AMERICAN COLLEGE OF EMERGENCY PHYSICIANS
SCIENTIFIC ASSEMBLY
1999

Clinical Guidelines: Attorneys Know About Them---Do You?

Clinical guidelines increasingly influence the way emergency physicians practice and help establish standards of care and may contribute to cost effectiveness. The lecturer will describe the pros and cons of using such guidelines, as well as practical approaches to their implementation in emergency medicine practice. It will include methods to track compliance and show quality improvement. The effect on resource utilization, cost, and consumer expectation will also be covered.

- Outline a process of implementing clinical guidelines and tracking their effects in an emergency medicine practice.
- Explain how practice guidelines can be used to improve the QI process and reduce medicolegal risk.

TH-234
Thursday, October 14, 1999
12:00 PM - 12:55 PM
Room # N250
Las Vegas Convention Center

FACULTY

Andy S Jagoda, MD, FACEP

Associate Professor and Associate Residency Director, Department of Emergency Medicine, Mount Sinai School of Medicine, New York, New York

CLINICAL GUIDELINES: ATTORNEYS KNOW ABOUT THEM, DO YOU?

ANDY JAGODA, MD, FACEP
ASSOCIATE PROFESSOR
DEPARTMENT OF EMERGENCY MEDICINE
MOUNT SINAI SCHOOL OF MEDICINE

CLINICAL POLICIES: PRACTICE GUIDELINES: PRACTICE PARAMETERS

"SYSTEMATICALLY DEVELOPED STATEMENTS TO ASSIST PRACTITIONER AND PATIENT DECISIONS ABOUT APPROPRIATE HEALTH CARE FOR SPECIFIC CLINICAL CIRCUMSTANCES"

"REPRESENT AN ATTEMPT TO DISTILL A LARGE BODY OF MEDICAL KNOWLEDGE

INSTITUTE OF MEDICINE 1990
EICHWALD ET AL JAMA 1995

"I BELEIVE IN RUNNING EVERYTHING DOWN TO PRIMARY SOURCES"

"IN OTHER WORDS, IF YOU PURSUE THE TRUTH AS FAR AS YOU CAN, YOU'LL FIND OUT MANY TIMES THAT IT AIN'T SO"

DAVID SHULMAN, NEW YORK TIMES, 1/11/99

OBJECTIVES

- TO DISCUSS CLINICAL POLICY DEVELOPMENT
- TO PROVIDE A FORMAT FOR EVALUATING THE QUALITY OF A CLINICAL POLICY
- TO DISCUSS THE ROLE OF MULTI-DISCIPLINARY POLICY

WHY ARE CLINICAL POLICIES BEING WRITTEN

- DIFFERENTIATE "EVIDENCE BASED" PRACTICE FROM "OPINION BASED"
  - CLINICAL DECISION MAKING
  - EDUCATION
  - REDUCING THE RISK OF LEGAL LIABILITY FOR NEGLIGENCE
- IMPROVE QUALITY OF HEALTH CARE
  - ASSIST IN DIAGNOSTIC AND THERAPEUTIC MANAGEMENT

WHO IS WRITING CLINICAL POLICIES?

- NATIONAL MEDICAL SOCIETIES (e.g. ACEP, AANS, AAP)
- VOLUNTARY HEALTH ORGANIZATIONS (e.g. AHA, AM CANCER SOCIETY)
- GOVERNMENT AGENCIES (e.g. AHCPR, NIH, NINDS, CDC)
- UNIVERSITIES / MEDICAL CENTERS (e.g.

HISTORY

- 1938 AAP
- 1959 ACOG: PROBLEM SPECIFIC ADVISORIES
- 1980 ACP
- 1986 ASA: 12 POINT PRACTICE GUIDELINE
  - IMPROVED CARE
  - DEC MEDICAL MALPRACTICE PREMIUMS
- AHCPR
  - FUNDING CUT 1996

MEDLINE SEARCH

1970-1990	0
1991	2
1993	592
1995	1300
1997	2952

DIFFICULTIES IN GUIDELINE DEVELOPMENT

- VALIDATION
- SCIENTIFIC EVIDENCE
- DISTRIBUTION AND UTILIZATION
- MECHANISMS TO FUND THE PROCESS

TIME AND COST OF GUIDELINE DEVELOPMENT

- TIME: 1 - 3 YEARS
- COST:
  - ACEP: $10,000
  - AANS: $100,000.00
  - AHCPR: $1,000,000.00

PRACTICE GUIDELINES DEVELOPMENT

- INFORMAL CONSENSUS
- FORMAL CONSENSUS
- EVIDENCE-BASED

INFORMAL CONCENSUS CLINICAL GUIDELINES

- GROUP OF EXPERTS ASSEMBLE
- "GLOBAL SUBJECTIVE JUDGMENT"
- RECOMMENDATIONS NOT NECESSARILY SUPPORTED BY SCIENTIFIC EVIDENCE
- LIMITED BY BIAS

FORMAL CONCENSUS CLINICAL GUIDELINES

- GROUP OF EXPERTS ASSEMBLE
- APPROPRIATE LITERATURE REVIEWED
- RECOMMENDATIONS NOT NECESSARILY SUPPORTED BY SCIENTIFIC EVIDENCE
- LIMITED BY BIAS AND LACK OF DEFINED ANALYTIC PROCEDURES
- EXAMPLES: ACEP's CHEST PAIN POLICY, AAP's "FEBRILE SEIZURE" POLICY

EVIDENCE BASED CLINICAL GUIDELINES

- REVIEW THE LITERATURE
- SEPARATES EVIDENCE BASED KNOWLEDGE FROM OPINION
- IDENTIFIES AREAS IN NEED OF FUTURE RESEARCH

CLINICAL POLICIES

- DEFINE THE CLINICAL QUESTION
  - FOCUSED QUESTION MORE USEFUL THAN GLOBAL QUESTION
- GRADE THE STRENGTH OF EVIDENCE
- INCORPORATE PRACTICE PATTERNS, AVAILABLE EXPERTISE AND RESOURCES, AND RISK BENEFIT RATIOS

DESCRIPTION OF THE PROCESS

- MEDLINE SEARCH
- SECONDARY SEARCH OF REFERENCES
- ARTICLES GRADED
- RECOMMENDATIONS BASED ON STRENGTH OF EVIDENCE
- MULTI-SPECIALTY AND PEER REVIEW

INTERPRETING THE LITERATURE

- TERMINOLOGY
- PATIENT POPULATION
- INTERVENTIONS / OUTCOMES

DESCRIPTION OF THE PROCESS

- STRENGTH OF EVIDENCE
  - **A:** UNBIASED INTERVENTIONAL STUDIES FOR THERAPEUTIC EFFECTIVENESS; OBSERVATIONAL STUDIES (PROSPECTIVE COHORT) FOR DIAGNOSTIC TESTING OR PROGNOSIS; META ANALYSES
  - **B:** UNBIASED OBSERVATIONAL STUDIES; RETROSPECTIVE COHORT, CASE CONTROL, CROSS-SECTIONAL
  - **C:** UNBIASED OBSERVATIONAL REPORTS INCLUDING CASE SERIES, CASE REPORTS; PANEL CONSENSUS BY EXPERTS

CRITICALLY ASSESSING PRACTICE GUIDELINES

- WHY WAS THE TOPIC CHOSEN
- WHAT ARE THE AUTHORS' CREDENTIALS
- WHAT METHODOLOGY WAS USED
- WAS IT FIELD TESTED OR REVIEWED IN CLINICAL PRACTICE
- WHEN WAS IT WRITTEN / UPDATED

CLINICAL PATHWAYS

- IMPLEMENTATION TOOL
- ALGORITHMIC APPROACH
- CONSENSUS VS ANNOTATED

MEDICAL LEGAL IMPLICATIONS

- PRACTICE GUIDELINES CAN SET STANDARDS FOR CARE AND HAVE BEEN USED IN MALPRACTICE LITIGATION
- SHOULD PROTECT AGAINST "EXPERT" TESTIMONY
- GUIDELINES DEVELOPED USING FLAWED METHODOLOGY CAN BE CHALLENGED

"DO THE AUTHORS SERIOUSLY BELEIVE THAT PATIENTS WITH A FIRST SEIZURE CAN BE DISCHARGED FROM THE ED AFTER A SERUM GLUCOSE AND A PRGENANCY TEST WITHOUT ADDITIONAL LAB TESTING? THIS FLIES IN THE FACE OF COMMON SENSE AND WOUND PERHAPS BE CONSIDERED MALPRACTICE IN SOME PARTS OF THE COUNTRY."

MAYO CLINIC PROCEEDINGS REVIEWER

MEDICAL LEGAL IMPLICATIONS

- 1994 REPORT TO THE PHYSICIAN PAYMENT REVIEW COMMISSION; HYAMS ET AL
- 32 CASES REVIEWED WHERE GUIDELINES WERE USED TO DEMONSTRATE DEPARTURE FROM STANDARD OF CARE
- 259 CLAIMS FROM 2 INSURANCE CARRIERS WERE POOLED; 6.6% CITED GUIDELINES
- 980 ATTORNEYS SURVEYED:

GARNICK ET AL. CAN PRACTICE GUIDELINES REDUCE THE NUMBER AND COSTS OF MALPRACTICE CLAIMS? JAMA 1991;266:2856

- MUST BE DEVELOPED FOR CONDITIONS OR PROCEDURES THAT FREQUENTLY LEAD TO EVENTS FOR WHICH NEGLIGENCE CLAIMS ARE FILED
- MUST BE WIDELY ACCEPTED
  - –MULTISPECIALTY ENDORSEMENT
- MUST BE FULLY INTEGRATED INTO PRACTICE

MAINE MEDICAL LIABILITY DEMONSTRATION PROJECT

- STATE LEGISLATURE INCORPORATED 22 GUIDELINES
- 2 FROM EMERG MED: C-SPINE AND PATIENT TRANSFER
- DESIGNED TO ELIMINATE REQUIREMENT OF ESTABLISHING STANDARD OF CARE THROUGH LITIGATION
- COULD NOT BE USED FOR INCULPATORY PURPOSES

PRACTICE GUIDELINES AND RESEARCH

- EBM DEMONSTRATES THAT CLINICAL PRACTICE IS FREQUENTLY BASED ON LIMITED SCIENTIFIC INFORMATION
- IMPACT OF GUIDELINES MUST BE TESTED
  - CLINICAL OUTCOMES
  - FEASIBILITY
  - FISCAL OUTCOMES
- USE AS A TEACHING TOOL

CLINICAL POLICIES IN SEIZURE MANAGEMENT

- ACEP: 1993, 1997: CLINICAL POLICY FOR THE INITIAL APPROACH TO PATIENTS PRESENTING WITH A CHIEF COMPLAINT OF SEIZURE WHO ARE NOT IN STATUS EPILEPTICUS
- ACEP, AAN, AANS, ASN: 1996: PRACTICE PARAMETER: NEUROIMAGING IN THE EMERGENCY PATIENT PRESENTING WITH SEIZURE
- AAP: 1996: PRACTICE PARAMETER: THE NEURODIAGNOSTIC EVALUATION OF

A 30 YEAR OLD WOMAN WITH NO MEDICAL PROBLEMS HAS A FIRST TIME SEIZURE WITHOUT AN IDENTIFIABLE ETIOLOGY BY HISTORY.

HER MENTAL STATUS HAS RETURNED TO NORMAL AND SHE HAS A NORMAL NEUROLOGIC EXAM.

WHAT LABORATORY TESTS ARE INDICATED?

ACEP CLINICAL POLICY

- COMPLAINT BASED
- METHODOLOGY POORLY DEFINED
- RECOMMENDATIONS PRIMARILY CONSENSUS DRIVEN
  - REFERENCES RATED BY

ACEP CLINICAL POLICY

- RULE: "AN ACTION REFLECTING PRINCIPLES OF GOOD PRACTICE IN MOST SITUATIONS. THERE MAY BE CIRCUMSTANCES WHEN A RULE NEED NOT OR CANNOT BE FOLLOWED; IN THESE SITUATIONS, IT IS ADVISABLE THAT DEVIATION FROM THE RULE BE JUSTIFIED IN WRITING."
- GUIDELINE: "AN ACTION THAT MAY BE CONSIDERED, DEPENDING ON THE

ACEP CLINICAL POLICY: LABORATORY TESTING IN THE FIRST TIME SEIZURE

- RULE:
  - PREGNANCY (LIMITED RESEARCH BASED EVIDENCE AND CONSENSUS)
  - SODIUM (MODERATE RESEARCH BASED EVIDENCE)
  - GLUCOSE (MODERATE RESEARCH BASED EVIDENCE)
- GUIDELINE:
  - K, Cl, HCO3

WHAT NEUROIMAGING STUDY IS INDICATED AND WHEN SHOULD IT BE PERFORMED?

ACEP CLINICAL POLICY

- RULE: NONCONTRAST HEAD CT OR SCHEDULE NEUROIMAGING
- INDICATIONS GIVEN FOR EMERGENT NEUROIMAGING
- SCHEDULE NEUROIMAGING IMPLIES REFERRING THE PATIENT TO THE PRIMARY CARE PROVIDER WHO WILL DO THE

NEUROIMAGING PRACTICE PARAMETER

- MULTIDISCIPLINARY: ACEP, AAN, AANS, ASN
- METHODOLOGY CLEARLY DEFINED
- LITERATURE GRADED, STRENGTH OF EVIDENCE:
  - CLASS I: RANDOMIZED CONTROLLED STUDIES
  - CLASS II: CLINICAL STUDIES eg CASE CONTROL, COHORT
  - CLASS III: CASE REPORTS, EXPERT

NEUROIMAGING PRACTICE PARAMETER

- NO STANDARDS
- GUIDELINE: EMERGENT CT (-) WHEN SERIOUS STRUCTURAL LESION SUSPECTED: FOCAL DEFICIT, ALTERED MENTAL STATUS, FEVER, TRAUMA, HEADACHE, HX CANCER, ANTICOAGULATION, AIDS
- OPTION: URGENT SCAN FOR PATIENTS WHO HAVE COMPLETELY RECOVERED AND NO ETIOLOGY IDENTIFIED: URGENT SCAN MAY BE

WHY THE DIFFERENCE BETWEEN THE STRENGTH OF RECOMMENDATIONS OF THE ACEP CLINICAL POLICY AND THE JOINT NEUROIMAGING PRACTICE PARAMETER?

- THE ACEP CLINICAL POLICY ON SEIZURES IS DIAGNOSIS (DISPOSITION) BASED
- THE JOINT NEUROIMAGING PRACTICE PARAMETER IS

ONE HOUR PRIOR TO ED ARRIVAL, A 20 MONTH CHILD IN EXCELLENT HEALTH DEVELOPS A TEMPERATURE OF 104 AND HAS A GENERALIZED TONIC-CLONIC CONVULSION LASTING 5 MINUTES. THERE IS NO PAST MEDICAL HISTORY. CHILD HAS RETURNED TO BASELINE AND APPEARS WELL. YOU SUSPECT A SIMPLE FEBRILE SEIZURE. DOES THIS CHILD REQUIRE DIAGNOSTIC TESTING?

AAP PRACTICE PARAMETER: THE NEURO-DIAGNOSTIC EVALUATION OF THE CHILD WITH A FIRST SIMPLE FEBRILE SEIZURE

- METHODOLOGY WELL DESCRIBED
- STRENGTH OF EVIDENCE NOT PROVIDED
- STRENGTH OF RECOMMENDATIONS NOT

AAP PRACTICE PARAMETER: THE NEURO-DIAGNOSTIC EVALUATION OF THE CHILD WITH A FIRST SIMPLE FEBRILE SEIZURE

- "IN A CHILD OLDER THAN 18 MONTHS . . . A LP IS NOT ROUTINELY WARRANTED . . ."
  - "THE AAP . . . RECOMMENDS . . . (AN LP) IN INFANTS YOUNGER THAN 12 MONTHS . . ."
  - "IN A CHILD BETWEEN 12 AND 18 MONTHS OF AGE, A LP SHOULD BE CONSIDERED"
- RECOMMENDS THAT LYTES, Ca,

AN 18 YEAR OLD MALE IS IN THE TRAUMA CENTER WITH AN ISOLATED CLOSED HEAD INJURY FROM A MVA. THE VITAL SIGNS ARE STABLE; THE GCS IS 6. SHOULD THIS PATIENT RECEIVE ANTI-SEIZURE PROPHYLAXIS?

AANS GUIDELINES FOR THE MANAGEMENT OF SEVERE HEAD INJURY

- JOINT INITIATIVE BY THE AANS; PARTICIPANTS FROM THE AAN, ACEP, BTF
- METHODOLOGY CLEARLY DEFINED
- LITERATURE GRADED, STRENGTH OF EVIDENCE:
  - CLASS I: PROSP, RANDOMIZED CONTROLLED TRIALS
  - CLASS II: PROSP CLINICAL STUDIES OR RETROSPECTIVE ANALYSES BASED ON RELIABLE DATA
  - CLASS III: RETROSPEC DATA

AANS GUIDELINES FOR THE MANAGEMENT OF SEVERE HEAD INJURY

- STANDARD: PROPHYLACTIC AEDs ARE NOT RECOMMENDED FOR PREVENTING LATE POSTTRAUMATIC SEIZURES
- GUIDELINES: NONE
- OPTIONS: AEDs MAY BE USED TO PREVENT EARLY PTS IN PATIENTS AT HIGH RISK FOR SEIZURES FOLLOWING HEAD INJURY.

CLINICAL POLICIES: CONCLUSIONS

- MAY FACILITATE THE PROVISION OF EFFICIENT, COMPREHENSIVE CARE
- MAY FACILITATE RESOURCE UTILIZATION AND MANAGEMENT DECISION MAKING
- MUST UNDERSTAND THE METHODOLOGY USED IN CREATING THE POLICY
- MOST POLICIES ALLOW FOR

SELECTED READING

American Medical Association. Attributes to Guide the Development of Practice Parameters. Chicago, IL: American Medical Association; 1990.

Eddy D. Practice Policies: Where Do They Come From? JAMA 1990;1269-1275.

Eichorn J. Prevention of intraoperative anesthesia accidents and related severe injury through safety monitoring. Anesthesiology 1989; 70:572-577.

Ellrodt A, Conner L, Riedinger M, Weingarten S. Measuring and improving physician compliance with clinical practice guidelines. Ann Int Med 1995;122:277-282.

Field M, Lorh K (eds). Guidelines for Clinical Practice: From Development to Use. Committee on Clinical Practice Guidelines, Division of Health Care Services of the Institute of Medicine. Washington, DC: National Academy Press, 1994.

Garnick D, Hendricks A, Brennan T. Can practice guidelines reduce the number and cost of malpractice claims. JAMA 1991 266:2856-2860.

Gray J, Haynes R, Sackett D, et al. Transferring evidence from research into practice: Developing evidence-based clinical policy. Evid Based Med 1997; 2:36-38.

Hadorn D, McCormick K, Diokno A. An annotated algorithm approach to clinical guideline development. JAMA 1992; 267:3311-3314.

Hayward R, Wilson M, Tunis S, et al. Users' Guide to the medical literature VIII. How to use clinical practice guidelines. JAMA 1995; 274-570-574.

Hyams A, Brandenburg J, Lipsitz S, Brennan T. Report to physician payment review commission on practice guidelines and malpractice litigation. Physician Review Commission Grant No. 92-G04, January 25, 1994.

Kosecoff J, Kanouse D, Rogers W, et al. Effects of the National Institutes of Health consensus development program on physician practice. JAMA 1987; 258:2708-2713.

Lomas J, Anderson G, Domnick-Pierre E, et al. Do practice guidelines guide practice? The effect of a consensus statement on the practice of physicians. N Engl J Med 1989;321:1306-1311.

Schriger D, Baraff L, Rogers W, Cretin S. Implementation of clinical guidelines using a computer charting system. JAMA 1997; 278:1585-1590.

Smith G. A case study in progress: Practice guidelines and the affirmative defense in Maine. J Qual Improv 1993; 19:355-362.

Wigder H, Arai D, Narasimhan K, Cohan S. ACEP chest pain policy: Emergency physician awareness. Ann Emerg Med 1996; 27:606-609.

Woolf S. Practice Guidelines, a New Reality in Medicine: II. Methods of Developing Guidelines. Arch Int Med 1992; 152:946-952.