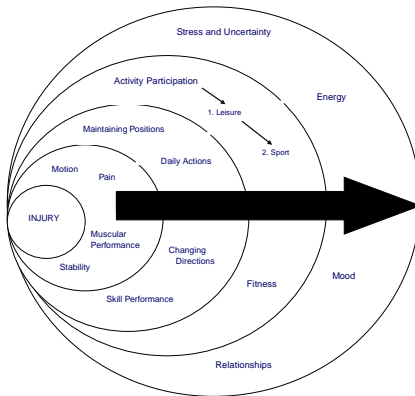


Evaluation and data synthesis

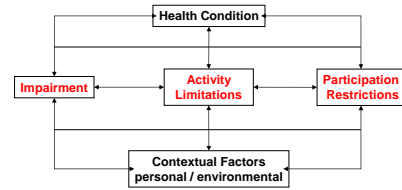
- Synthesis of data gathered to establish a diagnosis*, prognosis, and plan of care.
- Include problem list – impairment, function, participation, quality of life



Prognosis and plan of care

- Consider the problems identified
- Identify all elements in a plan of care
- Link the clinical research and your clinical experience in formulating a prognosis

WHO-ICF



Diagnoses and syndromes

- Medical (eg patellofemoral pain)
- Biomechanical (patellofemoral pain due to excessive hip adduction / internal rotation in landing)
- Important consideration when considering the inclusion/exclusion criteria in clinical research

Interventions

- What is known regarding the impact of an intervention on goal achievement in patients similar to the one in your care?
 - Intervention may include the use of a modality, prescription of an exercise regimen, use of a device or orthosis, a change in behavior, planned patient education individually or in any combination

Outcomes

- Results of patient/client management
 - Impact on:
 - Pathology/pathophysiology
 - Impairments
 - Functional limitations
 - Disability
 - Risk reduction
 - Societal resources
 - Patient satisfaction

Outcomes

- Patient derived
- Clinician derived
- Longitudinal *
 - important in assessing change in risk
 - also important to consider with regard to follow-up (are benefits of care maintained, further improve or diminish over time)

OUTLINE

- Making Evidence-Based Clinical Decisions
- **Strategies for Finding Clinical Evidence**
- Critical Appraisal Strategies
- Applying Research Findings
 - Prevention
 - Treatment
 - Diagnosis
- Teaching Strategies

WHERE TO FIND CLINICAL EVIDENCE?

- Mailbox
- Cross-referencing
- Search engines
- Resources that specialize in EBP



FINDING EVIDENCE IN YOUR MAILBOX

- Wait for the evidence to come to you



Cross-referencing

- Identifying related articles in the bibliography of an article you're reading
- Not very efficient, but should always be done



SEARCH ENGINES



KEYS TO USING SEARCH ENGINES

- Use all appropriate search terms
 - Patellofemoral pain, anterior knee pain,...
- Combining search terms
 - “AND” vs. “OR”
 - “NOT”
- Setting search limits
 - Human subjects
 - Language
 - Dates
 - Type of study (RCT, systematic review,...)
 - Patient demographics (age,...)
- Use your librarian to help teach search strategies!

Accessing and reading research literature
in a focused manner

- **Table of Contents notification**
 - Many journals feature this service
 - Register at journal websites
- **Create Email alerts from PubMed**
 - <http://biomed.ucsd.edu/pubmed/myncbi.pdf>
 - Automatic notification of new articles that meet your search terms
- **Sports Med Research Blog**
 - <http://www.sportsmedres.org/>
 - Provide daily email with summary of a new article
 - Focus on clinical trials, systematic reviews, clinical practice guidelines, and position stands
 - Discussion board linked to each article summary
 - Repository of all articles reviewed on website

EXAMPLES OF FILTERED RESOURCES THAT
SPECIALIZE IN EBP

- sportsmedresearch.blogspot.com/



- Cochrane Reviews



- POEMs

POEMs: PATIENT-ORIENTED
EVIDENCE THAT MATTERS

- PEDro

Accessing and reading research literature
in a focused manner

- Activities in your practice to facilitate discussion of recent research results
 - Question of the week
 - Journal clubs
 - Inservices
 - Case study and case series presentations
- } Link these to specific clinical problems

CLINICAL EVIDENCE STRATEGIES

- Make the evidence come to you
- BUT, know how to find evidence when you need to
 - Be systematic in your searches
 - Look for quality meta-analyses, systematic reviews, & critically-appraised topics first
 - Review individual studies when needed
 - Concentrate on the “**best evidence**”
- Build discussion of “evidence” into your work routine

OUTLINE

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CRITICAL APPRAISAL

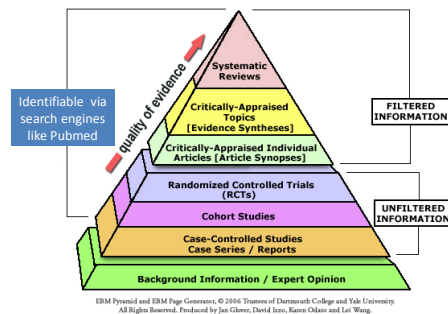
- Why do we need to critically appraise research if it is peer-reviewed?
- All Evidence is NOT EQUAL

Evidence₁ ≠ Evidence₂

Appraising Evidence: FACE VALIDITY

- Do the characteristics of the study I am appraising match my PICO question?
 - **P**atients
 - **I**ntervention
 - **C**omparison
 - **O**utcomes
- Is the study relevant to your patients?
- When this isn't possible, still must identify and interpret the "best available evidence" for your question

Appraising Evidence: LEVEL OF EVIDENCE



CEBM "Levels of Evidence 2"

Question	Step 1 (Level 5) Local and current random sample surveys (or consensus)	Step 2 (Level 3) Systematic review of surveys that allow meta-analysis to local clinicians**	Step 3 (Level 2) Local non-random sample**	Step 4 (Level 1) Case-control**	Step 5 (Level 1) N/A
How common is the problem?	Local and current random sample surveys (or consensus)	Systematic review of surveys that allow meta-analysis to local clinicians**	Local non-random sample**	Case-control studies, or prior or non-independent reference standards**	Mechanism-based reasoning
Is this diagnostic or monitoring test accurate?	Systematic review of cross-sectional studies with consistently applied reference standard and blinding	Individual cross-sectional studies with consistently applied reference standard and blinding	Non-cohort studies, or studies without consistently applied reference standards**	Case-control studies, or prior or non-independent reference standards**	Mechanism-based reasoning
What will happen if we do not add a therapy?	Systematic review of inception cohort studies	Inception cohort studies	Cohort study or control arm of randomized trial	Case-control studies, or poor quality prognostic cohort study**	N/A
Does this intervention help?	Systematic review of randomized trials or n-of-1 trials	Randomized trial or observational study with dramatic effect	Non-randomized controlled cohort/follow-up study**	Case-control studies, or poor quality prognostic cohort study**	Mechanism-based reasoning
What are the common harms?	Systematic review of randomized trials, systematic review of nested case-control studies, or n-of-1 trial with the patient you are asking the question about, or observational study with dramatic effect	Individual randomized trial or (preferentially) observational study with dramatic effect	Non-randomized controlled cohort/follow-up study (post-marketing surveillance) provided there are sufficient numbers to rule out a common harm. (Use long term harms the duration of follow-up must be sufficient.)**	Case-series, case-control studies, or historically controlled studies**	Mechanism-based reasoning
What are the rare harms?	Systematic review of randomized trials or n-of-1 trial	Randomized trial or (preferentially) observational study with dramatic effect	Non-randomized controlled cohort/follow-up study**	Case-series, case-control or historically controlled studies**	Mechanism-based reasoning
Is this (early detection) test worthwhile?	Systematic review of randomized trials	Randomized trial	Non-randomized controlled cohort/follow-up study**	Case-series, case-control or historically controlled studies**	Mechanism-based reasoning

* Level may be graded down on the basis of study quality, imprecision, indirectness (study PICO does not match questions PICO), because of inconsistency between studies, or because the absolute effect size is very small; level may be graded up if there is a large or very large effect size.
 ** As always, a systematic review is generally better than an individual study.

SORT Levels of Evidence

Study quality	Diagnosis	Treatment/prevention/screening	Prognosis
Level 1—good-quality patient-oriented evidence	Validated clinical decision rule SR/meta-analysis of high-quality studies High-quality diagnostic cohort study†	SR/meta-analysis of RCTs with consistent findings High-quality individual RCT‡ All-or-none study§	SR/meta-analysis of good-quality cohort studies Prospective cohort study with good follow-up
Level 2—limited-quality patient-oriented evidence	Unvalidated clinical decision rule SR/meta-analysis of lower-quality studies or studies with inconsistent findings Lower-quality diagnostic cohort study or diagnostic case-control study§	SR/meta-analysis of lower-quality clinical trials or of studies with inconsistent findings Lower-quality clinical trial‡ Cohort study Case-control study	SR/meta-analysis of lower-quality cohort studies or with inconsistent results Retrospective cohort study with poor follow-up Case-control study Case series
Level 3—other evidence	Consensus guidelines, extrapolations from bench research, usual practice, opinion, disease-oriented evidence (intermediate or physiologic outcomes only), or case series for studies of diagnosis, treatment, prevention, or screening		

†—High-quality diagnostic cohort study: cohort design, adequate size, adequate spectrum of patients, blinding, and a consistent, well-defined reference standard.
 ‡—High-quality RCT: allocation concealed, blinding if possible, intention-to-treat analysis, adequate statistical power, adequate follow-up (greater than 80 percent).
 §—In an all-or-none study, the treatment causes a dramatic change in outcomes, such as antibiotics for meningitis or surgery for appendicitis, which precludes study in a controlled trial.

Appraising Evidence: METHODOLOGICAL QUALITY

- Is the study you are evaluating internally valid?
 - RAMMbo
- Quantifying the quality of individual studies
 - PEDro
 - CONSORT

RAMMbo

- **R**epresentative
 - Who did the subjects represent?
- **A**llocation
 - Was the assignment to treatments randomised?
 - Were the groups similar at the trial's start?
- **M**aintenance
 - Were the groups treated equally?
 - Were outcomes ascertained & analyzed for most patients?
- **M**easurements **b**linded OR **o**bjective
 - Were patients and clinicians “blinded” to treatment?
OR
 - Were measurements objective & standardised?

PEDro Scale



- **P**hysiotherapy **E**vidence **D**atabase
 - <http://www.pedro.fhs.usyd.edu.au/>
- 10-point scale that allows quantification of the quality of a research study
 - Yes = 1 point, No = 0 point
 - Higher total score = Higher quality of study
- Designed specifically for clinical trials of treatment and prevention interventions, but may also be used for other types of human studies

PEDro Scale Item 1



1. eligibility criteria were specified.

- This criterion is satisfied if the report describes the source of subjects and a list of criteria used to determine who was eligible to participate in the study.

***Not used to compute the total Pedro score**

PEDro Scale



2. subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received).
3. allocation was concealed.
4. the groups were similar at baseline regarding the most important prognostic indicators.

PEDro Scale



5. there was blinding of all subjects.
6. there was blinding of all therapists who administered the therapy.
7. there was blinding of all assessors who measured at least one key outcome.

PEDro Scale



8. measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups.
9. all subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by "intention to treat".

PEDro Scale



10. the results of between-group statistical comparisons are reported for at least one key outcome.
11. the study provides both point measures and measures of variability for at least one key outcome.

CONSORT STATEMENT

- What is it?
 - Consolidated Standards for Reporting Trials
 - Recommendations for reporting clinical trials
- Why is it needed?
 - Inconsistency in reporting in the previous literature
- Many journals now require clinical trial submissions to comply with these guidelines

22 Items on Consort Checklist
Title/Abstract/Intro

PAPER SECTION And topic	Item	Description	Reported on Page #
TITLE & ABSTRACT	1	<u>How participants were allocated to interventions</u> (e.g., "random allocation", "randomized", or "randomly assigned").	
INTRODUCTION Background	2	<u>Scientific background and explanation of rationale.</u>	

22 Items on Consort Checklist
Methods

METHODS	Item	Description	Reported on Page #
Participants	3	<u>Eligibility criteria for participants and the settings and locations where the data were collected.</u>	
Interventions	4	<u>Precise details of the interventions intended for each group and how and when they were actually administered.</u>	
Objectives	5	<u>Specific objectives and hypotheses.</u>	
Outcomes	6	<u>Clearly defined primary and secondary outcome measures, and, when applicable, any methods used to enhance the quality of measurements</u> (e.g., multiple observations, training of assessors).	
Sample size	7	<u>How sample size was determined</u> and, when applicable, <u>explanation of any interim analyses and stopping rules.</u>	
Randomization -- Sequence generation	8	<u>Method used to generate the random allocation sequence, including details of any restrictions</u> (e.g., blocking, stratification)	
Randomization -- Allocation concealment	9	<u>Method used to implement the random allocation sequence</u> (e.g., numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned.	
Randomization -- Implementation	10	<u>Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.</u>	
Blinding (masking)	11	<u>Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment.</u> When relevant, <u>how the success of blinding was evaluated.</u>	
Statistical methods	12	<u>Statistical methods used to compare groups for primary outcome(s).</u> Methods for additional analyses, such as subgroup analyses and adjusted analyses.	

22 Items on Consort Checklist
Results

RESULTS	Item	Description	Reported on Page #
Participant flow	13	<u>Flow of participants through each stage</u> (a diagram is strongly recommended). Specifically, for each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome. <u>Describe protocol deviations from study as planned, together with reasons.</u>	
Recruitment	14	<u>Dates defining the periods of recruitment and follow-up.</u>	
Baseline data	15	<u>Baseline demographic and clinical characteristics of each group.</u>	
Numbers analyzed	16	<u>Number of participants (denominator) in each group included in each analysis and whether the analysis was by "intention-to-treat"</u> . State the results in absolute numbers when feasible (e.g., 10/20, not 50%).	
Outcomes and estimation	17	<u>For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision</u> (e.g., 95% confidence interval).	
Ancillary analyses	18	<u>Address multiplicity by reporting any other analyses performed,</u> including subgroup analyses and adjusted analyses, indicating those pre-specified and those exploratory.	
Adverse events	19	<u>All important adverse events or side effects in each intervention group.</u>	

22 Items on Consort Checklist Discussion

DISCUSSION Interpretation	20	<u>Interpretation of the results</u> , taking into account study hypotheses, sources of potential bias or imprecision and the dangers associated with multiplicity of analyses and outcomes.	
Generalizability	21	<u>Generalizability (external validity) of the trial findings</u> .	
Overall evidence	22	<u>General interpretation of the results in the context of current evidence</u> .	

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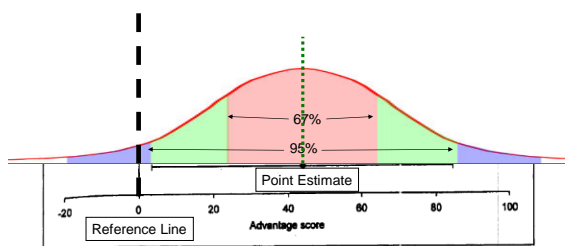
Appraising and applying research results of intervention studies

- How large is the treatment effect?
- Is the magnitude of the treatment effect clinically meaningful?
- Would the size of the treatment effect help my patients enough to change my clinical decision-making?

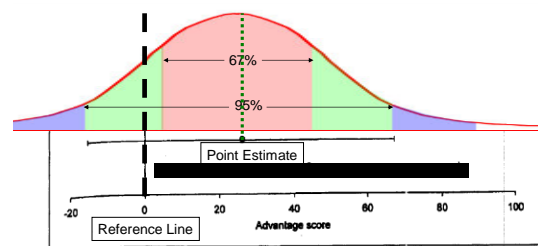
Appraising and applying research results of intervention studies

- How precise is the treatment effect?
 - How wide is the confidence interval?
 - Does it cross into zones of uncertainty or irrelevance?

Interpreting width of CI in relation to zero



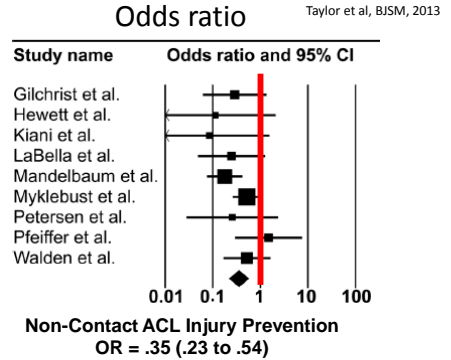
Interpreting width of CI in relation to zero



Appraising and applying research results of intervention studies

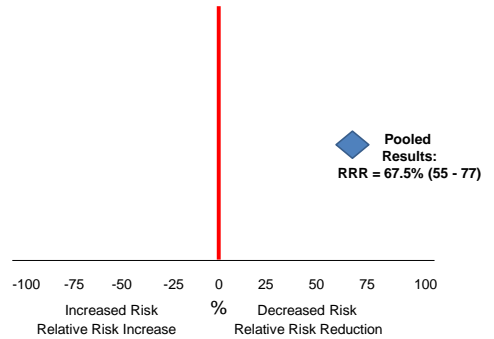
- Measures of treatment effect:
 - Unit of measure (days to RTP, °ROM,...)
 - Effect size (Cohen's *d*, Hedges *g*, ...)
 - Unitless measure of effect
 - Dichotomous outcomes
 - Odds ratio
 - Numbers needed to treat

INJURY PREVENTION RESULTS:

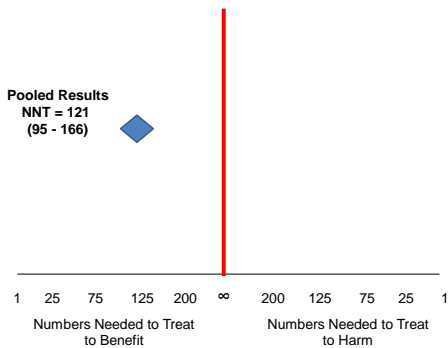


Article	Study Design	PEdno Score	Population	ACL Injuries	Number of Female Athletes	ACL Injury Risk
Hewett et al. 1999	Non-RCT; cohort	4	High School Basketball & Soccer	Control = 5 Intervention = 0	Control = 92 Intervention = 181	Control = 0.13 Intervention = 0
Soderman et al 2000	RCT	4	Adolescents & Young Adult Soccer Players	Control = 4 Intervention = 1	Control = 78 Intervention = 62	Control = 0.051 Intervention = 0.036
Heidt et al 2000	RCT	4	High School Soccer players	Control = 8 Intervention = 1	Control = 258 Intervention = 42	Control = 0.031 Intervention = 0.024
Myklebust et al. 2003	Non-RCT; crossover	4	Elite Norwegian Handball Players	Control = 18 Intervention = 17	Control = 942 Intervention = 1705	Control = 0.029 Intervention = 0.030
Mandelbaum et al. 2005	Non-RCT; cohort	5	Ages 14-18 Soccer Players	Intervention = 6 Control = 5	Intervention = 1985 Control = 142	Intervention = 0.003 Control = 0.035
Petersen et al. 2005	Non-RCT; cohort	4	Elite German Handball Players	Intervention = 0 Control = 5	Intervention = 134 Control = 778	Intervention = 0 Control = 0.064
Olsen et al. 2005	RCT	7	Ages 15-17 Soccer Players	Intervention = 1 Control = 3	Intervention = 808 Control = 862	Intervention = 0.001 Control = 0.003
Pfeiffer et al. 2006	Non-RCT; cohort	5	HS Soccer, Volleyball, & Basketball Players	Intervention = 3 Control = 10	Intervention = 577 Control = 852	Intervention = 0.005 Control = 0.011
Gilchrist et al 2008	RCT	4	Collegiate Soccer Players	Intervention = 2 Control = 4	Intervention = 583 Control = 947	Intervention = 0.003 Control = 0.005
Steffen et al 2008	RCT	8	High School Soccer players	Intervention = 5 Control = 4	Intervention = 1073 Control = 729	Intervention = 0.004 Control = 0.007
Kiani et al 2010	Non-RCT Cohort	4	High School Soccer & basketball players	Intervention = 2 Control = 0	Intervention = 737 Control = 755	Intervention = 0 Control = 0.008
LaBella et al 2011	RCT	5	High School Soccer & basketball players	Control = 6 Intervention = 2	Control = 755 Intervention = 2479	Control = 0.003 Intervention = 0.007
Walden et al 2012	RCT	7	Adolescent soccer players	Control = 14 Intervention = 7	Control = 2085 Intervention = 1268	Control = 0.007 Intervention = 0.003
Total				Intervention=44 Control=11043		Intervention = 0.004

ACL Prevention Programs: RRR



ACL Prevention Programs: NNT



Main Findings: ACL Prevention Programs

Relative Risk Reduction

A program of neuromuscular training incorporating plyometrics & balance exercises decreases the incidence of ACL injuries in female athletes by 67.5% (95% CI: 55-77%)

Numbers Needed to Treat

In order to prevent one ACL injury, 121 (95% CI: 95-166) female athletes would need to participate in a neuromuscular training program over the course of one season

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 - **Diagnosis**
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Identifying Effective Diagnostic Tests: Likelihood ratios and ROC curves

How is effectiveness of diagnostic tests measured?

- **How can good diagnostic procedures (or clusters of tests) be differentiated from poor ones.**
- **Sensitivity, specificity, and likelihood ratios**

		Gold Standard Result	
		Condition Present	Condition Absent
Clinical Examination Procedure Result	Positive	<i>Cell A</i> True positive	<i>Cell B</i> False positive
	Negative	<i>Cell C</i> False negative	<i>Cell D</i> True negative

Sensitivity

- **Sensitivity- the number of injuries (or illness) that are diagnosed by a test divided by the true number of injuries based upon gold standard**

$$\frac{\text{\# of injuries dx}}{\text{\# of true injuries}} = \frac{A}{A+C}$$

Specificity

- **Specificity number of negative exams based upon a test divided by number of negative cases based on gold standard.**

$$\frac{\text{\# dx without the injury}}{\text{\# true negatives}} = \frac{D}{B + D}$$

Interpretation

- Values for Sp and Sn range from 0.0-1.00 with higher values representing better tests

SpPIn – few false positives so a positive test is conclusive

		Gold Standard Result	
		Condition Present	Condition Absent
Clinical Examination Procedure Result	Positive	Cell A True positive	Cell B False positive
	Negative	Cell C False negative	Cell D True negative

SpPIn and SnNOOut

- Sacket et al - Tests with high **specificity** are good at ruling **in** a condition, those with high **sensitivity** good at ruling **out** a condition
- Counterintuitive? Remember where the false negative and false positives lie!

SnNOOut – few false negatives so a negative test is conclusive

		Gold Standard Result	
		Condition Present	Condition Absent
Clinical Examination Procedure Result	Positive	Cell A True positive	Cell B False positive
	Negative	Cell C False negative	Cell D True negative

Interpretation

- Sp and Sn are useful but ...
- Tests may have high Sp and low Sn or vice versa
- Difficult to apply directly in clinical practice

Likelihood Ratios

- A logical extension of Sn and Sp
- A positive likelihood (+LR) ratio is indicative of the impact of a positive examination finding on the probability that the condition in question exists.
- **+ LR= Sensitivity / (1 – Specificity)**

Likelihood Ratios

- A negative likelihood ratio addresses the impact of a negative examination on the probability that the condition in question is present.
- **- LR = (1 – Sensitivity) / Specificity**

Interpretation

- (+ LR > 10 or –LR < .1) – large, often conclusive shift in probability a condition is present
- (+LR of 5-10 or – LR 0.1-0.2) – moderate, but usually important shifts in probability a condition is present

Interpretation

- (+LR of 2-5 or –LR 0.2-0.5) – small, sometimes important shifts in probability a condition is present,
- (+LR of 1-2 or –LR 0.5-1) – very small, usually unimportant shifts in probability a condition is present.

Connecting the Dots in Evaluation

- Pre-test probability? (remember your interview and review of the medical record)
- Shifts in probability with testing results?
- Certainty is fleeting – and uncertainty uncomfortable!
- **Key points**
 - Before you begin a physical exam what you think is wrong? The probability of 1 or more differential diagnoses must be weighed
 - Remember: **Diagnostics is an uncertain business**

Application of LRs

- Consider a 38 year old teacher and avid tennis player who presents complaining of intermittent medial knee pain of insidious onset, with occasional catching and giving way (primarily while playing tennis) and intermittent swelling. History of 1 prior knee injury (believes an MCL sprain) in high school that prevented participation in football for 3 weeks) **What do you think is wrong?**

Application of LRs

- **Pre-test probability - e.g. 80%**
- **Pre-test odds - probability / (1-probability) .8/(1-.8) = 4**
- **Pre-test odds x LR = post-test odds**
- **If LR = 3 then post-test odds would be 12:1**
- **Convert post-test odds to probability by post-test odds / post-test odds + 1 (92%)**

Certainty

- What level of certainty is sufficient to recommend a course of treatment?
- How serious is the condition? What are the consequences of being wrong? Greater certainty is warranted as the stakes rise!

Notes on methodological issues in studies of diagnostic tests.

- How “gold” is the standard
- Are investigators blinded to the results of other testing
- What is the patient sample (selection bias)
- Do all subjects receive the same work-up (work-up bias)

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Continuous rather than dichotomous data?

- Receiver Operator Characteristic (ROC) curves provide information regarding the discriminating effects of specific values
- A very important concept with applications to risk, prevention and diagnostics

Methodological issues in studies of diagnostic tests.

- Reliability of testing
- Qualifications of those performing the diagnostic tests - Can we generalize between, for example orthopaedic surgeons and physical therapists?

Teaching Strategies

- Entry-level
- Post-professional
- Continuing education (in the workplace)

RESOURCES

- WWW.CEBM.NET
- WWW.NNT.COM

CONCLUSIONS

- Keep patient care decisions at the center of evidence-based practice
- Have strategies to make the evidence find you
- Not all evidence is equal
- **Confidence (intervals)** to appraise the clinical applicability of research results



THANK YOU



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