A Patient-Centered Approach to the Process of Making Clinical Decisions

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Clinical Practice

- A problem-solving process that requires decisions –
  - Patient history questions focused on acquisition of the information needed to establish an accurate diagnosis
  - Clinical test selection guided by the need for more information to support or refute differential diagnoses
  - Information synthesized to establish prognosis and to select treatment for realization of a favorable outcome
  - Each step in the decision-making process requires estimation of the likelihood for correct categorization

Evidence-Based Medicine (1996)

- The conscientious, explicit and judicious use of current best evidence in making clinical decisions about the care of individual patients
  - The integration of best research evidence with clinical expertise and patient values
  - Clinicians' preferences (as distinct from clinical expertise) often play a large role in their actions, leading to large practice variations in managing similar cases

Basis for clinical decisions?

- Use of the research literature
  - Overwhelming volume
  - Relevant information not readily accessible
  - Variation in research methods
  - Conflicting results

Clinical Decision Making

- Historically, decision-making has been based on –
  - Expert opinion
  - Clinical experience
  - Intuition
  - Simple “rules of thumb” –
    - Easily distorted by personal needs and/or preferences
    - Can lead to potentially harmful incorrect decisions

Institute of Medicine
Health Professions Education: A Bridge to Quality (2003)

- Competencies:
  - Habitual and judicious use of communication, knowledge, technical skills, clinical reasoning, emotions, values, and reflection in daily practice
  - Employ evidence-based practice
  - Provision of patient-centered care
  - Ability to work in interdisciplinary teams
  - Application of quality improvement
  - Utilization of information technology
Patient-Centered Care Definition

- Institute of Medicine*

Care that is respectful and responsive to individual patient preferences, needs, and values, and ensures that patient values guide all clinical decisions.

INSTITUTE OF MEDICINE

* An independent, nonprofit organization that works outside of government to provide unbiased and authoritative advice to decision makers and the public.


Factors Influencing Clinical Decisions

**Personal**
- Moral Philosophy
- Integrity
- Ambition - Ego
- Security - Acceptance

**Professional**
- NATA Code of Ethics
- BOC Standards of Practice
- State Practice Regulations
- Mentors & Colleagues

**Organizational**
- Institution Administration
- Athletic Director
- Coaches
- Team Physician – Med. Dir.


What currently guides clinical practice?

- "Perceived behavioral control was the greatest predictor of whether an AT followed the recommended concussion-management guidelines."

- "ATs are less likely to implement recommended concussion-management guidelines when they do not believe they have the power to do so."

Evidence-Based vs. Patient-Centered Care

- The individual patient's needs and preferences are often neglected as relevant factors in decision-making

  - EBM can be more "disease-oriented" than "patient-centered"
    - Psychosocial elements are as important as biomedical factors
  - EBM emphasis on RCTs as highest quality source of evidence
    - Results applied to patients who would have been excluded from study


Clinical Expertise

- Accuracy of the “clinical impression”
  - Prerequisite for every decision
    - Diagnosis – Prognosis – Treatment

- Comparison of the individual patient to other patients
  - Individual patient’s experience will differ to some extent
    - Research reports the collective experience of patient groups

- Key factor influencing the patient’s outcome –
  - Synthesis of information (history, attributes, presentation)
    - Skill in making comparison to experiences of similar patients
    - Identification of "unique" characteristics of patient's case
Clinical Decision-Making

- Evidence-Based Medicine:
  - The application of "Clinical Epidemiology" to the care of patients

- Clinical Epidemiology
  - The science of making predictions about individual patients by counting clinical events in groups of similar patients and using scientific methods to ensure that the predictions are accurate.


Outcomes

- Preventive measures
  - How does the clinician decide if an exercise or device intended to reduce the risk of injury should be recommended to an athlete/patient?

- Treatment effectiveness
  - How does the clinician decide which treatments to recommend and what can the athlete/patient be told about the likelihood of success?

Decision-Making Under Uncertainty

- Subjective Expected Utility (SEU)
  - Degree of belief in the validity and usefulness of an association between a present circumstance and a future outcome
  - Conceptual basis for Bayesian statistical inference
  - Emergence of decision analysis as an applied science in engineering, business, and economics


Drop vs. Don't Drop Depth Charge

- Drop
- Don't Drop

Every decision is a balance between 2 things!
1. Possible consequence of the choice
2. Confidence in the outcome
Prediction Accuracy

- Key consideration: consequences of misclassification
  - Poor prognosis without treatment
  - Side-effects of diagnostic or therapeutic procedure
  - Unnecessary cost
    - Low Sensitivity
      - Some positive cases do not receive the benefit of treatment
    - Low Specificity
      - Some negative cases are unnecessarily subjected to treatment

Objective Probability

- The expected frequency of occurrence of a specified event in relation to the set of possible events
  - Always associated with some degree of uncertainty
  - Expressed as a proportion (or percentage)
    - Coin toss: 2 possible events: Head or Tail
      - .5 probability for either one (1/2)
    - Probability of Heads on consecutive coin flips
      - 2 consecutive tosses: (.5)^2 = .25
      - 3 consecutive tosses: (.5)^3 = .12
      - 4 consecutive tosses: (.5)^4 = .06
      - 5 consecutive tosses: (.5)^5 = .03

Likelihood for Injury Occurrence (Risk)

- Based on incidence (proportion injured) in a particular population within a specified time period
  - For an individual, the injury either occurs or does not occur within a given period of time
    - Not Injured or Injured (0 or 1.0 status)
  - Key consideration: Comparability of the individual patient's injury susceptibility to that of a high-risk population or that of a low-risk population

Probability vs. Odds

- The likelihood for occurrence of a given outcome
  1. Expressed as proportion or percentage (proportion x 100)
  2. Expressed in terms of odds “for” vs. “against” outcome
    - Probability vs. Odds of “Heads” on both of 2 coin flips:
      - 4 possibilities:
        - HH – HT – TH – TT
        - Probability = 1/4 = .25
        - Odds for 1:3 = 1/3 = .33
        - Odds against 3:1

Likelihood for Existence of a Condition

- Based on prevalence (proportion of positive cases) in a particular population
  - Key consideration:
    - Comparability of the individual patient's clinical presentation to that of a high-risk population versus that of a low-risk population

Risk Ratio (RR) vs. Odds Ratio (OR)

- Risk Ratio (or Relative Risk):
  - Ratio of the probability for a specified outcome (injury) for one group in relation to that for another group
    - Low-risk group vs. High-risk group
    - If the probability is the same for both groups, RR = 1.0
  - Odds Ratio:
    - Ratio of the odds for a specified outcome (injury) for one group in relation to the odds for another group
    - If the odds are the same for both groups, OR = 1.0
What is the level of risk?

**Exposure-Outcome Association**

- Risk Ratio (RR)
  - Injury Incidence Within Groups (Proportions): Hi-Risk/Lo-Risk
- Odds Ratio (OR)
  - Injury Occurrence vs. Non-Occurrence Odds: Hi-Risk/Lo-Risk

**Meaningful:** RR > 1.0 OR ≥ 2.0

**Moderate:** RR ≥ 1.5 OR ≥ 4.0

**Substantial:** RR ≥ 3.0 OR ≥ 8.0

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**Levels of Evidence Quality**

Oxford Centre for Evidence-Based Medicine

- **Level 1:** Randomized Clinical Trial (RCT)
  - Random selection of subjects from population
  - Random assignment of subjects to groups
  - Rigorous control of extraneous variables
- **Data analysis**
  - Parametric statistical procedures
  - Sample statistics estimate population parameters
  - “Frequentist” interpretation of results
  - Arbitrary standard for statistical significance

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**“Frequentist” Hypothesis Testing**

Based on theoretical “normal” distribution

α = .05

- Rejection of null hypothesis of no difference (α = .05)

For a given sample size (number of subjects) and 100 replications of the random sampling process –

- The expected “frequency” that a mean difference as large as that observed will result from random variation:
  - No more than 5 times with 100 replications of the study
- Difference between groups attributable to a treatment effect, rather than random sampling error

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**Parametric Comparison of Central Tendency Values for Randomly Formed Groups**

\[
I = \frac{\bar{X}_E - \bar{X}_C}{\sqrt{\frac{s_E^2}{n_E} + \frac{s_C^2}{n_C}}}
\]

\[H_0: \bar{X}_E = \bar{X}_C\]

\[\alpha = .05\]
Questionable Evidence

Sifting the evidence – What’s wrong with significance tests?
Sterne JAC, Davey Smith G. BMJ. 2001;322:226-231

- Use of statistics in medicine dominated by division of results into significant or non-significant
- Type II error rate receives little or no consideration
- Confidence intervals should be reported to move us away from a mechanistic accept-reject dichotomy

Perspective

- WW Rozeboom (Dept of Psychology, University of Alberta)

“Null hypothesis significance testing is surely the most bone-headedly misguided procedure ever institutionalized in the rote training of science students.”

Clinical Utilization of Research Evidence: Treatment Plan

- **Efficacy**: Level of benefit observed when -
  1) treatment is applied under ideal conditions
  2) to a clearly defined population of subjects
  - Random assignment to experimental and control groups
- **Effectiveness**: Level of benefit expected when -
  1) treatment is provided in customary practice setting
  2) to typical patients

Analysis & Interpretation of Results

- **External validity**
  - Extent to which results can be generalized
    - Laboratory to “real world” application

RCTs vs. Observational Research

- Many discount the value of any research that does not involve **randomization**
- Strict application of the experimental method of problem solving can sometimes hinder rather than advance clinical practice
  - Ethical considerations often preclude random assignment of subjects
  - Research conducted in a clinical setting makes rigorous control of variables extremely difficult

Levels of Evidence Quality

**Oxford Centre for Evidence-Based Medicine**

- **Level 1**: Randomized Clinical Trial or Systematic Review of RCTs
- **Level 2**: Cohort study, low-power RCT, or prospective outcomes study
- **Level 3**: Case-control study or retrospective outcomes study
- **Level 4**: Case series (no control/comparison group)
- **Level 5**: Case report or expert opinion

http://www.cebm.net
Evidence-Based Practice

- Cohort study design offers major advantages
  - No need for randomized assignment to groups
  - Data acquired during routine clinical activities
  - Development of multi-factor prediction models
  - Individualization of intervention programs

Contrasting Research Paradigms

- Parametric statistics (Frequentist approach)
  - Key assumption: RANDOMIZATION
    - Null hypothesis: no difference between group means
    - Statistical test p-value < specified alpha level (typically .05)

- Bayesian analysis of cohort study data
  - Association between "exposure(s)" and "outcome"
    - Group comparison: Risk Ratio (RR) or Odds Ratio (OR)
    - Lower limit of confidence interval for RR or OR > 1.0

Factors Affecting Injury Risk, Recovery Rate, and/or Susceptibility to Re-Injury

"Exposures"

- Age
- Gender
- Sport / Position
- Injury History
- Joint Stability
- Structural Alignment
- Movement Symmetry
- Mobility
- Reaction Time
- Body Composition
- Strength
- Fatigue Resistance
- Aerobic Fitness
- Neuromuscular Control
- Agility
- Neurocognitive Function
- Psychosocial Status
- Social Support

Cohort Study Design

- Cohort: A group of people with a common experience over a defined period of time

  - Observation to determine differences in incidence or injury odds in relation to exposure to risk factor(s)
  - Risk Ratio: Incidence for "exposed" cases (high risk) divided by incidence for "unexposed" cases (low risk)
  - Odds Ratio: Injury odds for "exposed" cases (high risk) divided by injury odds for "unexposed" cases (low risk)

Bayesian Analysis of Observations

- Association between “exposure” and “outcome”
  - Dichotomized Exposure (High-Risk vs. Low-Risk)
    - Trait, status, behavior, event, treatment, etc.
  - Dichotomized Outcome:
    - Injury vs. No Injury
    - Diagnosis Positive vs. Negative
    - Optimal vs. Suboptimal Recovery
  - Null Hypothesis: No exposure-outcome association
    - Lower limit of confidence interval for RR or OR ≤ 1.0
    - Incidence of outcome same for both groups

Receiver Operating Characteristic (ROC) Analysis: Trunk Flexion Hold

- Core or LE Sprain or Strain
  - 1=Injured (N=39) 0=Non-Injured (N=44)
  - 45° line: 50% prediction accuracy

- Sensitivity:
  - Proportion injured classified as high risk
- Specificity:
  - Proportion non-injured classified as high risk

<table>
<thead>
<tr>
<th>Cutoff</th>
<th>Injury</th>
<th>No Injury</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 161 s (High Risk)</td>
<td>32</td>
<td>23</td>
<td></td>
</tr>
<tr>
<td>&gt; 161 s (Low Risk)</td>
<td>7</td>
<td>21</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>39</td>
<td>44</td>
<td></td>
</tr>
</tbody>
</table>

Sensitivity: 82%
Specificity: 48%
Prediction Accuracy

- Sensitivity (0.00 – 1.00)
  - Proportion of True-Positive classifications among Criterion-Positive cases
- Specificity (0.00 – 1.00)
  - Proportion of True-Negative classifications among Criterion-Negative cases
- +LR (≥ 1.0)
  - Increase in odds for Criterion-Positive status as a result of positive test
- -LR (≤ 1.0)
  - Decrease in odds for Criterion-Positive status as a result of negative test
- Odds Ratio (≥ 1.0)
  - Group 1 Incidence / Group 2 Incidence
- Risk Ratio (≥ 1.0)
  - Group 1 Incidence / Group 2 Incidence

Assess the 90% Confidence Interval for the most appropriate accuracy indicator (depends on CPR’s purpose).

Prediction of Core or LE Sprain or Strain 2009-2011 Football Seasons (N=256)

<table>
<thead>
<tr>
<th>Starter Status ≥ 1 Game</th>
<th>Injury</th>
<th>No Injury</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES (106)</td>
<td>63</td>
<td>43</td>
</tr>
<tr>
<td>NO (128)</td>
<td>40</td>
<td>110</td>
</tr>
<tr>
<td>Total (234)</td>
<td>103</td>
<td>153</td>
</tr>
</tbody>
</table>

Sensitivity = 61%
Specificity = 72%

Risk Ratio vs. Odds Ratio

Starter Status ≥ 1 Game

| Reaction Time Mean Difference | Injured vs. Uninjured | t(74) = 0.842; P = .403 |

ImPACT Neurocognitive Test Scores
Swank et al, AJSM, 2007

- Pre-season assessment of college athletes at 18 universities
  - 80 non-contact ACL tear cases (45 female, 35 male)
  - 80 matched controls (gender, height, weight, age, sport, position)
- Non-contact ACL tear cases compared to controls –
  - Lower verbal memory and visual memory scores
  - Slower processing speed and reaction time

ImPACT™ Neurocognitive Composite Reaction Time
76 NCAA Division I-FCS Football Players; Range = 470 – 790 milliseconds

- Reaction Time: Cases: 570 ms; Controls: 530 ms

Injury Risk for an Individual Athlete

- Based on injury incidence in a particular population
- For an individual, the injury occurs or does not occur within a given period of time
  - 0% or 100% incidence
- Key consideration:
  - Comparability of the individual patient’s set of characteristics to those of a high-risk versus low-risk population

Bayesian Analysis Results
Clinical Prediction Rule
Clinical Decision Guide

- Logistic regression analysis of potential predictors
- A combination of 3-5 prospectively documented patient characteristics that predict outcome
- Provides a quantifiable likelihood for:
  1) Existence of a given condition (diagnosis)
  2) Change in current health status (prognosis)
  3) Realization of benefit from a therapeutic procedure

Clinical Prediction Guides (Predictive Modeling)

- Purpose:
  - Use of patient-specific information to predict outcome
- Potential benefit:
  - The patient can make an educated choice among treatment options on the basis of the outcome he or she is most likely to experience (given personal characteristics)
- Ultimate value:
  - Accuracy in discriminating between patients who will or will not experience a specified outcome


2009 – 2011 Combined Analysis
Wall-Sit Hold N=256

2009 – 2011 Combined Analysis
3-Factor Prediction Model N=256
1) Starter (≥1 game) 2) Hi ODI (≥4) 3) Lo WSH (≤88-41-30 s)

Core + LE Strains & Sprains (103)

<table>
<thead>
<tr>
<th>Injury</th>
<th>No Injury</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>58</td>
<td>30</td>
<td>88</td>
</tr>
<tr>
<td>45</td>
<td>123</td>
<td>168</td>
</tr>
<tr>
<td>103</td>
<td>153</td>
<td>256</td>
</tr>
</tbody>
</table>

Fisher’s Exact One-Sided p < .001
Sensitivity: .56
Specificity: .80
AUC = .72

+LR = 2.87
-LR = .54
Odds Ratio 2.87/.54 = 5.28
90% CI: 3.31 – 8.44

Risk Ratio = .659/.268 = 2.46
90% CI: 1.93 - 3.14

2009 – 2011 Combined Analysis
N=256 Starter Status Stratification

Logistic Regression Result

<table>
<thead>
<tr>
<th>Factor</th>
<th>Cut-Point</th>
<th>p</th>
<th>Adj. OR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starter</td>
<td>≥1 game</td>
<td>&lt;.001</td>
<td>4.22</td>
</tr>
<tr>
<td>Hi ODI</td>
<td>≥4 points</td>
<td>.006</td>
<td>2.26</td>
</tr>
<tr>
<td>Lo WSH</td>
<td>≤88-41-30 s</td>
<td>.005</td>
<td>2.22</td>
</tr>
</tbody>
</table>

Model χ² = 43.64; p <.001
Nagelkerke R² = .212

2009 – 2011 Combined Analysis
N=256

Risk Factors Injury No Injury Incidence

<table>
<thead>
<tr>
<th>0</th>
<th>9</th>
<th>47</th>
<th>16.1%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>36</td>
<td>76</td>
<td>32.1%</td>
</tr>
<tr>
<td>2</td>
<td>45</td>
<td>25</td>
<td>64.3%</td>
</tr>
<tr>
<td>3</td>
<td>13</td>
<td>5</td>
<td>72.2%</td>
</tr>
</tbody>
</table>

Total 103 153 40.2%
Magnitude-Based Inference

Making Meaningful Inferences About Magnitudes
Alan M. Batterham, Will G. Hopkins
Sportscience 9, 6-13, 2005 (sportsci.org/journal/05a/ambwhg.htm)

- An alternative approach to reporting results
- Interpretation of confidence intervals
- Judgment about real world application of results

Confidence Interval Function

Graphic representation of magnitude and precision of estimate of exposure-outcome association

Risk Ratio = 2.46 (90% CI: 1.93 – 3.14)
Odds Ratio = 5.28 (90% CI: 3.31 – 8.44)

2009 – 2011 Combined Football Data (N=256)
≥ 2 of 3 Risk Factors (Starter, WSH, ODI)

Different Inferential Paradigms

Frequentist Approach
- Randomized Assignment
- IV: Group membership
- DV: Continuous measure
- Error: Random variation
- Focus: Statistical significance
  - Difference between groups
    - Mean values (central tendency)

Bayesian Approach
- Observation of Cohort
- IV: Exposure status
- DV: Binary outcome
- Error: Misclassification
- Focus: Precision of estimate
  - Exposure-Outcome association
  - Risk Ratio and Odds Ratio

Medicine 40+ Years Ago (1969)

- “…current undergraduate curricula in epidemiology and biostatistics are viewed with disdain by the overwhelming majority of medical students.”
- “Do medical students fail to see the relevance of epidemiology and biostatistics, or does the faculty, through the failure either to recognize or to approve of student motivation, fail to make the curriculum in epidemiology and biostatistics relevant to these students?”
- “Other health professionals could effect substantial similar improvements in patient care through a clinical epidemiologic approach to teaching and research.”

Summary

- Therapeutic interventions should be individualized
  - Targeted training adaptations to address specific deficiencies
    - Weakness, Rapid Fatigue, Postural Instability, Slow Reaction Time
- The predictive value of a given risk factor varies
  - Dependent on sport, gender, age, injury type, etc.
    - Cut-points for categorization of High-Risk vs. Low-Risk vary
- Interactions among predictive factors are important
  - Multiple risk factors can dramatically increase susceptibility
    - A modifiable factor may compensate for a non-modifiable factor

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