

# Newsletter of the International Society for Evidence-Based Health Care

## Newsletter 11, April 2013

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### Mission

*The mission of the International Society for Evidence-Based Health Care is to develop and encourage research in evidence-based health care and to promote and provide professional and public education in the field.*

### Vision

The society is inspired by a vision to be a world-wide platform for interaction and collaboration among practitioners, teachers, researchers and the public to promote EBHC. The intent is to provide support to frontline clinicians making day-to-day decisions, and to those who have to develop curricula and teach EBHC.

### Key objectives of the Society

- To develop and promote professional and public education regarding EBHC
- To develop, promote, and coordinate international programs through national/international collaboration
- To develop educational materials for facilitating workshops to promote EBHC
- To assist with and encourage EBHC-related programs when requested by an individual national/regional organization
- To advise and guide on fundraising skills in order that national foundations and societies are enabled to finance a greater level and range of activities
- To participate in, and promote programs for national, regional and international workshops regarding EBHC
- To foster the development of an international communications system for individuals and organizations working in EBHC-related areas
- To improve the evidence systems within which health care workers practice.



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## Teaching tips: Critical appraisal of meta-narrative systematic reviews using insights from the Users' Guides to the Medical Literature Guide and GRADE

Abd Moain Abu Dabrh, Noor Asi, Tarig Elraiayah and M. Hassan Murad

There is currently general consensus (we hope) that clinical decision making should incorporate high-quality systematic reviews when available. In recognition of this, evidence based medicine (EBM) learners are interested in gaining knowledge and skills on how to read, interpret and critically appraise systematic reviews. When quantitative analysis is conducted as part of a systematic review and a pooled effect size is provided (i.e., meta-analysis), interpretation of findings is more focused and perhaps easier. EBM learners can evaluate their confidence in the estimate of treatment effect; discuss issues of consistency, precision and applicability of the findings. However; it is not uncommon to encounter meta-narrative synthesis of evidence, a meta-narrative systematic review (MNSR). What should we teach EBM learners about appraising this kind of reviews?

As a first step, it is important to provide learners with a definition of MNSR and when this type of synthesis is used. MNSR is defined by Greenhalgh as *“a systematic, theory-driven interpretive technique developed to help make sense of heterogeneous evidence about complex interventions applied in diverse contexts in a way that informs policy”*.<sup>1</sup> MNSRs are conducted following 6 basic phases: planning (defining the question at hand and a priori criteria for study selection), search (comprehensive systematic review), mapping (identify the conceptual key elements of the research paradigm such as constructs, definitions, confounders, etc.) , appraisal (analogous to quality assessment of the included studies), synthesis (describe associations, subgroup effects, etc.) and lastly, making final conclusions. <sup>1</sup> After discussing the definition, we

usually ask learners to think about situations in which someone who is conducting a systematic review may resort to synthesis of data in this manner. It is likely that learners will come up with two main reasons: 1) heterogeneous data (in terms of population, intervention, comparison, outcome and study design) to the extent that providing a pooled effect is inappropriate; and 2) complex evidence, such as the outcome is a construct with multiple domains or that the analytic framework of the review includes multiple questions derived from multiple types of studies. It is also important here to ask learners to differentiate MNSR's from a traditional review articles (narrative or non-systematic review articles).

Various approaches have been suggested to appraise traditional review articles; however, none of these approaches became popular because these articles are very heterogeneous in nature and their methods and potential biases are never explicit. In the case of MNSRs; however, the situation is different since such studies follow an explicit protocol and standards of reporting exist.<sup>2,3</sup> While there are no established frameworks for appraisal, one can use the framework of critical appraisal provided in the Users' Guides to the Medical Literature (how valid are the results? What are the results? how do these results apply to my patient?). One can also take this process one step further and attempt to rate the confidence in the results using the GRADE framework realizing the limitation of MNSR in that they do not always provide a pooled estimate of effect. Therefore, learners can look for clues for inconsistency across studies, the overall risk of bias and indirectness. Although they may not be able to give a discrete category of confidence (e.g., moderate), they will be able to express whether the results are sufficiently believable or not. The rating exercise itself is a valuable learning opportunity. In BOX, we provide a sample case and an example of brief appraisal of a relevant MNSR.

### Scenario and clinical question

A 19 year old female presents with a concern about cervical cancer screening. From existing guidelines and systematic reviews, we know that there is mortality benefit. However, this benefit is derived from studies in older women. Therefore, we searched for evidence about epidemiologic and contextual data and risk factors of cervical cancer in younger women to help in decision making. We found a meta-narrative systematic review<sup>4</sup>

### Are the results valid?

*-Did the Review Explicitly Address a Sensible Clinical Question?*

Yes, in the absence of definite benefit in this age group, epidemiologic and contextual data will be helpful.

*-was the search exhaustive and study selection and assessments reproducible?*

The systematic review was comprehensive, searched multiple databases without language restrictions with multiple synonyms and search terms that appeared adequate. Article selection, quality appraisal, and data abstraction was done in duplicate.

*-Were the Primary Studies of High Methodological Quality?*

Most of the studies were observational and had variable risk of bias; however, the reviewer selected the best available evidence to inform each question

### What are the results?

-Infection with high-risk human papillomavirus (HPV) types is a necessary, although not sufficient, cause of almost all cases of cervical cancer

-High-risk HPV infection regress with age (prevalence drops from 35% (age 14 to 19) to 6% (50- 65 years). Infection with HPV is very likely to regress among women with both normal and abnormal cytology results

- The age-adjusted incidence rate of cervical cancer among women younger than 20 years is extremely rare (0.05 case per 100 000)

-National screening programs have not reduced the incidence of cervical cancer diagnosed before age 30

- The risk factors identified for cervical cancer were: the number of lifetime sexual partners, co-infection with other sexually transmitted infections, HIV infection, history of smoking, younger age at first

intercourse and at first pregnancy, high parity, and long-term use of oral contraceptives

-Harms of screening are high false positive rate (particularly in younger women), pain and bleeding from biopsies and possible increased risk for preterm delivery (after cold-knife conization)

### Confidence in findings

Incidence estimates, effect of national screening programs and association estimates of risk factors were derived mostly from observational studies. Hence, the confidence is low to moderate. Eligible studies were properly adjusted for potential confounders. There was no imprecision (very large studies). There was no indirectness as the population was quite representative of our patient characteristics

### How can I apply the results to patient care?

-Considering that the patient has none of the risk factors identified in this review, we discussed with her the very low likelihood of benefit from cervical cancer screening in her age group and the fact that HPV infection frequently regresses with time. Harms of screening were also discussed, and the patient opted for no screening at this point

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3. Tong A, Flemming K, McInnes E, Oliver S, Craig J. Enhancing transparency in reporting the synthesis of qualitative research: ENTREQ. *BMC Medical Research Methodology* 2012, 12:181
4. Vesco KK, Whitlock EP, Eder M, Burda BU, Senger CA, Lutz K. Risk factors and other epidemiologic considerations for cervical cancer screening: a narrative review for the U.S. Preventive Services Task Force. *Ann Intern Med.* 2011 15;155(10):698-705

## Teaching tip: analogy of subgroup analysis and rain-dance rituals

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Rain-dancing is an ethnographic term for rituals intended to invoke rain. This ritual has been performed for centuries by Native Americans, Slavic, Romanian, and others all around the world. Many people attest to its validity. The ritual consists of performing a dance to call the rain during drought season. The dance often works! The most logical reason for its success is that firm believers dance every day until it rained and would not stop before the rain.

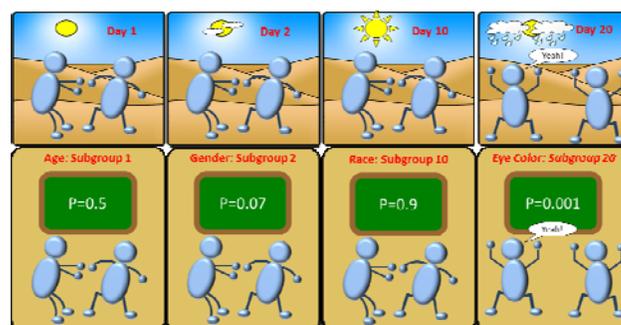
As Evidence Based Medicine (EBM) teachers and practitioners, this dance reminded us of several important topics that we frequently encounter while communicating certain concepts to learners. We believe the analogy with rain dance is quite helpful as a teaching concept.

EBM learners and practitioners often struggle with subgroups analyses reported in systematic reviews and in randomized controlled trials (RCTs). We know that most of these interactions are spurious and would fail to meet many of the 11-criteria for a believable subgroup analysis<sup>1</sup>. Yet, subgroup analyses are often quite compelling to readers because of the desire to provide individualized care to patients with characteristics consistent with the subgroup variable. A formal study has found that 44% of RCTs report subgroups analyses with a median of 6 per outcome<sup>2</sup> and a range of 1 to the exorbitant number of 144. Reporting of subgroup analyses is more common among RCTs sponsored by industry in which the primary outcome is non-significant<sup>3</sup>. Systematic reviewers may overuse subgroups analysis as well. For example, a systematic review<sup>4</sup> evaluating the benefits and harms of Vitamin D (Vit D) for reducing mortality in adults performed different subgroup analyses on this outcome and they made a strong claim for their validity. For instance, regarding a mortality benefit by using Vit D3 and the lack of such benefit when using Vit D2 claimed by the authors failed to meet some important criteria. The authors did not perform an interaction test between Vit D3 and Vit D2 estimates and they did not pre-specified the

direction of the subgroup effect. Also they perform 18 other subgroup analysis increasing the likelihood to discover interactions only by chance.

We are proposing an analogy (figure 1) between rain-dancing rituals and overuse of subgroup analysis in RCTs and systematic reviews. We believe this example highlights the importance of conducting a limited number of subgroup analyses that are specified a priori. This analogy can also be used to explain another unfortunate and prevalent practice which is data mining and fishing for significance in observational datasets. It is very common for these studies to fail to report how many analyses were actually done and how many hypothesis were tested; and only present significant findings<sup>5</sup>. Type 1 error in repeated testing and multiple comparisons may become intuitive to EBM learners when they are introduced to the analogy of dancing for the rain.

Figure 1.



### References:

1. Sun X, Briel M, Walter SD, Guyatt GH. Is a subgroup effect believable? Updating criteria to evaluate the credibility of subgroup analyses. *BMJ* 2010;340:c117.
2. Sun X, Briel M, Busse JW, et al. The influence of study characteristics on reporting of subgroup analyses in randomised controlled trials: systematic review. *BMJ* 2011;342:d1569.
3. Sun X, Briel M, Busse JW, et al. Credibility of claims of subgroup effects in randomised controlled trials: systematic review. *BMJ* 2012;344:e1553.
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## Time to highlight reflection in action as a key component of reflective practice

**Victoria Hodgetts, Sadia Malick,**

Reflective practice involves self-awareness, self-criticism and self-assessment as well as a desire for continuing professional development.

Shon<sup>1</sup> describes two types of reflection

- 'reflection-in-action' where the competent practitioner uses knowledge, experience and judgment to guide decisions in real life clinical situations as they are happening.
- 'reflection-on-action' which happens after the experience, enables learning about clinical practice and promotes development of such practice.

Retrospective reflection (reflective on action) is now a key component of trainee education across all specialties in the UK. This reflection requires the identification of a prescribed number of cases and consideration of actions and review of best practice.

In the UK the Royal College of Obstetricians and Gynaecologists recently underwent a major change in its curriculum for trainees; specifically, reflection and reflective practice was brought to the forefront in teaching and learning. The College implemented this change in recognition that learning to reflect and learn from difficult clinical situations in which the trainees have been directly involved is a crucial part of being a good doctor. Most importantly it was acknowledged that an adverse clinical situation is a significant event and either merely discussing it with colleagues or, worse, ignoring it, will lead to a high probability that it will happen again.

Formal evaluation of reflection by colleagues creates an opportunity for

- Self awareness.
- Analysis and evaluation of the experience and the assumptions underlying it.
- Integration of a range of experiences.
- Identification of learning needs and addressing them
- Critically appraising practice and planning for the future

Greenwood<sup>2</sup> describes reflection in action as the ability "to think about what one is doing whilst one is doing it; it is typically stimulated by surprise, by something which puzzled the practitioner concerned". This ability often defines good clinicians as they have the ability to think and do at the same time.

In the context of healthcare there must be a culture of 'reflection in action' during everyday routine clinical work to produce competent clinicians of the future. An integral culture of openness in clinical decisions and a relationship between trainer and trainee to review each part of the clinical ward round, clinical consultation and surgical procedure as it occurs. This approach will help to shine a critical light on historical practice patterns. Reflection in action implemented as described will ultimately provide a vehicle for the incorporation of EBM into practice.

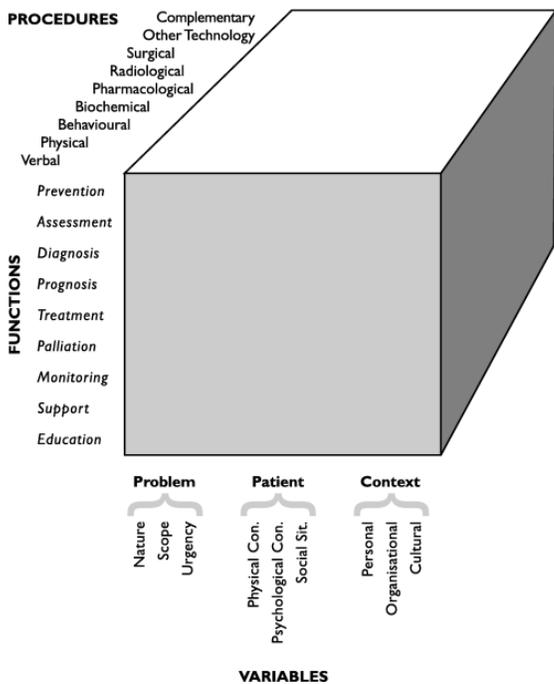
An important question is: How should we be developing trainee's reflection in action? Squires<sup>3</sup> suggested a framework for learning medicine. This framework centers around a three dimensional model and according to Squires provides a "scaffolding" to allow practitioners to reflect.

Dimensions 1 – "What do doctors do?"<sup>3</sup> Functions of a doctor.

Dimension 2 – "What affects what a doctor does?"<sup>3</sup> Variables.

Dimension 3 – "How do they do it?"<sup>3</sup> Procedures.

Understanding this three dimensional model allows a clarity of thinking when performing the duties of doctor and gives a framework that develops reflection in action and reflection on action by allowing doctors to understand what they do.



**Figure 1** Squires three dimensional model. Figure taken from Squires G Modeling Medicine. Med Educ. 2002 Nov 36(11):1077-82

**References:**

- Schön, D. (1983) *The Reflective Practitioner. How professionals think in action*, London: Temple Smith.
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**Complexity offers opportunities for innovation in teaching and transfer of information**

**Osama Altayar, Noor Asi, M. Hassan Murad**

Network meta-analysis (NMA) allows for the simultaneous comparison of multiple therapies using direct evidence (head-to-head studies) and indirect evidence (evidence extrapolated from comparison with a common comparator). NMA is complex by nature and more difficult for evidence-

based medicine (EBM) teachers to explain to learners compared to usual pairwise comparisons derived from 2x2 tables. The assumptions of NMA, particularly the Bayesian ones, are often implicit and critical appraisal is challenging. Furthermore, depicting the result of NMA in a figure is problematic. Compared to traditional forest plots, which are very helpful for graphically representing each trial's contribution to a pooled effect estimate, in NMA there are multiple domains of information to be conveyed to readers (the interventions, comparisons, effect size, network consistency or coherence, quality of evidence, etc.).

Therefore, innovations are needed to 1) improve the transfer of information to evidence users through figures and visual aids, and 2) facilitate evidence appraisal in a journal club or other educational settings. We provide a figure that describes several domains or categories of information, that we believe provides a helpful framework for addressing the aforementioned issues.

The figure compares interventions used to prevent symptomatic venous thromboembolism<sup>1</sup> in hospitalized medical patients:

- The figure focuses on the most important outcome that drives decision making in terms of benefit (symptomatic venous thromboembolism derived from randomized trials) conveyed using relative effects (odds ratio). Odds ratios are followed by a verbal qualifier to imply directionality (a problem in current network meta-analysis graphs).
- Each intervention is represented by a cylinder. The area of the circular surface is proportionate to the sample size.
- The tradeoff or most important burden of treatment is depicted as the depth of the cylinder (trying to convey a negative tradeoff with the figure sinking away from reader). In this case it is the bleeding rate. The treatment burden is presented here as an absolute rate associated with each intervention. The burden of treatment may be more appropriately derived from large observational studies (not included in the network of trials), from economic analysis if it was cost outcome, from qualitative studies if it was burden of administration, etc. Therefore, measures of

types other than a ratio of risks and odds can be presented as a second dimension (depth).

4. Direct comparisons are represented by the connecting lines. The width of the lines reflects the number of direct comparison studies. Dotted lines represent indirect comparisons.
5. The color of connecting lines reflects the quality of evidence (i.e., confidence in the estimates: green is high, yellow is moderate, red is low and black is very low).
6. When the direct and indirect comparisons are different in terms of quality of evidence (confidence level) or magnitude (inconsistent network), then both are displayed. Otherwise, they were combined.

In a journal club, discussants often avoid NMA's because of their complexity and the inability of the facilitator to explain the barrage of information in such articles. However, if information is conveyed using intuitive graphic means, a journal club can focus on the important components presented in the attached figure and deemphasize other information and jargon.

Examples of educational opportunities from this figure:

**For beginners (EBM newbies), discuss:**

- What are the different relative effect measures, how they are calculated, how do we determine their direction, and when is it appropriate to use each of them?
- Why do we need indirect comparisons in the first place? Discuss industry sponsored trials and why we don't have too many head-to-head trials
- Why is evidence graded, what is GRADE, what is confidence in estimates?

**For advanced users (EBM veterans), discuss:**

- Imprecision and how it relates to the confidence in the estimates (LMWH vs. UFH bid)
- Explain how direct and indirect evidence can give disparate results (UFH tid vs. placebo), have varying levels of confidence in the estimates (UFH tid vs. LMWH), or consistent effect and confidence (LMWH vs. placebo)
- The tradeoffs of benefits and harms in this specific scenario

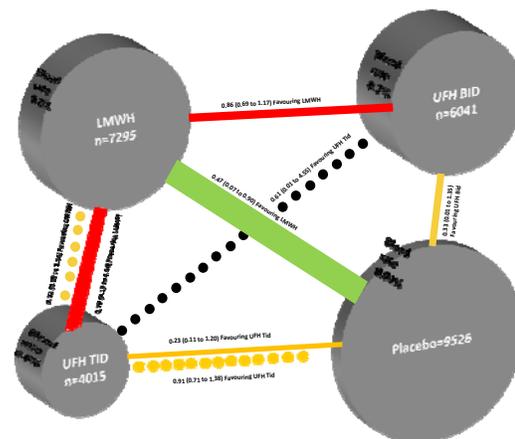
Many other examples of educational opportunities can be derived from reviewing this figure with learners. Such discussion will shift their focus from

the complicated statistics to core concepts (confidence in estimates, consistency, etc.) that are more proximal and relevant to learners and those interested in applying EBM in practice.

With the explosion of information and increasing complexity of decision making, future innovations in communicating multifaceted information will likely involve animation, sound and other effects beyond what print media currently offers.

**Legend:**

\*Adapted from Phung et al, fictitious data added for demonstration purposes, the outcome of most importance represented in this graph is symptomatic venous thromboembolism.



**References:**

1. Phung OJ, Kahn SR, Cook DJ, Murad MH. Dosing frequency of unfractionated heparin thromboprophylaxis: a meta-analysis. Chest. 2011 Aug;140(2):374-81

**Merits and demerits of risk difference (RD), risk ratio (RR) and odds ratio (OR) as measures of treatment effects**

**Kameshwar Prasad**

To communicate the effects of treatment, ideal effect measures should –

1. be easy to understand

2. be meaningfully applicable to all kinds of patients
3. convey the same idea whether you measure unfavourable (e.g. death) or favourable (e.g. survival) outcomes

### Example

Let us say the results of a study showed that 50% of stroke patients treated in a general medical ward (herein after called 'ward') were dead or institutionalised at follow-up whereas only 25% of similar patients treated in a stroke unit suffered these outcomes. Thus, stroke unit –reduced the risk of death or institutionalisation by 25% (25%-50%).

### Odds Ratio (OR)

We often express statements such as, "odds of the England team winning the cricket match are 1:4". What does this mean? It means: if there is one chance of winning, there are four chances of losing. In other words, one in five (20%) chance of winning and four in five (80%) chance of losing. Chance is probability. Odds of 1:4 means 20% probability of winning and 80% probability of losing. Thus, odds looks at both sides of the coin – win vs. lose, death vs. survival, improvement vs. deterioration. Odds of 1:4 is equal to  $\frac{1}{4}$ , which is 0.25 or 25%. You can see that 25% odds of winning means 20% probability of winning. You need not bother about this interrelationship. All you need to remember is that odds expression requires probability of one side of the coin (winning, for example) in the numerator and probability of the other side of coin (losing, in our example) in the denominator.

Let us say, 20% of the patients in the treatment group died, that means 80% survived in the treatment group. So, what is odds of death in the treatment group? Remember, for odds we will have to have chance (probability) of death in the numerator, which is 20%; and chance of survival in the denominator, which is 80%. So, the odds will be 20%/80% (in decimals, 0.2/0.8). This is equal to  $\frac{1}{4}$ .

Now, let us say, 25% of the patients in the control group died, which means 75% survived. So, the odds of death in the control group is 25%/75% (or 0.25/0.75) = 1/3.

Therefore, the **odds ratio** which usually has odds of death (or any adverse event) in the treatment group as the numerator and odds of death in the placebo group in the denominator will be equal to  $\frac{1/4}{1/3} = \frac{1}{4} \div \frac{1}{3} = \frac{1}{4} \times \frac{3}{1} = \frac{3}{4} = 0.75$  (or 75%) Thus one way of expressing the treatment effect is the odds ratio = 0.75 (=75%).

In the example above, the odds of death or institutionalisation in the 'stroke unit' group is 50:50 = 1, whereas in the 'general ward' group it is 25:75=1/3 75:25 = 3. The odds ratio for institutionalisation with stroke unit vs. general ward is 1/3.

### Risk Difference (RD) or Absolute Risk Reduction (ARR)

Risk difference has three merits:

- (i) Easy to calculate and interpret: You have to do only a subtraction, RD tells you how much difference the intervention could make.
- (ii) It is symmetrical i.e. conveys the same effect whether you measure the favourable or unfavourable outcome. In the example above, if you measured the favourable outcome like 'going home', still the difference will be the same. 50% went home in the 'ward' group and 75% went home in the stroke unit group – a difference of 25%, which is the same in magnitude as earlier.
- (iii) It facilitates calculation of the Number Needed to Treat (NNT).
- (iv) A confidence interval can be calculated even when no patient had the outcome of interest in any group. For example no patient was institutionalised or died in any group. However, it has some demerits:
  - (i) Sometimes, it contains so many zeros that it takes effort to read out and interpretation becomes difficult. and interpreted easily (for example mammography programme over seven years makes a difference of 0.0006 i.e 0.06%. in breast cancer mortality. The number is difficult to read and comprehend.
  - (ii) It cannot apply equally to all types of patients. Consider the **two patients with acute stroke** - one mild and one severe. You might think (though it is not correct) that a severe patient's risk of death / institutionalisation whose baseline risk was 90% would be down to 65% (90% - 25%), but what about the mild patient – whose baseline risk is 2%. How can the stroke

unit make a difference of 25%, when the total risk is 2%? This illustrates the difficulty in using the RD (or ARR) from the study data (However, RR is equally applicable in both cases - see below).

### **Risk Ratio or Relative Risk (RR)**

It has the merit of applicability to all kinds of patients. For example, in the example above, RR would be  $25\% / 50\% = 0.5$  (=50%). That means risk of institutionalisation or death with treatment in a stroke unit is 50% of that with treatment in general medical ward. Thus, the RR would be 45% (half of 90) with the stroke unit treatment in severe stroke cases, whereas it would be 1% (half of two percent) in mild stroke cases. RR easily applies to both.

However, the demerit in RR is that it's not symmetrical. Above you have seen the stroke unit halves the risk of unfavourable outcome. If you measure favourable outcome here (like 'going home'), then it should double its rate; but no. With 75% going home in the stroke unit group and 50% in the ward treatment group, RR of 'going home' is  $75\% / 50\% = 1.5$ , rather than two. The other demerit which you might have noticed is that it does not sound right to say risk of 'going home'. Going home is a favourable outcome and risk is a rather loaded concept which sounds awkward in association with favourable outcome.

To summarise, merits of RR is

- (i) Applicability to all kinds of patients
- (ii) Easier to interpret than odds ratio

Its demerits are:

- (i) Asymmetry: If there is 10% risk of death in experimental group; and 40% in control group;  $RR = 0.25$  i.e.  $RRR = 1 - 0.25 = 0.75$ ; or 75% risk reduction. If we counted survival, risk of survival in experimental group will be 90% and in control group 60%;  $RR = 1.5$ , that means relative risk increase of survival 50%. You can see that one way it is 75%, the other way 50%. This is the asymmetry. Risk of survival sound awkward. Risk sounds alright only for unfavourable outcomes; not favourable ones. So this is not a neutral concept.
- (ii) Lack of neutrality
- (iii) There is no way to calculate confidence interval of RR when there is zero event in both the

treatment groups, for example, no death in any of the two groups in a study.

### **Odds Ratio (OR):**

The merits of OR is that:

- (i) Like RR, it is applicable to all kinds of patients, irrespective of their level of risk without the treatment.
- (ii) It is not a loaded concept. It's neutral. Odds of going home sounds as appropriate as odds of institutionalisation or death. Just as odds of winning or losing both sound acceptable.
- (iii) It is symmetrical. In one example above, the odds of institutionalisation or death in the 'stroke unit' group is  $50:50 = 1$ , whereas in the 'general ward' group it is  $25:75 = 1/3$ . The odds ratio for institutionalisation or death with stroke unit vs. general ward is  $1/3$ . Now, let us see what happens if we measured odds of going home. This is  $50:50 (=1)$  with stroke unit group and  $75:25$  with the general ward group is 3. Therefore, odds ratio of going home is  $3 \div 1 = 3$ . Thus odds of institutionalisation with stroke unit care is  $1/3$  of that with general ward. Similarly odds of going home with stroke unit is 3 times that with general ward. The symmetry is clear and no matter what you measure – the favourable or unfavourable outcome, it gives the same impression.
- (iv) The fourth merit of OR is that it can be used in one of the commonest form of adjusted analysis (using logistic regression), whereas RD or RR cannot be
- (v) It has certain mathematical properties that make it a favoured measure for some statistical calculations including meta-analysis.

The demerits of OR is that:

- (i) It is a difficult concept to understand and interpret for health professionals
- (ii) If interpreted like RR, it overestimates the treatment effects. OR and RR are similar only when events in the control and experimental group is 10% of less or when they are close to one.
- (iii) As with the RR, there is no way to calculate the confidence interval around OR, when there are zero events in both the treatment arms. Only RD lends itself to calculation of confidence intervals in this situation.

## An EBM curriculum for medical students – are we there yet?

Philip Clayton and Craig Mellis

The teaching of evidence based medicine (EBM) to medical students, once controversial, is now considered essential. However, developing a medical school EBM curriculum can be challenging. Issues include deciding what do new graduates really need to know to practice EBM effectively; overcoming time constraints which prevent us teaching everything we would like to cover; competing curriculum demands from other important disciplines; students preference to focus their learning on topics that they perceive to be more directly relevant to clinical practice; and students generally have little clinical experience with which to understand the critical role that EBM plays in modern medical practice. While ideally, most of the teaching should occur routinely during clinical practice, shortages of clinical tutors with EBM knowledge and skills make it difficult to ensure that all students are engaged in this manner. Consequently, at least some of our EBM teaching is, of necessity, centralised.

The International Society for Evidence –based Health Care (ISEHC) is in the process of developing a generic EBM curriculum for Medical Schools, and although some progress has been made, we are certainly not there yet. Sydney Medical School was an ‘early adopter’ of EBM, having introduced EBM as a key theme for medical students 15 years ago. We recently carried out an extensive review of EBM components within our Medical Program in order to update and refresh our EBM curriculum.

Our goal is for all our medical graduates to be proficient *users* of the EBM literature – that is, they need to acknowledge gaps in their knowledge, be able to ask answerable clinical questions, rapidly acquire the best available evidence, to be aware of how to critically appraise that evidence, and to appropriately apply evidence to their individual patients. We do not seek to teach students how to conduct research studies in order to *generate* EBM

literature (although many students optionally undertake supervised research projects).

Our EBM curriculum is integrated across all 4 years of the course through a combination of (a) early introduction via formal lectures on basic EBM principles, (b) small group tutorials and written tasks designed to guide students through the process of using EBM in their clinical practice, and (c) assessment of student's EBM knowledge. The essential topics covered in our curriculum, their timing, plus assessment tasks, are detailed in the Table.

Since our EBM curriculum was originally designed there has been a dramatic change in access to information brought about by the proliferation of electronic devices such as smartphones and tablet computers, expansion of the Cochrane Library, availability of pre-appraised sources of evidence such as “UpToDate” and “BestPractice”, and new, freely available search tools such as PubMed “Clinical Queries”, and Google Scholar. One of our major challenges is to help students navigate the large range of available search tools and evidence sources. Like others, we have found that students and junior doctors commonly refer to pre-appraised evidence sources such as “UpToDate” to answer their clinical questions. While our initial curriculum was strong on the appraisal of primary studies, it was weak on the appraisal of these pre-appraised resources. We have therefore modified our curriculum to include specific teaching on pre-appraised evidence sources such as electronic textbooks (“UpToDate” and “BestPractice”), as well as clinical practice guidelines.

Sydney Medical School has now had 15 years of experience teaching a comprehensive EBM curriculum. We are consistently impressed by the very high quality of the senior students formal EBM presentations (“PEARLS”; ref #1), and their sophisticated knowledge of EBM principles. We believe our experience confirms that comprehensive EBM knowledge and skills are absolutely essential for new medical graduates.

### Components of Sydney Medical Program EBM curriculum

Formal lectures and tutorials, years 1-2 – focus on

#### core EBM knowledge

- Asking questions
- Study types
- Measures of disease and effect
- Bias and confounding
- Basic statistical inference
- Randomised controlled trials
- Observational studies
- Systematic reviews of randomised and observational studies
- Diagnostic tests
- Screening
- Pre-appraised evidence
- Application of EBM to individual patients
- Evidence based health policy and miscellaneous topics

Tutorials years 3-4 (integrated into clinical rotations) – focus on applying EBM to individual patients

- PEARLS (Presentations of Evidence Abstracted from Research Literature to Solve real peoples' problems)
- EBM activities within specialty rotations (eg EBM report on a particular patient, journal club, incorporation of EBM into a "clinical reasoning session", application of a systematic review to a patient problem)

#### Assessments

- EBM questions in formal written examinations
- EBM tasks in years 3-4
- Optional projects

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### Using a teaching journal to improve one's teaching of evidence-based practice

#### W. Scott Richardson

One of the most useful pieces of advice I have received is to keep a teaching journal, analogous to the field notebooks of sociologists and historians and laboratory notebooks of researchers.<1> Let me explain:

#### Why keep a teaching journal?

1. Recording one's teaching plans prospectively helps develop the discipline to do that planning more deliberately and prepare needed materials ahead of time.
2. Recording one's teaching actions retrospectively helps develop the capacity for reflection-on-action and supports more accurate self-assessment of the encounter.
3. Recording specific details of the learning encounter helps identify particular things that went well and particular things that worked less well, since one can learn from both "successes" and "failures." <2, 3>
4. Recording specific details of the session also helps to recall them later when trying to interpret the written evaluations of one's teaching by the learners.
5. Writing the observations and suggestions for improvement from faculty peers may help provide a more well-rounded impression of one's teaching.
6. Recording observations of other teachers can provide specific alternative strategies to try in one's own subsequent teaching.
7. Writing selected contents and interpretations of written materials about teaching can provide additional alternative methods and can record the citation for later retrieval.

#### How can one get started using a teaching journal?

First, pick the physical format(s) in which you'll record your journal, balancing portability and ease of use with durability. I usually use a small notebook, so it fits in my pocket, with a sturdy cover, so it survives being in my pocket. I prefer gridded paper, because I record diagrams as well as words. Other teachers seem happy with their tablet computers. Next, pick a starting place, at least one teaching activity you do frequently enough to allow repeated cycles of observing, recording, reflecting, and improving. It's better to

sustain a journal on at least one form of teaching than to attempt to capture all yet fail to capture any. When recording your plans, consider writing out the learning objectives, how the session will meet them, and what materials you need. When recording after the session, consider recording what was done before addressing what went well and what didn't, in enough detail so you can remember it later. When watching others, considering trying to record more about how and how well they taught rather than about what they taught, as the teaching strategies and tactics may be useful even if you teach different subject material. When reading books or articles about learning and teaching, consider recording not only the citation but also some specific quotes and how they provoke you to consider changes in the content or process of your own teaching. Periodically, consider reading through your whole journal to reflect and record any additional interpretations, since sometimes a subtle pattern emerges only after multiple sessions.

#### **Who should use a teaching journal, and when should they start?**

Anyone who wants to improve their teaching of evidence-based practice should consider whether the future improvements in one's teaching are worth the current investment of time and effort it would take to do this in a sustained manner. And why not start now? I look forward to hearing from readers who try using a teaching journal about what they learn by doing so.

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### **Presenting continuous outcomes with a GRADE Summary of Findings table**

#### **HN Catalano, Gonzalez Malla, A Izcovich**

Pooling estimates of effects of different measures for continuous outcomes in an easily interpretable way presents challenges for authors of systematic reviews. Recently the GRADE working group published guidelines on this topic suggesting the application of multiple continuous data analytical approaches in the presentation of results<sup>1</sup>. We present an example of these guidelines using data from our systematic review of randomized control trials (RCT) that evaluated the efficacy and safety of midodrine on symptomatic orthostatic hypotension secondary to autonomic dysfunction.

We evaluated two continuous outcomes: Health Related Quality of Life (HRQL) and symptom improvement which were presented using different measures across eligible RCTs. Based on the GRADE guidelines<sup>1</sup>, we decided to analyze the results as follows:

- 1) **Pool as dichotomous data:** we analyzed the proportion of patients with significant improvement in Health related quality of life or symptoms related to orthostatic hypotension when available, or tried to convert the continuous data to probabilities using individual trial summary statistics and established minimally important differences (MID) for corresponding instrument<sup>2</sup> when this was not possible, we used Hasselblad and Hedges' statistical method<sup>3</sup>. If dichotomous and statistically converted continuous data were both available we converted all the individual trials results to logOR (SE) and pooled the results as suggested by The Cochrane Collaboration<sup>4</sup>. We calculated the relative risk (RR), Risk difference (RD), number needed to treat (NNT) and the 95% CI.
- 2) **Pool as continuous data:** We analyzed the results as continuous when available (Weighted difference of means when investigators have all used the same measure or conversion of the natural units of the most familiar instrument when available or standardized mean difference when investigators used different methods and no familiar instrument exists) or converted

dichotomous data using Hasselblad and Hedges' statistical method<sup>3</sup>. If continuous and converted dichotomous data were both available, we converted all the individual trials results to SMD (SE) and pooled the results as suggested by The Cochrane Collaboration<sup>4</sup>. We calculated RD, NNT and the 95% CI using Furukawa's statistical method<sup>3</sup>.

The results of the performed analysis are shown in the following table:

Outcome	No. of participants	Quality of the evidence (GRADE)	Relative effect	Risk with No midodrine	Risk difference with midodrine	Comments
HRQL improvement (SF-36) (Continuous)	121	Very low	MD 21.7 (CI 95% 1.51 - 41.03)	300 per 1000	131 more per 1000 (from 69 more to 263 more)	- High risk of attrition bias - CI that includes presence and absence of benefits - Insufficient length of follow up - Publication bias strongly suspected
Symptom improvement, (dichotomous)	557	Low/Moderate	RR 2.7 (CI 1.81 - 3.1)	300 per 1000	526 more per 1000 (from 250 more to 686 more)	- Insufficient length of follow up - Publication bias strongly suspected
Symptom improvement, (continuous)	557	Low/Moderate	SMD 1.3 (CI 0.56 - 2)	300 per 1000	476 more per 1000 (from 212 more to 625 more)	- Insufficient length of follow up - Publication bias strongly suspected

We were able to implement some of the GRADE working group recommendations when analyzing different measures of two continuous outcomes, by doing so; we managed to present the results in a transparent and easily interpretable manner.

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treatment response and numbers needed to treat: meta-epidemiological study. *Int J Epidemiol.* 2012 Oct;41(5):1445-59. doi: 10.1093/ije/dys124.

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## Public disclosure of early findings from outcomes trials: A worrisome trend!

Hertzel C. Gerstein

Imagine that your mother has just consented to participate in a 10,000 person international trial of a new, unmarketed drug that is designed to determine whether the drug can reduce the incidence of cardiovascular outcomes more than placebo and that is expected to run for several years. As a clinical trialist, you support her decision after reviewing the consent form because you understand the importance of clinical outcomes research such as this.

However, 2 years after your mother began participating you are surprised to see a piece in heart.org describing the emerging outcomes results of this ongoing trial. It says that although the trial is expected to run until 900 primary outcomes have accrued, the effect of the intervention on first 150 outcomes (i.e. 1/6 of the required number for this trial) have just been presented publicly at an FDA meeting to determine whether the drug is safe enough to be marketed while the trial continues to its planned conclusion. In that meeting the sponsor reported a hazard of 1.00 for the primary outcome (95% CI 0.70, 1.35) based on these 150 outcomes that accrued over a median follow-up period of 1 year. Your mother sees this in the news and asks your opinion on what she should do.

Although this may sound incredulous to experienced trialists, a very similar scenario indeed occurred quite recently and has raised disturbing questions for the future of large global outcomes trials. Large clinical outcomes trials are conducted

in a blinded fashion with emerging results kept confidential from everyone except an experienced independent data safety board, because early results are often misleading and not representative of the final results. Premature unblinding and public exposure of these results can have unpredictable serious consequences. First, it could lead to the premature discontinuation of the trial if the sponsor, physicians or patients conclude from the emerging results that a drug is beneficial when it would have in fact been shown to be neutral or even harmful had the trial continued to its scheduled end. An unfavorable early point estimate could also lead a sponsor to stop a trial and even development and marketing of a drug that would have in fact been shown to be beneficial had the trial continued to its scheduled end. Second, it jeopardizes the credibility of the trial's final results even if it continues to its planned end. Investigators and patients may behave unpredictably in response to the emerging information. This can include changing concomitant therapies, trial nonadherence, and withdrawing participation, all of which can bias the trial's results as well as reduce its power. Third, it violates the trust of both trial participants and society that permits these trials to be conducted. When participants consent, they are told that their participation can determine whether the possible benefits of the drug that they may be allocated to outweigh the possible harms. They (and society) reasonably trust that the trial will be conducted according to sound scientific principles and that the unknown risk that they are assuming by participating will allow future patients to receive better care. Premature exposure of an ongoing outcomes trial's results for commercial or other purposes, which damage its credibility (and thus its utility) for the reasons noted above, clearly undermines this trust and could irreparably prevent future human research and slow the future development and testing of lifesaving drugs.

Notwithstanding these and other real concerns, proponents of public disclosure of emerging results from long-term outcomes trials in both regulatory agencies and the pharmaceutical industry claim that it protects patient safety. These claims remain unsubstantiated and need to be refuted by the scientific community on solid methodologic grounds lest policies are adopted that violate the principles developed during more than 50 years of progress of clinical trial research.

## **An efficient strategy to allow English-speaking reviewers to identify foreign-language articles eligible for systematic review**

**Jason W. Busse, Paul Bruno,  
Keshena Malik , Gaelan Connell,  
David Torrance , Trung Ngo, Karin Kirmayr,  
Daniel Avrahami, John J. Riva,  
Shanil Ebrahim, Peter Struijs,  
David Brunarski, Stephen Burnie,  
Frances LeBlanc, Eric A. Coomes,  
Ivan A. Steenstra, Tesha Slack,  
Robert Rodine, Janey Jim,  
Victor M. Montori, Gordon H. Guyatt**

Systematic reviews endeavour to capture all publications that meet pre-defined eligibility criteria, thereby reducing the chances of selection bias and improving the precision of results when meta-analysis is possible. Review authors sometimes, however, restrict themselves to articles reported in English. For instance, Gregoire and colleagues found that of a cohort of 36 meta-analyses, 28 (78%) reported language restrictions as part of their eligibility criteria of which 26 (93%) excluded all non-English articles.<sup>1</sup> The systematic exclusion of non-English articles may bias the results of systematic reviews.<sup>2,3</sup> In most cases, their inclusion will improve the precision of pooled estimates.<sup>4</sup> It is therefore desirable to avoid language restrictions when selecting articles for systematic review;

We conducted a systematic review of AMED, CINAHL, EMBASE, MEDLINE, HealthSTAR, PsycINFO, Articles First, Proceedings First and CENTRAL, from inception of each database to April, 2011, to identify all randomized controlled trials exploring any form of therapy for fibromyalgia. All non-English language articles were identified and screened for eligibility by native-language reviewers. English-speaking reviewers screened all non-English language studies, guided by 10 questions we developed, in order to identify those that were eligible for review. Teams of two native language speakers provided reference standard

judgments of eligibility for each non-English language article.

Of 15,466 potentially eligible articles we retrieved 763 in full text, of which 133 were published in 19 non-English languages; 53 trials published in 11 languages other than English proved eligible. Of the 53 eligible articles, 6 were mistakenly judged as ineligible by English language reviewers guided by the 10 questions; of the 80 ineligible, 8 were incorrectly judged eligible by English language reviews (sensitivity = 0.89; specificity = 0.90); ultimately, 10 non-English language review teams would have been required. Use of a simple 3-step rule (excluding languages with only one or two articles, reviewing titles and abstracts for clear indications of eligibility, and noting the lack of a clearly reported statistical analysis unless the word 'random' appears) led to accurate classification of 51 of 53 (sensitivity = 0.96) and high specificity (0.71), while limiting number of foreign-language reviewer teams needed to 9 (Table).

Although developed post-hoc in a single review, our optimal strategy shows promise for limiting the need for non-English language review teams in systematic reviews with large numbers of potentially eligible non-English language articles.

Screening Approach	Sensitivity	Specificity	Number of foreign-language teams required (%)	Number of ineligible articles requiring screening (%)	Number of eligible articles missed (%)
Review of all non-English articles by native-language reviewers	1.00	1.00	19 (100%)	80 (100%)	0 of 53 (0%)
Overall impression of English reviewers	0.89	0.90	13 (68%)	8 (10%)	6 of 53 (11%)
3-step decision rule	0.96	0.70	9 (47%)	24 (30%)	2 of 53 (4%)
Removal of all languages with only 1 potential article	0.96	0.06	12 (63%)	73 (91%)	2 of 53 (4%)
Removal of all languages with only 1 or 2 potential articles	0.96	0.11	10 (53%)	69 (86%)	2 of 53 (4%)

**Table: Comparison of screening approaches for identifying non-English language articles that are eligible for data abstraction**

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**Addressing the impact of missing participant data for continuous outcomes in systematic reviews**

**Shanil Ebrahim, Elie A. Akl,  
Reem A. Mustafa, Xin Sun,  
Stephen D. Walter,  
Diane Heels-Ansdell, Pablo Alonso-Coello,  
Bradley C. Johnston, Gordon H. Guyatt**

**Background:** Greater than 80% of randomized controlled trials (RCTs) published in top general medical journals suffer from missing participant data<sup>1</sup>. Missing participant data increases risk of bias in both individual trials and meta-analyses. This is especially a concern in positive trials (i.e., those with a significant treatment effect) if, in the intervention group, the outcomes of participants with missing data are worse than the outcomes of those with available data. No methods directly address missing participant data for continuous outcomes in systematic reviews.

**Objectives:** To develop an approach for addressing missing participant data for continuous outcomes in systematic reviews.

**Methods:** We reviewed the available literature on the topic including the Cochrane Handbook, and then conducted a consultative, iterative process to develop our approach. We considered sources

reflecting observed outcomes in participants followed-up in individual trials included in the systematic review, and developed a range of plausible strategies for imputing missing participant data. We applied our assumptions to a systematic review evaluating cognitive behavioural therapy (CBT) for depression in patients receiving disability benefits<sup>2</sup>.

**Results:** We used 5 sources of data for imputing the means for participants with missing data: [A] best mean score among the intervention arms of included trials; [B] best mean score among the control arms of included trials; [C] mean score from the control arm of the same trial; [D] worst mean score among the intervention arms of included trials; [E] worst mean score among the control arms of included trials. To impute standard deviation (SD) for participants with missing data, we used the median SD from the control arms of all included trials. Using these sources, we developed four progressively more stringent imputation strategies (Table 1).

In the example review (Figure 1), the complete case analysis showed a mean difference of -4.56 (95% confidence interval [CI] of -7.35 to -1.76) [2]. Strategy 1 resulted in some loss of effect but maintained statistical significance. Strategy 2 resulted in further loss of effect and a loss of statistical significance. Strategies 3 and 4 resulted in even further loss of effect and much larger p-values (Figure 1).

**Conclusions:** In the CBT review, effect estimates were diminished and lost significance as the strategies for imputing missing participant data became more stringent. This suggests that the results are vulnerable to risk of bias, and applying the GRADE/Cochrane handbook criteria for confidence in estimates of effect (quality of evidence)<sup>3</sup>, one would rate down for risk of bias as a result of missing participant data.

Our approach provides a useful, reasonable and relatively simple, quantitative guidance for judging the impact of risk of bias as a result of missing participant data in systematic reviews of continuous outcomes.

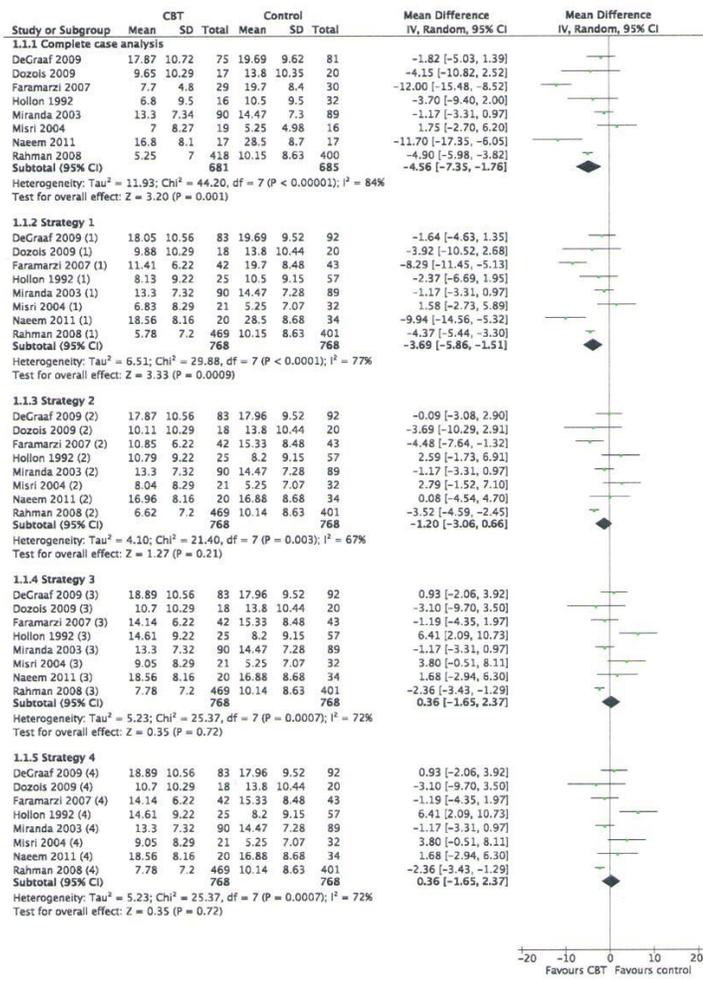
*\*Ebrahim S, Akl EA, Mustafa RA, Sun X, Walter SD, Heels-Ansdell D, Alonso-Coello P, Johnston*

*BC, Guyatt GH. Addressing continuous data for participants excluded from trial analysis: a guide for systematic reviewers. Submitted revisions to J Clin Epidemiol.*

**Table 1.** Matrix of assumptions for participants with missing data for continuous outcomes in intervention and control arms

		Assumptions about the means of participants in intervention arm				
		← Extreme Non extreme Extreme →				
		Source A	Source B	Source C	Source D	Source E
Assumptions about the means of participants in control arm	Extreme	Source A				Strategy 4
	Non extreme	Source B			Strategy 2	Strategy 3
	Non extreme	Source C		Strategy 1		
	Non extreme	Source D				
	Extreme	Source E				

**Source A** – Best mean among intervention arms of included trials; **Source B** – Best mean among the control arms of included trials; **Source C** - Mean score from the control arm of the same trial; **Source D** – Worst mean among the intervention arms of included trials; **Source E** – Worst mean among control arms of included trials



**Figure 1** - Forest plots of the complete case analysis and sensitivity analyses using the four strategies for handling participants with missing data for continuous outcomes in a systematic review evaluating CBT for depression in patients receiving disability benefits

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**Considering intellectual, in addition to financial, conflicts of interest proved important in a clinical practice guideline.**

**Elie A. Akl, Pierre El-Hachem, Hiba Abou-Haidar, Ignacio Neumann, Holger J. Schünemann, Gordon H. Guyatt**

**Background:** The conflict of interest (COI) policy of the American College of Chest Physicians 9<sup>th</sup> iteration of the Antithrombotic Guidelines (AT9) considered both intellectual and financial COI. To what extent, beyond assessing financial COI, assessing intellectual COI affected management of COI is uncertain.

**Objectives:** To describe financial and intellectual COI among AT9 panelists and assess how frequently intellectual COI would have, in the absence of financial COI, resulted in restrictions for participation in decision-making.

**Methods:** We included all AT9 panelists (including methodologists and content experts) involved in at least in one of the guideline chapters. We further classified financial and intellectual COI into primary and secondary (see table 1 for examples). While secondary COI had no implications beyond the need for disclosure, primary COI meant that the panelist could not engage in the discussion of, or in the voting on the recommendations on which he/she is conflicted. We analyzed the distribution of COI disclosures by recommendation and then by panelist. We also analyzed the associations between the role the panelist (i.e., editor, deputy editor, expert, frontline clinician, and resource use consultant) and COI.

**Results:** Of 104 panelists who were eligible to vote on recommendations, 102 (98%) disclosed their COI but two didn't. The 102 panelists reported a total of 4,030 disclosures (including both 3866 financial and 3789 intellectual COI disclosures) for 431 recommendations.

*COI per recommendation:* Disclosures of COI were available for 431 recommendations. The median number (and range) of panelists per recommendation who disclosed COI (including absence of COI) was 9 (2-14). The median number (and range) of panelists per recommendation who disclosed COI was: 0 (0-5) for primary financial COI, 0 (0-4) for secondary financial COI, 0 (0-7) for primary intellectual COI, and 1 (0-6) for secondary intellectual COI. Of the 431 recommendations, 63 (14.6%) had at least one panelist with a primary intellectual COI but no primary financial COI.

*COI per panelist:* Disclosures of COI were available for 102 panelists. The median number (and range) of recommendations for which the panelist disclosed COI (including absence of COI) was 26 (1-141). The median number (and range) of recommendations for which they disclosed COI was: 0 (0-21) for primary financial COI, 0 (0-33) for secondary financial COI, 0 (0-32) for primary intellectual COI, and 1 (0-63) for secondary intellectual COI. Of the 102 panelists, 37 (36%) disclosed a primary intellectual but no primary financial COI for at least one recommendation.

*COI association with panelist role:* The analysis of the 4,030 disclosures revealed that methodologists' disclosures included no (0%) primary or secondary financial COI. Content experts' disclosures were more likely to include primary and secondary COI ( $p < 0.001$ ; see table 2). The findings for intellectual COI were similar ( $p < 0.001$ ; see table 3).

**Conclusions:** There was relatively low prevalence of COI in AT9. The distribution of COI was skewed (many with none, some with many). In the absence of financial COI, a substantial number of disclosures would have resulted in restrictions based on intellectual COI. The Cochrane Collaboration should ask systematic review authors to disclose both their financial and intellectual COIs.

**Table 1:** Types and examples of conflicts of interest (COI) as defined for the 9<sup>th</sup> iteration of the American College of Chest Physicians (ACCP) Antithrombotic Guidelines (AT9)

Type of COI		Example of COI
Financial	Primary	<ul style="list-style-type: none"> <li>• Consultancies</li> <li>• Advisory board membership</li> <li>• COI applies to other products in the same therapeutic area produced by the relevant company</li> </ul>
	Secondary	<ul style="list-style-type: none"> <li>• As above, but COI relates to products in other therapeutic areas produced by the relevant company</li> </ul>
Intellectual	Primary	<ul style="list-style-type: none"> <li>• Authorship of original studies, directly bearing on a recommendation</li> <li>• Peer-reviewed grant funding, directly bearing on a recommendation.</li> </ul>
	Secondary	<ul style="list-style-type: none"> <li>• Participation in previous guideline panels</li> <li>• Authorship on systematic reviews that provided recommendations</li> </ul>

**Table 2:** Distribution of financial conflicts of interest amongst panelists' disclosures (N=4,030) according to panelist role \*

	None	Primary	Secondary
Editor	428 (100%)	0 (0%)	0 (0%)
Deputy editor	298 (81%)	36 (10%)	36 (10%)
Expert	2256 (89%)	130 (5%)	155 (6%)
Frontline clinician	261 (93%)	0 (0%)	19 (7%)
Resource use consultant	245 (99%)	2 (1%)	0 (0%)

\* Each AT9 chapter was co-led by an editor (a methodologist) and a deputy editor (a thrombosis expert), and included a number of thrombosis experts and in most cases a frontline clinician and a resource use consultant.

**Table 3:** Distribution of intellectual conflicts of interest amongst panelists' disclosures (N=4,030) according to panelist role

	None	Primary	Secondary
Editor	413 (97%)	1 (0%)	14 (3%)
Deputy editor	198 (54%)	51 (14%)	121 (33%)
Expert	1918 (78%)	195 (8%)	351 (1%)
Frontline clinician	278 (99%)	1 (0%)	1 (0%)
Resource use consultant	228 (92%)	2 (1%)	17 (7%)

## Testing treatments *interactive*

**Douglas Badenoch, Amanda Burls, Iain Chalmers and Paul Glasziou**

Testing Treatments *interactive* is a suite of websites and an international editorial collaboration that aims to broaden awareness and understanding of the importance of fair tests of treatments.

The website achieves this by augmenting the full text of the book *Testing Treatments* with videos,

games, cartoons and other media (we are calling them "TTextras") that illustrate key aspects of clinical research.

The intent is to reach as wide an audience as possible and support effective communication of the need for fair tests of treatments.

To this end, we have also established a multilingual Editorial Alliance to run "sibling" versions of the website in multiple languages.

### It started with a book

The project started in 2011 by putting a PDF of the second edition of *Testing Treatments* online and creating placeholder websites in English, German, Turkish and Arabic. In August 2012 we added the full text as a hypertext and started to build up links to TTextras. At the same time, we developed a framework that would allow translated versions of the book content to be linked directly to one another.

Since then, we have built up a collection of around 40 TTextras, identified by the Development team and by users of the website. On average, we add one new TTextra each week. We have included resources from mainstream satirical websites, such as "Despondex": The Onion's satire on disease mongering by the pharmaceutical industry.

The website was developed using the widely-used open source platform WordPress. We have limited the amount of customisation to minimise compatibility problems with future releases of the software.

### Understanding more about our target audience

Testing Treatments *interactive* is aimed at "intermediaries": anyone who is involved in communicating information about health research to patients or the public.

Unfortunately, people who are interested in research methods are few and far between. Most of our target audience is primarily interested in a specific clinical topic, not randomization, intention to treat or confidence intervals. We still face a substantial challenge in understanding how best to frame messages about method so that they are engaging and comprehensible to a lay audience.

For this reason we have embarked on a programme of user engagement involving teachers, journalists, information specialists, advocates, health professionals and patients. This programme has already started to yield important insights into how our message about fair tests of treatments is understood (or not!) by people who are involved with communicating health research.

### **The TTi Editorial Alliance**

Of course, it is not just English-speakers that need fair tests of treatments. A further aim of Testing Treatments interactive is to help our colleagues around the world to increase awareness of EBHC in their own language.

In December 2012 we launched the Spanish version of Testing Treatments interactive. Users of the website can switch between English and Spanish when they are reading the book hypertext. The Spanish sibling website is run by Giordano Perez Gaxiola in Mexico, and contains its own collection of TTextras that are particular to the Spanish language.

In January 2013 we formalised the international collaboration as the Testing Treatments interactive Editorial Alliance in a meeting in Oxford.

We now have sibling websites under development in Arabic, Armenian, Basque, Chinese, Croatian, French, German, Indonesian, Norwegian, Polish, Portuguese, Russian and Turkish.

### **How you can help**

1. Visit the website and tell us what you think: [www.testingtreatments.org](http://www.testingtreatments.org)
2. Send us your TTextras: links to freely available slide shows, videos, podcasts, anything that YOU have found useful in explaining the messages of EBHC to a broader audience.
3. Follow us on Twitter: @TestTreatments

## **How can EBM become successful?<sup>1</sup>**

**Brian Haynes**

In 2001, a US Institute of Medicine report<sup>1</sup> declared: "The evidence base for clinical effectiveness has become so vast that it is

essentially unmanageable for individual providers." This dire pronouncement wasn't really true then and certainly isn't true now. During the past 2 decades, technology and evidence-based information resources have evolved so that there is now no technical reason why a practitioner and a patient can't have real time access to current best evidence for the diagnosis, prognosis, and treatment of any disorder for which there is reasonably high quality evidence<sup>2</sup>.

But access to best current evidence alone is not enough. The spread of evidence-based principles into policy-making and public health is behind that for clinical practice, but is increasingly supported by specialized evidence services, notably [Health Systems Evidence](#), [Health Evidence](#), and WHO's [Health Evidence Network](#).

And then there is implementation: for many advances in health care knowledge, this requires building programs to deliver better services, and changing clinicians' practices and patients' actions. For example, optimal care for patients with stroke requires public education (so that people are aware of the symptoms and signs of stroke and promptly call for health services when they occur), training of emergency crews, allocation of resources for specialized stroke care units, training programs for the staff who will work in these units, and follow-up services for rehabilitation and secondary prevention. The infrastructure, policies and procedures necessary to support such an initiative take years to set up, and are dependent on exceptional leadership and organization, grit and determination, and often siphoning of attention and resources from other (hopefully less useful...) activities. When all is in place, more patients live and remain independent<sup>3</sup>.

Dire pronouncements about information overload notwithstanding, the future looks bright for moving sound evidence from health research into practice. But there is a lot of work to do if we are to realize consistent success in improving patient-important outcomes. EBMers wanting to keep up with advances in moving evidence into practice are invited to subscribe to KT PLUS (<http://plus.mcmaster.ca/KT>), a continuously updated alerting service for studies of knowledge translation, implementation science and comparative effectiveness research. It's free!

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## The Cochrane Musculoskeletal Group - Outcome measures in rheumatology working group

Rachelle Buchbinder, Ernest Choy,  
Lara Maxwell, Jordi Pardo,  
Elizabeth Tanjong-Ghogomu, Peter Tugwell

The Cochrane Musculoskeletal Group (CMSG; [www.musculoskeletal.cochrane.org](http://www.musculoskeletal.cochrane.org)) and OMERACT (Outcome Measures in Rheumatology; [www.omeract.org](http://www.omeract.org)) have established a Working Group to examine how the CMSG may use the framework of OMERACT's new 'Filter 2.0' to guide the choice of which outcomes are reported in CMSG systematic reviews.

Cochrane systematic reviews use 'Summary of Findings (SoF)' tables to present the key results of a systematic review. Up to seven outcomes may be included in a SoF table; they should be those that are deemed most important from a patient perspective and represent both benefit and harm. As well, reported outcomes should be based on instruments possessing adequate psychometric

properties. Standardizing SoF table outcomes, by condition and perhaps by intervention and stakeholder audience, would improve the quality of reviews and provide readers with a level of consistency across reviews.

OMERACT 'Filter 2.0' builds on the original OMERACT Filter of 'Truth, Discrimination, and Feasibility' in the assessment of outcome measures, and provides a more explicit framework for this assessment. Further elaboration and explanation of the concept of Filter 2.0, as discussed at the last OMERACT meeting, will be published shortly in the Journal of Rheumatology.

The CMSG-OMERACT Working Group plans to focus first on the outcome of pain and conduct a systematic review of measurement instruments with the aim of determining a hierarchy of instruments used to assess chronic pain.

The Working Group is also keen to expand to involve partners from other leading outcome measurement groups to achieve consensus around 'best-practice' methodology for establishing high-quality, patient-important outcomes.

For further information, please contact Lara Maxwell, Managing Editor, Cochrane Musculoskeletal Group at [lmaxwell@uottawa.ca](mailto:lmaxwell@uottawa.ca)

## New reporting guidelines for equity-focused systematic reviews were published in October 2012

Jennifer O'Neill, Peter Tugwell,  
Vivian Welch

The Campbell and Cochrane Equity Methods Group has recently developed consensus-based reporting guidelines for equity-focused systematic reviews, called PRISMA-E 2012. These reporting guidelines were developed building on a body of methodological work led by the Campbell and Cochrane Equity Methods Group to help reviewers identify, extract, and synthesise evidence on equity in systematic reviews and to improve transparency and reporting. We have defined equity-focused systematic reviews as those with interventions:

- that target disadvantaged populations,
- aimed at reducing social gradients across populations, or
- not aimed at reducing inequities but likely to have important effects on equity.

The overall goal of PRISMA-E 2012 is to contribute to improving the evidence base for evidence-informed, equity-oriented policies.

Updates, webinars, training material and a Microsoft Word version of the PRISMA-Equity 2012 checklist are available at <http://equity.cochrane.org/equity-extension-prisma>.

**Reference:** Welch V, Petticrew M, Tugwell P, Moher D, O'Neill J, et al. (2012) PRISMA-Equity 2012 Extension: Reporting Guidelines for Systematic Reviews with a Focus on Health Equity. PLoS Med 9(10): e1001333. doi:10.1371/journal.pmed.1001333

## The addition of World Health Organization documents portal to Health Systems Evidence

Sue Johnston

Health Systems Evidence (HSE) has again expanded its role as a top resource for evidence regarding health systems with the addition of the beta version of a new portal consisting of World Health Organization (WHO) documents that address health systems.

The Intergovernmental Organizations' Health Systems Documents Portal includes a continuously updated repository of policy-relevant WHO documents, and provides 'one-stop-shopping' for the many types of documents that can support health systems strengthening by policymakers and stakeholders around the world.

The beta version contains World Health Assembly resolutions and WHO guidance, but over the summer the portal will expand to contain 22 types of documents. These documents will address important health system governance, financial and

delivery arrangements, and implementation strategies for programs, services and drugs.

Documents are obtained through searches of the WHO website and referrals from health systems experts. Once deemed eligible for inclusion, the documents are coded based on global or regional focus, the year they were published, and how they inform health systems strengthening or reform.

The integration of the new portal with the existing HSE ([www.healthsystemsevidence.org](http://www.healthsystemsevidence.org)) database allows the WHO documents also to be searched for using the various limits already available on the website, such as topic, theme, domain, and whether they have a general or specific focus. Results of searches for WHO documents will prompt users to view related documents in Health Systems Evidence that can provide related research evidence (such as systematic reviews and economic evaluations) on the same topic, further enhancing the usefulness of the new portal.

New search limits and design elements were introduced on the HSE website at the same time the first WHO documents were added, to increase ease of navigation and expand the options for searching for documents. The new limits – including a general or specific focus, the theme of health promotion/primary prevention and a country focus – can be combined with all other search options for HSE, as well as the complementary content, to provide additional ways for users to find the type of evidence they require.

The design changes recently implemented for HSE make it easier to navigate all areas of the site, and help users to more rapidly identify information that can assist them in their roles within health systems.

In addition to the new search limits added to HSE, the existing Evidence-Informed Healthcare Renewal (EIHR) Portal – the only part of the site that has a focus on Canada – has a new jurisdiction search function that allows users to look for policy-relevant documents focused on Canada's federal/national level, or on specific provinces or territories.

The WHO documents and the EIHR Portal are available to anyone who registers for Health Systems Evidence, the world's most

comprehensive free access point for evidence to support policymakers, stakeholders and researchers interested in strengthening or reforming health systems.

## **New tool for knowledge dissemination in Orthopedics**

**Nasir Hussain, Mohit Bhandari**

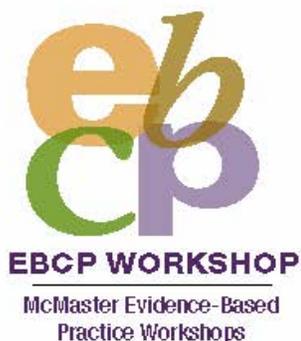
Present day physicians are increasingly interested in basing their clinical decisions and actions on the best available scientific evidence in conjunction with their own expertise and their patient's values and preferences. Keeping up to date with the published literature can be a daunting task for any clinician, however, given the rate at which new studies now appear. Current point-of-care resources such as UpToDate, DynaMed and First Consult can be excellent resources for summaries of evidence; however, the proportion of overall surgery-related content is small. A recent systematic review conducted by Turvey et al. (2013) found that the average orthopaedic content within five commonly used point-of-care resources was 2.04% (range 0.2% - 4%) (1). For the practicing surgeon, using such resources may not

provide adequate results and as a result it may be cumbersome to find relevant content.

OrthoEvidence ([www.myorthoEvidence.com](http://www.myorthoEvidence.com)) is unique in that it focuses particularly on presenting high-quality evidence within the field of orthopaedics, thereby providing orthopaedic healthcare professionals with only relevant content. The website is designed to save clinician the most time by 1) searching for randomized controlled trials and meta-analyses in over 60 orthopaedic journals each month, 2) critically appraising each included article, and 3) creating a unique summary report (Advanced Clinical Evidence Report) which highlights the important take-home information. Thus, OrthoEvidence directly aids the physician desiring to incorporate evidence into practice. Resources such as OrthoEvidence may prove to be invaluable to the medical practitioner who does not have the large amount of time that is required to search for relevant and high-quality evidence within their field.

### **References:**

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**June 10-14, 2013**

**McMaster University**

**Come to McMaster, the birthplace of evidence-based health-care, to join in one of two closely related workshops.**

**The first caters to clinicians who wish to improve their clinical practice through enhanced skills in reading, interpreting, and applying the medical literature.**

**The second is designed for clinician educators interested in enhancing their skills for teaching the principles of evidence-based practice to others.**

**Both workshops are tailored to faculty and community internists, hospitalists, and senior and incoming chief residents.**

## *McMaster Evidence-Based Practice Workshops*

*Monday, June 10th — Friday, June 14th, 2013*

### **WHAT IS EVIDENCE-BASED CLINICAL PRACTICE / EVIDENCE-BASED MEDICINE?**

Evidence-based clinical practice (EBCP) is an approach to health-care practice that explicitly acknowledges the evidence that bears on each patient management decision, the strength of that evidence, the benefits and risk of alternative management strategies, and the role of patients' values and preferences in trading off those benefits and risks.

### **WHY ARE EVIDENCE AND VALUES OR PREFERENCES IMPORTANT?**

Clinicians are confronted daily with questions about the interpretation of diagnostic tests, the harm associated with exposure to an agent, the prognosis of a disease in a specific patient, the effectiveness of a preventive or therapeutic intervention, and the relative costs and benefits associated with these decisions. Both clinicians and policy makers need to know whether the conclusions of a primary study or a systematic review are valid, and whether recommendations in clinical practice guidelines are sound.

Members of the Department of Clinical Epidemiology and Biostatistics at McMaster University, in collaboration with other colleagues trained in both medicine and in clinical epidemiology, have developed a set of common sense strategies

to assist in the critical appraisal of evidence. They have also developed approaches to explicitly considering values and preferences in clinical decision-making, thereby encouraging the practice of EBCP.

### **WORKSHOP OBJECTIVES**

- **Both streams:** To help participants advance their skills in critically appraising the literature, and their skills in acknowledging and incorporating values and preferences in clinical decision making
- **Improve your practice stream:** To acquire an understanding of common epidemiological concepts (e.g. interpreting hazard ratios, confidence intervals, critical appraisals of a systematic review) and advance their skills in using the literature for quality assurance, improving practice, and judging comparative effectiveness of health care interventions.
- **Teaching stream:** To help participants learn how to teach EBCP using a variety of educational models in different settings, with different types of learners.

### **WORKSHOP FORMAT**

The workshop is offered as a one-week intensive course.

Participants will be learning in interactive small groups led by clinical epidemiologists and

practitioners from McMaster and other institutions. The workshop will consist of small and large group sessions, individual study time and, for the teaching stream, opportunities for workshop participants to lead teaching sessions using their own ideas, materials, and reflecting their own experiences.

#### WORKSHOP MATERIALS

Prior to and at the workshop, participants will have access on-line to educational materials that include literature on critical appraisal and EBCP; the small group learning format, a set of clinical problems, JAMA evidence, and a variety of other EBCP aids.

#### WHY COME TO MCMASTER UNIVERSITY?

McMaster University is not only the birthplace of evidence-based medicine, and has produced the definitive evidence-based health care texts. We also continue to lead the world in innovation and advances in EBHC practice and teaching. McMaster's workshop, running for more than 25 years, has provided the model for EBHC workshops throughout the world. Over this time, we have developed a cadre of the best EBHC educators in North America who return to the workshop year after year because of the intensely stimulating and educational environment. Come to experience the best in EBHC education!

#### TRAVEL, FACILITIES AND ACCOMMODATION

The workshop will be held at McMaster University. Upon confirmation of a definite placement in the workshop, you will receive a formal letter, access to the website and background and introductory materials will be provided with general information regarding specifics of the workshop, accommodation and travel. TRAVEL AND ACCOMMODATION ARRANGEMENTS ARE THE RESPONSIBILITY OF THE REGISTRANT. Modest accommodation is available on campus. Other accommodations are available in city hotels, 10-30 minutes away by foot, bus or car.

REGISTRATION FEES	CDN \$*	US \$
One member from an institution	\$2800	\$2885
Two members from an institution	\$2500 each	\$2575 each
Three or more members from an institution	\$2200 each	\$2270 each

\*Includes 13% Harmonized Sales Tax (HST # R119-035-988). Tuition includes all workshop materials, photocopying services, access to computer literature searching and dinner on the first and last evenings.

#### REGISTER ON-LINE AT:

[http://ebm.mcmaster.ca/registration\\_online.htm](http://ebm.mcmaster.ca/registration_online.htm)

Please return the completed application form and registration fee (North American registrants please send cheque or money order; non-North American registrants please send international money order drawn on a USA or Canadian bank).

Please make the registration fee payable to **MCMASTER UNIVERSITY**, and send to

**Laurel Grainger**  
EBCP Workshop Registrar  
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## MAILING LIST

We would like to keep our mailing list as up to date as possible. If you are planning to move, have moved, or know someone who once received the newsletter who has moved, please e-mail [maddock@mcmaster.ca](mailto:maddock@mcmaster.ca) or write your new address here and send to Deborah Maddock, CE&B, HSC 2C12, McMaster University Health Sciences Centre, 1280 Main Street West, Hamilton, ON L8S 4K1, Canada. Thank you!

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## SIGN UP A COLLEAGUE!

If you would like to encourage a colleague to attend the workshop next year, please e-mail [maddock@mcmaster.ca](mailto:maddock@mcmaster.ca) or write the address here and send to Deborah Maddock, CE&B, HSC 2C12, McMaster University Health Sciences Centre, 1280 Main Street West, Hamilton, ON L8S 4K1, Canada. Thank you!

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