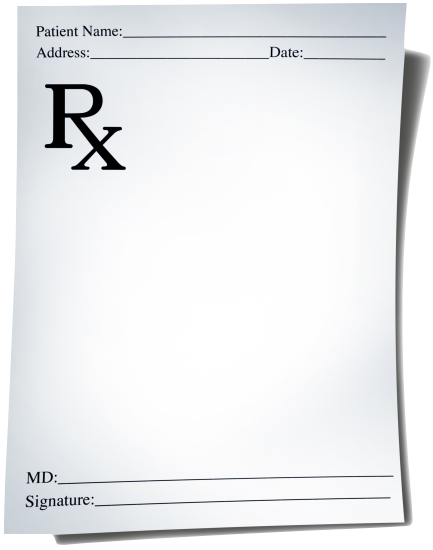
Evidence-Based Practice Intro

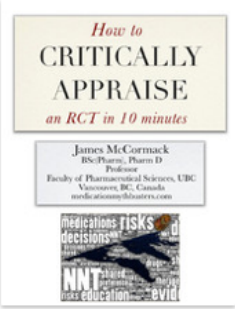


Outline

Evidence Based Practice (EBP)

- EBP overview and process
- Formulating clinical questions (PICO)
- Trial design
- Critical appraisal
  - Assessing the validity of trial design
- Interpreting results
  - p values and confidence intervals
  - Statistical vs clinical significance
  - Magnitude of effect (ARR, RRR, NNT)

How to Critically Appraise an RCT in 10 minutes - free iBook



Free Book

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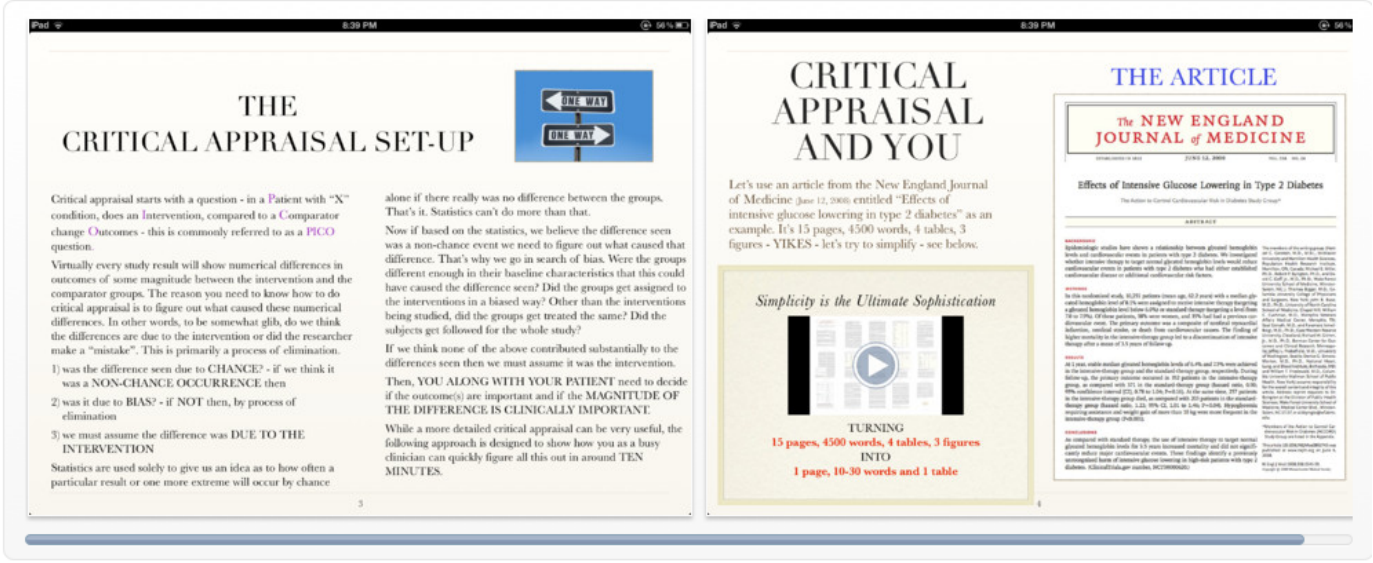
Category: Medical
Published:Jul 04, 2012
Publisher: James McCormack
Seller: Therapeutics Education Collaboration
Print Length: 17 Pages
Size: 79.1 MB
Language: English

Requirements: This book can only be viewed using iBooks 2 or later on an iPad with iOS 5 or later.

How to Critically Appraise an RCT In 10 Minutes

Description

If the thought of reviewing a clinical study seems like an insurmountable task, this book was developed to show you how to critically evaluate a randomized controlled trial in around 10 minutes.



FREE http://wiki.ubc.ca/Critical_Appraisal_Tutorial

What is Evidence-Based Practice?

"The integration of best research evidence with clinical expertise and patient values"

Sackett et al 2000

When these three elements are integrated, clinicians and patients form a diagnostic and therapeutic alliance with optimized clinical outcomes and quality of life

The Process

Clinical Scenario

Clinical Question (PICO)

Search

Critical Appraisal

Integrate & Apply

Clinical Questions (PICO)

Patient
- Description of the most important characteristics of the patient or target disorder

Intervention
- What do you want to do for the patient?
- Could include exposure, diagnostic test, prognostic factor, surgery, therapy or patient's perception

Comparator (s)
- Relevant alternative(s) most often considered for this type of patient

Outcome
- Clinical outcome of interest to you and your patient

PICO

A 45 yo female with 3 year history of elevated blood pressure/cholesterol has come to your office. Her family physician gave her ramipril 5mg BID and she says her BP is 145/95mmHg and her total cholesterol is 7.1 mmol/L and she is taking niacin. What should she do?

Patient

Intervention

Comparison

Outcome

Clinical Questions (PICO)

Patient

45 yo female – 3 year history of elevated blood pressure/cholesterol – ramipril 5mg BID, BP is 145/95mmHg, total cholesterol is 7.1 mmol/L – taking niacin

Intervention

Increase ramipril, add new agent (ARB, statin)

Comparator(s)

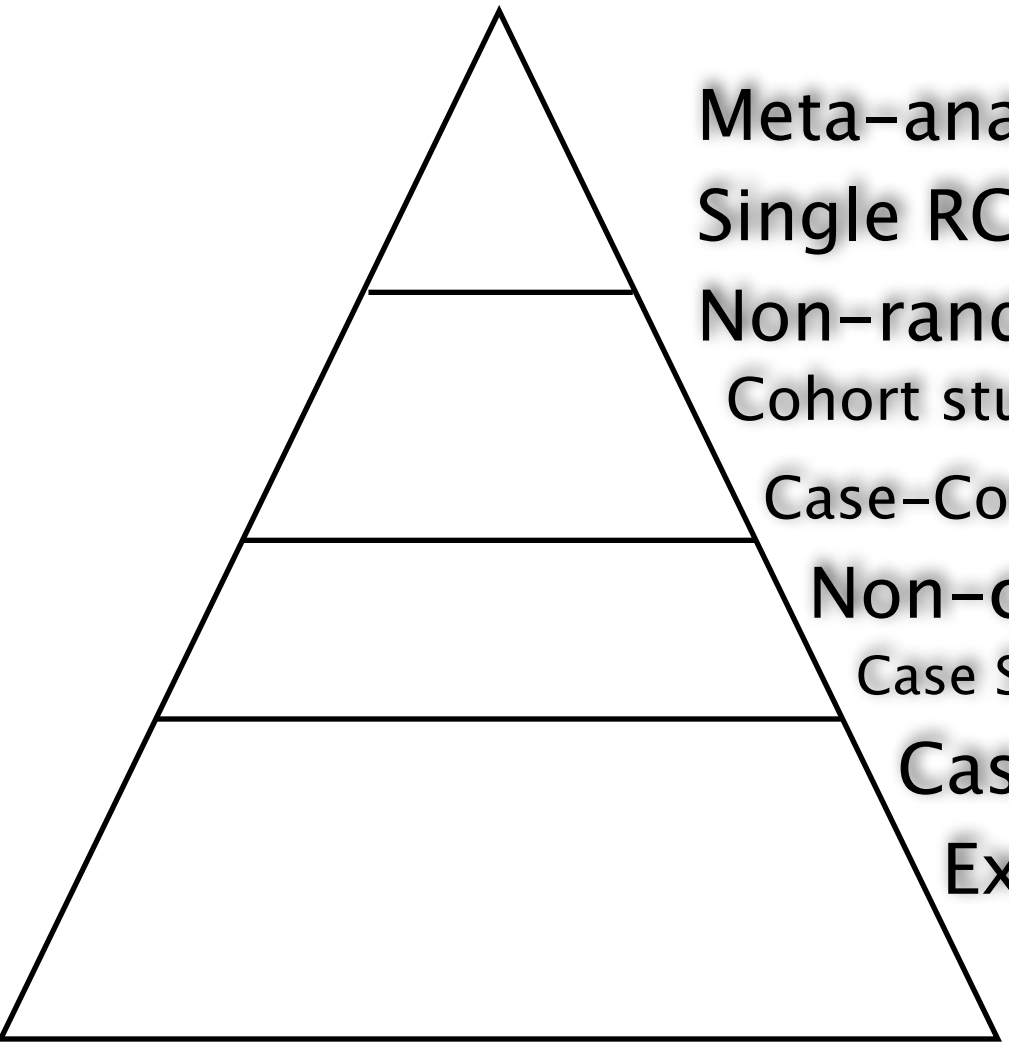
Placebo/other treatment option (HBP/cholesterol)

Outcome

HEART ATTACKS, STROKES, MORTALITY

BP, cholesterol

The Hierarchy of Evidence for Therapy Studies



Meta-analysis of RCTs

Single RCTs

Non-randomized comparative studies

Cohort studies

Case-Control studies

Non-comparative studies

Case Series (open trial)

Case reports

Expert opinion

Efficiently Appraising 'Usable Evidence'

Right patient population (external validity)

Study design (right for the question?)

Internal validity

Results

- are they meaningful and useful?
- outcome measure?
- can they be applied to my CQ?

Top 5 trial design features of prospective controlled trials

1. Randomized
2. Double blind
3. Allocation concealment
4. > 80 % of patients at study completion
5. Important, valid clinical outcomes selected

p-value

The probability of the data, or more extreme data, occurring in the long run when there is NO treatment effect; i.e. how often this result or one more extreme will occur by chance alone

p-value

The p-value tells us if the difference was due to chance

p=0.013…what does that mean?

1.3% chance the difference was due to just chance (T or F)

98.7 % chance the difference was due to the intervention (T or F)

What can account for the difference?

1. A true difference
2. Bias
3. Confounding factors
4. Random error (chance)
5. All of the above

p-value

The p-value does NOT tell us …

If the difference is valid

If the difference is clinically meaningful

If the difference is real

If the drug works

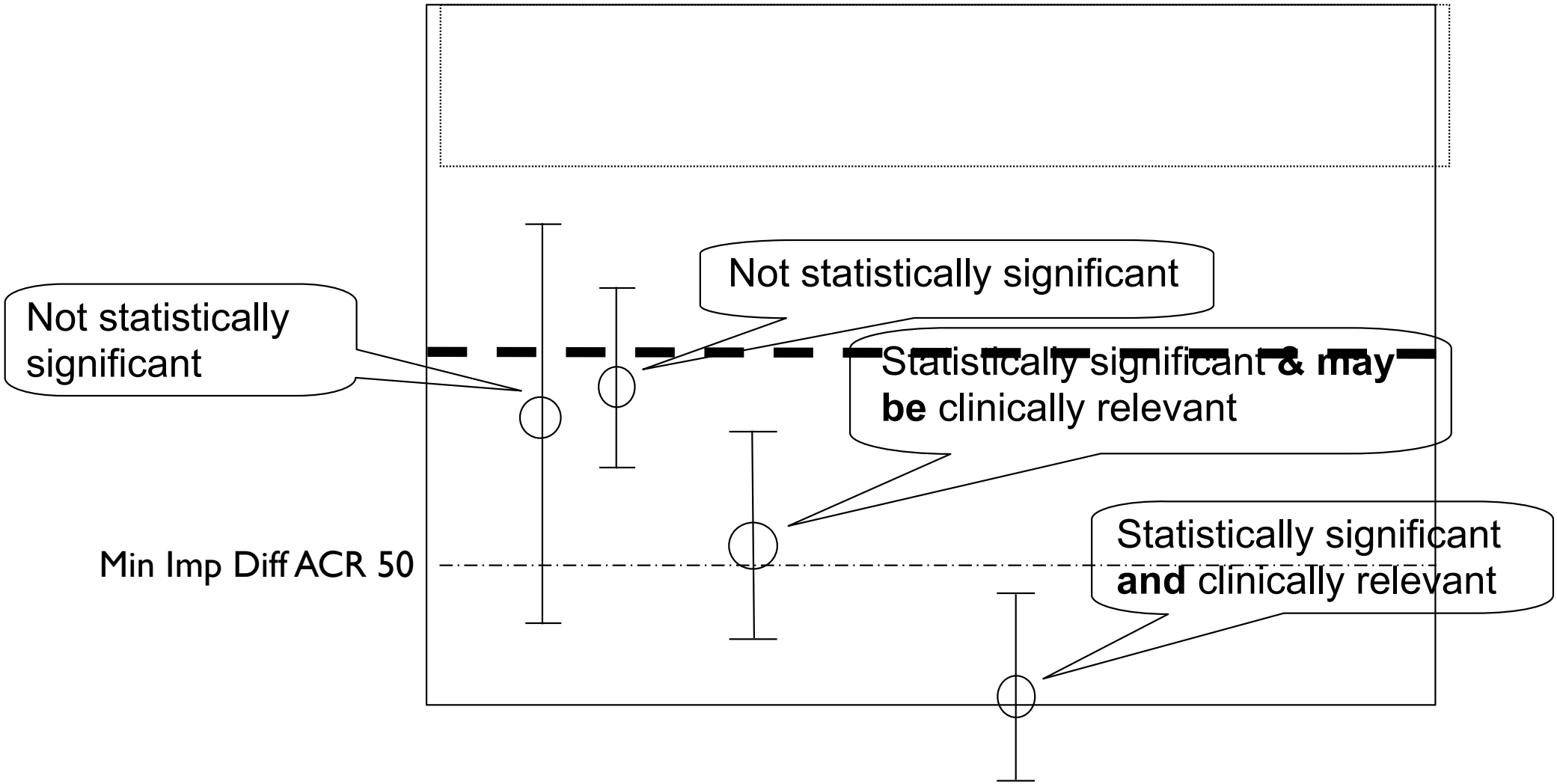
Etc.

What is a Confidence Interval?

- Quantifies the uncertainty in measurement
  - A measure of the precession of the “effect estimate” from the study
- Usually reported as 95% CI
  - In a very large number of repetitions of the study, 95% of all CIs obtained will contain the “true” value of the treatment effect in the population studied (assuming random sampling)

Statistical vs. Clinical Significance:

ACR 50 - marker of disease control in RA

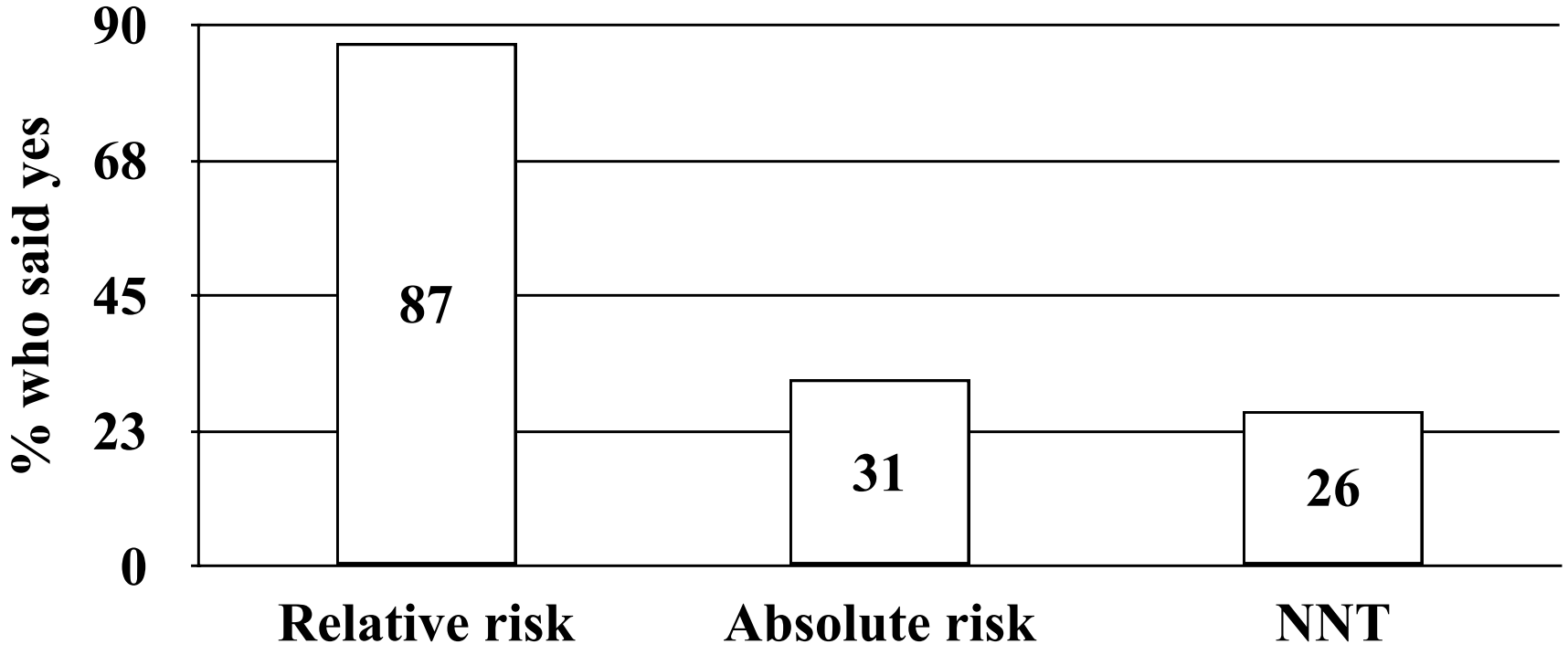


Imagine that you just found out you have a risk factor for cardiovascular disease (e.g., high blood pressure or high cholesterol).
A drug that will treat this risk factor is available and it has no side effects and its cost is covered by a plan.
Consider the following three scenarios. Would you be willing to take this drug every day for the next five years if it had been shown in a clinical trial that:

1) patients treated with this cholesterol pill had been shown to have 33% fewer heart attacks than the non-treated patients; or if
2) it was found that 2% of the patients who took this cholesterol pill had a heart attack, compared to 3% who did not take this pill – a difference of 1%; or if
3) in 100 patients who took this cholesterol pill for five years the medicine would prevent one of the 100 from having a heart attack. There is no way of knowing in advance which person that might be?

Primary Prevention Statins & Mortality

Study	Risk Estimate	Authors Conclusion
BMJ 2009;338:b2376	0.88 (0.81-0.96)	Decreases mortality
Arch Intern Med 2010;170:1024-1031	0.91 (0.83-1.01)	∅
Arch Intern Med 2005;165:725-730	0.86 (0.76 -0.99)	Decreases mortality
Arch Intern Med 2006;166:2307-2313	0.92 (0.84-1.01)	∅
J Am Coll Cardiol 2008;52:1769-81	0.93 (0.87-0.99)	Decreases mortality



RRR = 33% fewer heart attacks
ARR = 2% of patients on this drug had a heart attack compared to 3% on placebo – a difference of 1%
NNT = Drug would prevent 1 of 100 from having a heart attack

Relative reduction

A 33% Reduction Can Mean "Events" Were Reduced From:

BASELINE	CHANGED TO	ABSOLUTE REDUCTION	NNT
3/million	2/million	1/million	1,000,000
0.3 %	0.2 %	0.1%	1000
3 %	2 %	1%	100
6 %	4 %	2%	50
30 %	20 %	10%	10
100 %	67 %	33%	3

A 33% Reduction Can Mean Events Were Reduced From:

	Absolute reduction	NNT
3/million to 2/million	1/million	1,000,000
0.3 % to 0.2 %	0.1%	1000
3 % to 2 %	1%	100
6 % to 4 %	2%	50
30 % to 20 %	10%	10
100 % to 67 %	33%	3

Benefits Must Always Be Expressed Over a Period of Time

NNT (prevent a fatal heart attack) = 300

Chew an aspirin at onset of chest pain – YES

NNT (prevent a fatal heart attack/stroke/cancer) = 1

Chew some poison hemlock now – NO

NNT (prevent a heart attack/stroke) = 50

Take a drug for 5–10 years – side effects and cost – ????

Statin results in patients (45-60) without cardiac disease – 5-7 years treatment

	CHD deaths (%)	All deaths (%)	Coronary events (%)
Placebo	1.4	4.1	5
Statins	0.9	3.7	3.3
Relative risk reduction	35	NSS	35
Absolute risk reduction	0.5		1.7
Number needed to treat	200		59

(ACAPS,WOSCOPS,AFCAPS/TexCAPS) BMJ 2000;321:983-6

Summary Slide

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