit data tool

http://www.informatics-review.com/articles/isabel.htm

AHRQ meta analysis of Misdiagnosis by Joseph Britto MD and P Ramnarayan

http://www.amia.org/meetings/s08/dem.asp

1st conference on Dx error by AHRQ, AMIA, NPSF

Patient Communication Opportunities

- **Assessment**
- **Patient dialogue**
- **Goal contracting**
- **Informed Consent /** refusal
- **Health education**
- **Literacy**
- **Interpreters**

Organizational Information Flow

- **Communication gaps and barriers @ hand off** at transition points between providers – SBAR
- **Availability of Organizational Information**
  - **Patient information –** accurate, timely
  - **Policies & protocols –** clarity, consistency
  - **Dissemination of task-related information**
  - **Staff Education**
  - **Feedback,** on-going

Risky Communication STAFF & MEDICAL PROVIDERS

- Not **encouraging** patient /family feedback
  - 36% of physicians*
- Not working well with **colleagues**
  - **Disregarding** information needs of team
  - **Not responding** to calls in timely manner
- Disruptive provider syndrome
  - Follow-up as risk incident

* Archives of Int. Med. April 10, 2006

Staff members to **Report any Concern** about Safety or Quality of care - TJC, APR 17

- Any staff member who has a concern about safety or quality of care may **report concerns** to TJC **without fear of retaliation**.
- **Education about reporting** to be provided by organizations to **any staff and licensed independent practitioner** who provides care, treatment or services to patients.
- Joint Commission Perspectives, July 2008, Volume 28, Issue 7

MEDICAL RECORD LIABILITIES

- **Adjectives and blaming documented**
- **Contradictions between Providers**
- **Corrections –** no over-writing
- **Illegibility –** monitor & report
- **Abbreviations –** restricted list
- **"Late entries"** – cautions
- **Alterations –** "Biopsy not necessary at this time" vs. "patient does not want biopsy at this time" – WHITE OUT
- **Not state 'incident report completed'**

ABBREVIATIONS
"Do Not Use" list - TJC

- ***not*:** U (unit) or IU (international unit)
- ***not:*** Q.D. Q.O.D.
- ***not:*** MS MSO4 MgSO4
- ***not:*** Trailing zero *(X.0 mg)* but **write X** mg

- **DO** use leading zero (*NOT .X mg*) *instead*
- Do **write 0.X mg**

Clinical Care Quality

- **Complex medical conditions**
  - **Assessment, Diagnosis, Treatment, F.U.**
  - **Documentation**
- **Medication therapy**
- **Pre-natal risk factors, post natal care**
- **Pre- & post-surgical care**
- **Practice Guidelines**

- Sample protocols can be accessed at http://www.guideline.gov/

Needed Care Guidelines

Primary Care Ambulatory Services

- Respiratory impairment; Asthma
- Diabetes
- Chest Pain; Hypertension; CV disease
- Infectious disease
- G.I. ailments; Nutritional deficits
- Cancer
- Skin lesions and ailments
- Accidents and Injuries

Medication Error Prevention

- **Product labeling**
- **Prescribing:** Indication, interaction, off-label
  - Monitoring
  - *PHARMACIST ROLE*
- **Dispensing**
- **Administration**: wrong drug / dose / route

Source: National Coordinating Council on Medication Error Reporting and Prevention –www.nccmerp.org

Case Example: Medication Monitoring

- 28-year-old female patient is scheduled for elective C-section **at the hospital**
- Patient's **seizure medication is** not noted in the **copied medical record**
- **Blood level** not available and not recorded
- Medication **compliance** unknown
- Patient had grand mal seizure during C-section
- Intubation delayed with resulting brain damage

Case review

- Patient assessment & involvement
- Medication inventory list on medical record
- Medication monitoring
- Medical record documentation
- Hand off between providers & facilities
- Dual liability

DEVICE \ ENVIRONMENT \ EMERGENCY

- **Safe Medical device use –**
  Inspection \ Training \ Failure response by staff
- **Infection control & prevention**
- **Medical emergency & equipment**
  - **Pediatric emergencies**
- **Behavioral code**

Infection control & Prevention

- **Medication vials & syringes**
- **Dental equipment sterilization, etc.**
- **Active TB**

- **Infection control (I.C.) program & Report**
  - **I.C. program assessment**
- **Hazardous material – BBP, other**

Behavioral Emergencies

- Guard against **potentially dangerous confrontations**
  - *Visitors, family, patients, staff*
- **Prevent violence** against healthcare workers
- **Address** potential risks of violence

Source: ECRI, HRC Risk Analysis – *Overview: Managing Risks in Physician Practices*, July 2003.

Staff Performance

- Staffing **levels of qualified** staff & providers
- **Communication;** conflict management skill
- Job-tailored **training**, initial & ongoing
- **Human factors:**
  - distraction, fatigue, memory, confirmation bias
- Clear, written **directives**
- **Material** resources available
- Performance **audits** & data-based feedback

Initial Credentialing

MEDICAL PROVIDERS

- **Licensure**
- ***Specific References***
- **Education & *verified experience***
- **NPDB**
- **Provisional credentialing period**
  - **Proctoring**

Re-credentialing

- Need **Quality & Risk information**
- **Performance indicators selected**
- **Data collection:** who, how much, when
- **Reporting** quality & risk information
- Two **file sections**
  - **Risk** events, practice pattern, peer review
  - **Quality** and **utilization** data trends

Medical Provider Quality Data

- Quality Review
- **Volume and Scope**
- **Guideline use \ Occurrence screens**
- **Documentation quality**
- **Medication orders**

- Peer Review (discoverability)
- **Adverse outcomes; Inadequate processes**
- **Complaints; Disruptive behavior**

Peer review

Documentation "Pertinence"

- Adequate **health history & physical exam** as pertinent to pt. presentation & complaint
- Clinical problems /**risk factors** on Treatmt plan
- **Conclusion & diagnosis** supported by findings
- Diagnostic & therapeutic **orders** supported
- **Patient /family** involved in Treatment plan
- Progress notes indicate **continuity, prompt F.U.**
- **Abnormal findings addressed**

External Peer Review

- Purpose
  - **Baseline data \proctor role \SE case review**
- Contract w/ external qualified physician
  - **Designate external MD as official member of peer review committee of requesting facility**
  - **A contract protects MD reviewer under HCQIA**
  - **MD reviewer stays anonymous & unidentified**
  - **MD may clarify questions re: findings, BUT:**
  - **External reviewer is adjunct to internal peer review decision; NOT involved w/ investigation**

Risk-related Inventory
Reasons for Care Termination

- **Group A**
- 1. Repeatedly missing appointment, no prior notification
- 2. Disagreement over treatment recommendations
- 3. Non-adherence /non-cooperation w/ treatment plan
- **Group B**
- 1. Verbally disruptive, hostile behavior toward medical provider and/or staff [by patient or family /caregiver]
- 2. Threatening behavior toward medical provider/staff
- **Group C**
- 1. Noncompliance with office policy re: prescriptions
- **Group D**
- 1. Delinquency on bill payments

Termination of Care
Solution of 'last resort'

- Patient given notice of termination
  - Evidence of certified letter in chart
- Patient given reasonable amount of time in which to obtain alternative care
  - Usually thirty days
- Patient given assistance in obtaining alternative care
  - e.g., a list of appropriate potential providers

Perhaps not now -- Termination of Care

- During treatment for an imminent or unstable medical condition
  - Mental health disability if yet untreated
  - Pt. in process of medical workup for diagnosis
- Pregnant patient
  - Approx. last 2 trimesters if high risk
- Patient in immediate **postoperative** stage
- **Precaution w/discrimination issues, e.g. HIV**
- **Remote area** and lack of alternate providers