

# Clinical governance in sports medicine

P McCrory

## Sports ruling bodies should introduce clinical governance to ensure best practice treatment for athletes no matter what their sport nor where they play

In these days where corporate governance seems a watchword for dubious practice within multinational companies, such terms often are banded around without much thought given to their meaning. A similar word, clinical governance, is used within medicine particularly by administrators and funding bodies who set their own agendas within health care.

In 1998, the National Health Service (NHS) introduced into the United Kingdom namely, the concept of clinical governance. This was used to denote the systematic coordination and promotion of activities that contribute to continuous improvement of quality of care.<sup>1</sup>

The broad elements that make up the panoply of clinical governance include the processes of clinical audit, risk management, professional development and patient participation. As such, clinical governance requires better communication systems, organisational change and a paradigm shift on the part of clinicians toward more open and impartial evaluation of clinical care and its outcomes.<sup>2</sup> It is worth observing, albeit sadly for the traditionalists, that this laudable aim is consumer driven rather than medically determined.

Although there is currently little published evidence that clinical governance makes any measurable difference,<sup>3</sup> at the heart of the concept is the desire to evaluate the quality of medical practice against agreed standards and to remedy any gaps identified in routine practice.

Professional specialist groups, such as those that exist within sports medicine in various countries regard themselves as the legitimate arbiters of standards of athlete medical care. In doing so, these bodies present expert-endorsed best practice guidelines and position statements as evidence of their standing within this field.

But to what extent is routine care matching the predetermined standards? Unfortunately evaluation, at least at a national level, is fragmented in mainstream medicine and non-existent in sports medicine. Where this evaluation does occur, it is largely performed by

academics, health care organisations or by civil servants, all of whom have their own agendas in these matters. We, as sports physicians, lack standardised national and international benchmarks of quality of care in virtually all areas, which in turn impairs any ability to coordinate improvements in patient care.

In the UK, the Clinical Evaluation and Effectiveness Unit of the Royal College of Physicians, in collaboration with a number of other bodies, is mounting the Myocardial Infarction National Audit Project, which is a collaborative audit of the care of patients with myocardial infarctions involving nearly all of the hospitals in England.<sup>4</sup>

The difficulties of replicating such a concept in sports medicine may seem insurmountable; however, we have several areas that would lend themselves to such analysis. These areas may also provide the model by which other aspects of sports medicine may tackle the clinical governance issue and at an international level.

In 2001, the International Ice Hockey Federation in conjunction with the International Olympic Committee and FIFA ran a meeting in Vienna on the topic of concussion. The outcomes of this meeting, previously published in the Journal, were an international expert consensus set of guidelines.<sup>5</sup> In November 2004, the second such conference will be run in Prague and will develop the guidelines much further (see [www.iihf.com](http://www.iihf.com) for conference details). These meetings provide the basis of the first step in any such governance process, namely the establishment of agreed universal benchmarks of clinical care. Once this is done, then the second step will be reviewing the practice of individuals, teams and national governing bodies in this regard. Once that is complete then the issue of redressing any gaps in clinical performance can be undertaken.

Where do we proceed from there? For organisations that fare well in such analysis there is little more than the warm inner glow of satisfaction of a job well done. By contrast, organisations

that perform poorly on such analysis may be encouraged to improve by a combination of external funding pressures or ultimately by disgruntled athletes who sue the organisation because their regulations are not reflective of clinical best practice and fail to meet accepted benchmark criteria.

Medical insurance bodies also have a strong role to play by refusing to provide insurance to sports doctors whose management is not in line with agreed best practice standards. If the team doctors then are unable to attend athletes, then the organisations they work for will need to change in order to accommodate this development.

A practical example of such disparity can be found by examining some of the codes of football played in England. One code is in the process of developing clear guidelines for the management of concussion involving individualised cognitive assessment and medical education (as per the Vienna guidelines) whereas the other larger code still largely recommends a mandatory exclusion policy. From a clinical governance standpoint, the second organisation would have problems in justifying their procedures against national or international best practice. In part, some of these difficulties come about because we often work in an international environment that often requires extensive negotiation on rule changes. Nevertheless this can also be seen as an opportunity whereby improvement can be driven by a committed international organisation who see the obvious benefits that best practice has to offer.

As with much in medicine in this era we should consider change before the lawyers force us to!

*Br J Sports Med* 2003;37:472

Correspondence to: P McCrory, Centre for Sports Medicine Research Education, School of Physiotherapy, Level 1, 200 Berkeley Street, Parkville, Victoria 3052, Australia; [pmccrory@compuserve.com](mailto:pmccrory@compuserve.com)

## REFERENCES

- 1 Scally G, Donaldson L. Clinical governance and the drive for quality improvement in the new NHS in England. *BMJ* 1998;317:61–5.
- 2 Hine D. Clinical governance and the Commission for Health Improvement. In: West R, Norris R, eds. *Measurement of clinical performance: Practical approaches in acute myocardial infarction*. London: Royal College of Physicians; 2001:7–15.
- 3 Thomas M. The evidence base for clinical governance. *J Eval Clin Pract* 2002;8:251–4.
- 4 Birkhead J. Clinical audit of myocardial infarction: origin and development of the myocardial infarction national audit project. In: West R, Norris R, eds. *Measurement of clinical performance: Practical approaches in acute myocardial infarction*. London: Royal College of Physicians; 2001:71–9.
- 5 Aubry M, Cantu R, Dvorak J, et al. Summary and agreement statement of the first International Conference on Concussion in Sport, Vienna 2001. *Br J Sports Med* 2002;36:6–10.

# Cochrane Reviews: new blocks on the kids

I Shrier

The Cochrane Collaboration should be congratulated for its dedication to documenting continuing clinical trials, teaching critical appraisal, and supporting research into new methods of reviewing the literature. However, Cochrane Reviews can be created by untrained people who simply follow an algorithmic approach and are unaware of important methodological issues. Therefore, the objective of this article is to highlight important limitations of Cochrane Reviews, including the Review Manager software<sup>1</sup> that is required,<sup>2</sup> the inappropriate use of a summary statistic, and finally the restriction to only randomised controlled trial (RCT) data. To illustrate these points, I have used a 1% random sample of Cochrane Reviews—that is, 16 studies numbered 1, 101, 201...1501 of 1596 of the Cochrane Database on 3 April 2003.<sup>3–18</sup>

## LIMITATIONS OF THE COCHRANE APPROACH

There are important limitations to the software required by the Cochrane Collaboration (Review Manager). Most important is that Review Manager cannot include (a) results based on survival analyses—for example, most appropriate analysis for time to next injury—and instead calculates relative risks based on simple proportions (this leads to inappropriate estimates when patients have different lengths of follow up<sup>19</sup>) and (b) analyses adjusted for confounding—that is, multiple regression analysis. Software is available, but requires statistical expertise that would preclude the algorithmic approach.

Whereas the Cochrane Collaboration could improve its software, the other two major problems are process oriented. The Cochrane Collaboration promotes wide participation, and this leads to inexperienced authors and peer reviewers. For example, it is not always appropriate to pool data into one overall summary statistic,<sup>20</sup> and, even when it is, there are different methods—that is, fixed and random effects models—to be used depending on the structure of the data.<sup>20–21</sup> In the 1% sample of Cochrane reviews examined, five out of five

authors used the fixed effects model when it was clearly inappropriate to do so.<sup>10–12 16 17</sup> Secondly, only two of these five authors followed the Cochrane recommendations<sup>2</sup> to discuss differences in methodology and outcomes as a source of discrepancy between studies, and the papers still passed the Cochrane peer review process.<sup>12 16</sup>

**“The counter argument that disease management should not change without RCT evidence ignores the clinical reality facing the physician”**

Finally, the Cochrane Reviews currently only include RCT studies, a decision that remains controversial at this time.<sup>22–31</sup> What is the result? Of the 16 Cochrane Reviews retrieved, six included only zero, one, or two RCTs<sup>3–8</sup> (Cochrane Reviews publish reviews in which zero studies meet the inclusion criteria). In an additional seven studies, almost every analysis included two or less RCTs because of the particular question being addressed (158/183 analyses).<sup>9 13–18</sup> Given the limited number of RCTs included in 13/16 reviews, the inclusion of other types of evidence—for example, cohort, case-control, basic science—would probably have provided a stronger foundation for a rational decision of treatment. The counter argument that disease management should not change without RCT evidence ignores the clinical reality facing the physician. When a condition has not been appropriately studied with RCTs, and the currently prescribed treatment is based on a theory that has been proven incorrect, the physician has three options: (a) to continue to use a treatment that is unsupported by clinical, basic science or theoretical evidence; (b) to switch to a treatment that it is based on basic science or observational studies; (c) to abandon treatment altogether. If the operative word in “evidence based medicine” is “evidence”, then choice 2 is the most appropriate.

## ALTERNATIVE APPROACHES

Alternative approaches to the Cochrane Review include best evidence synthesis,

exploratory meta-analysis with or without meta-regression, and the Critical Review, all of which explore and focus on reasons for the differences in results between studies. Although some of these may be used within a Cochrane Review,<sup>2</sup> they are not required. Further, they acknowledge that clinicians first and foremost need to know if they should use a specific treatment, and the precision of the estimate is less important. For example, a clinician will prescribe a drug if it lowers blood pressure by 20 mm Hg (95% confidence interval (CI) 10 to 30 mm Hg) or by 15 mm Hg (95% CI 13 to 17 mm Hg). Where treatment effects are small but important, and the pooling of studies is appropriate, a summary statistic can still be provided.

**“As stronger types of evidence become available, weaker types of evidence are discarded”**

The best evidence synthesis approach is one used by the legal system and has been proposed for the medical literature.<sup>24 32 33</sup> As stronger types of evidence become available, weaker types of evidence are discarded. In legal terms, written notes supersede oral recall. The best evidence synthesis may be the basis of the Cochrane Review approach; if one RCT is available then all “weaker” data are ignored. However, it is not clear how much stronger the data needs to be to ignore “weaker” data.<sup>32</sup> Further, it ignores the fact that other types of studies could help the reviewer discuss treatment effectiveness in other populations—for example, different age groups—or similar but not identical conditions—for example, patellar tendinopathy versus Achilles tendinopathy.

An exploratory meta-analysis uses standard summary plots to look for outlying studies,<sup>34</sup> even if data pooling is appropriate. Reasons for the discrepancies between studies are explored, and conclusions are always cautious because this is a post hoc data driven approach. Preferably, authors look at subgroups based on their a priori knowledge of the condition.<sup>2</sup> A quantitative version of the exploratory meta-analysis is meta-regression. In the regression model, each aspect of the study is an independent variable—for example, study type, ejection fraction—and the outcome of interest—for example, five year re-injury rate—is the dependent variable. In general, meta-regression requires a minimum of five studies, but this increases when the number of variables increases.

The Critical Review approach<sup>35</sup> is similar to that used in Critical Thinking in Logic.<sup>36</sup> In contrast with

the quantitative and exploratory meta-analyses approaches, the Critical Review approach suggests that one should first separate studies into those that show a positive effect and those that show no effect or a negative effect (based on both point estimates and confidence intervals). The author then examines for differences in methodology. If a consistent difference is noted between these groups of studies, the author investigates further. Because this is data driven, the traditional statistical approach would be to test the hypothesis using an independent data set.<sup>37</sup> Because the original review already included all the RCTs (or RCT and cohort studies, etc), the Critical Review examines an independent type of data set—for example, basic science data, or cohort data if only RCTs were originally used—to see if the newly generated hypothesis is supported. Of course, this is still a post hoc approach and interpretations should be cautious.

This method was used to investigate whether stretching immediately before exercise prevents injury.<sup>38</sup> At the time of the review, the results showed that three of four RCTs suggested that stretching immediately before exercise was beneficial, but all had the co-intervention of warm up. On the other hand, the investigators of the cohort studies adjusted for a warm up co-intervention, and almost all of these studies suggested that stretching had no effect. The basic science data and other theoretical arguments were reviewed and suggested that stretching immediately before exercise would not decrease injuries. Shortly thereafter, a new RCT was published that used stretching without warm up, and suggested that there was no effect.<sup>39</sup> In two other studies that have been cited as evidence in favour of stretching before exercise, the intervention used was actually stretching outside periods of exercise. A review of basic science data suggests that long term stretching outside periods of exercise could theoretically increase the strength of tissue.<sup>40</sup> In effect, the Critical Review approach allowed for a unifying theory for all the results of the different studies in this situation.

## CONCLUSION

Cochrane Reviews currently enjoy a credibility level that may not be warranted. The required software is lacking in vital areas, the algorithmic approach to systematic review writing appears to lead to published papers that do not follow the Cochrane Collaboration's own recommendations, and reviews that are based on zero, one, or two RCTs without reference to other types of

evidence may be omitting important information that would be useful to a clinician who needs to treat actual patients. Another option is to promote critical thinking through the alternative approaches mentioned above.

*Br J Sports Med* 2003;**37**:473–474

## Author's affiliation

I Shrier, Lady Davis Institute for Medical Research, Montreal, Canada

Correspondence to: Dr Shrier, Lady Davis Institute for Medical Research, Centre for Clinical Epidemiology, SMBD-Jewish General Hospital, 3755 Cote Sainte-Catherine Road, Montreal H3T 1E2, Canada; lan.shrier@mcgill.ca

## REFERENCES

- 1 **Review Manager (RevMan) Home Page.** [www.cochrane-net.org/revman/](http://www.cochrane-net.org/revman/).
- 2 **Cochrane Collaboration.** *Cochrane reviewers' handbook.* Oxford: The Cochrane Collaboration, 2003.
- 3 **D'Angelo A,** Amsol N. "Coasting" (withholding gonadotrophins) for preventing ovarian hyperstimulation syndrome (Cochrane Review). *Cochrane Library.* Issue 1. Oxford: Update Software, 2002.
- 4 **Walker GJ.** Antibiotics for syphilis diagnosed during pregnancy (Cochrane Review). *Cochrane Library.* Issue 1. Oxford: Update Software, 2001.
- 5 **Van Vliet H,** Grimes D, Helmerhorst F, et al. Biphasic versus monophasic oral contraceptives for contraception (Cochrane Review). *Cochrane Library.* Issue 1. Oxford: Update Software, 2001.
- 6 **Chambers HM,** Chan FY. Support for women/families after perinatal death (Cochrane Review). *Cochrane Library.* Issue 1. Oxford: Update Software, 1998.
- 7 **Davies MW,** Woodgate PG. Tracheal gas insufflation for the prevention of morbidity and mortality in mechanically ventilated newborn infants (Cochrane Review). *Cochrane Library.* Issue 1. Oxford: Update Software, 2002.
- 8 **Soll RF,** Edwards WH. Emollient ointment for preventing infection in preterm infants (Cochrane Review). *Cochrane Library.* Issue 1. Oxford: Update Software, 2000.
- 9 **Hayes RL,** McGrath JJ. Cognitive rehabilitation for people with schizophrenia and related conditions (Cochrane Review). *Cochrane Library.* Issue 1. Oxford: Update Software, 2000.
- 10 **Gandolfo C,** Sandercock P, Conti M. Lubeluzole for acute ischaemic stroke (Cochrane Review). *Cochrane Library.* Issue 1. Oxford: Update Software, 2002.
- 11 **Oldman AD,** Smith LA, McQuay HJ, et al. Rizatriptan for acute migraine (Cochrane Review). *Cochrane Library.* Issue 1. Oxford: Update Software, 2001.
- 12 **Nelson R,** Singer M. Primary repair for penetrating colon injuries (Cochrane Review). *Cochrane Library.* Issue 1. Oxford: Update Software, 2002.
- 13 **De Paoli AG,** Davis PG, Faber B, et al. Devices and pressure sources for administration of nasal continuous positive airway pressure (NCPAP) in preterm neonates (Cochrane Review). *Cochrane Library.* Issue 1. Oxford: Update Software, 2002.
- 14 **Warach PS,** Adams CE, Roque M, et al. Haloperidol dose for the acute phase of schizophrenia (Cochrane Review). *Cochrane Library.* Issue 1. Oxford: Update Software, 2002.
- 15 **Lister P,** Iles R, Shaw B, et al. Inhaled steroids for neonatal chronic lung disease (Cochrane Review). *Cochrane Library.* Issue 1. Oxford: Update Software, 2000.
- 16 **Walker GJ,** Johnstone PW. Interventions for treating scabies (Cochrane Review). *Cochrane Library.* Issue 1. Oxford: Update Software, 2000.
- 17 **Cools F,** Offringa M. Neuromuscular paralysis for newborn infants receiving mechanical ventilation

- (Cochrane Review). *Cochrane Library.* Issue 1. Oxford: Update Software, 2000.
- 18 **Counsell C,** Warlow C, Naylor R. Patches of different types for carotid patch angioplasty (Cochrane Review). *Cochrane Library.* Issue 1. Oxford: Update Software, 2000.
- 19 **Vale CL,** Tierney JF, Stewart LA. Effects of adjusting for censoring on meta-analyses of time-to-event outcomes. *Int J Epidemiol* 2002;**31**:107–11.
- 20 **Deeks JJ,** Altman DG, Bradburn MJ. Statistical methods for examining heterogeneity and combining results from several studies in meta-analysis. In: Egger M, Smith GD, Altman DG, eds. *Systematic reviews in health care. Meta-analysis in context.* London: BMJ Publishing Group, 2001:285–312.
- 21 **Poole C,** Greenland S. Random-effects meta-analyses are not always conservative. *Am J Epidemiol* 1999;**150**:469–75.
- 22 **Schriger DL.** Evidence-based emergency medicine/perspectives. One is the loneliest number: be skeptical of evidence summaries based on limited literature reviews. *Ann Emerg Med* 2000;**36**:517–19.
- 23 **Benson K,** Hartz AJ. A comparison of observational studies and randomized, controlled trials. *Am J Ophthalmol* 2000;**130**:688.
- 24 **Barton S.** Which clinical studies provide the best evidence? The best RCT still trumps the best observational study. *BMJ* 2000;**321**:255–6.
- 25 **Concato J,** Shah N, Horwitz RL. Randomized, controlled trials, observational studies, and the hierarchy of research designs. *N Engl J Med* 2000;**342**:1887–92.
- 26 **Linde K,** Scholz M, Melchart D, et al. Should systematic reviews include non-randomized and uncontrolled studies? The case of acupuncture for chronic headache. *J Clin Epidemiol* 2002;**55**:77–85.
- 27 **Kaptchuk TJ.** The double-blind, randomized, placebo-controlled trial: gold standard or golden calf? *J Clin Epidemiol* 2001;**54**:541–9.
- 28 **Black N.** Why we need observational studies to evaluate the effectiveness of health care. *BMJ* 1996;**312**:1215–18.
- 29 **Egger M,** Smith GD, Schneider M. Systematic reviews of observational studies. In: Egger M, Smith GD, Altman DG, eds. *Systematic reviews in health care. Meta-analysis in context.* London: BMJ Publishing Group, 2001:211–27.
- 30 **Rovers MM,** Straatman H, Engels K, et al. Generalizability of trial results based on randomized versus nonrandomized allocation of OME infants to ventilation tubes or watchful waiting. *J Clin Epidemiol* 2001;**54**:789–94.
- 31 **McKee M,** Britton A, Black N, et al. Methods in health services research. Interpreting the evidence: choosing between randomised and non-randomised studies. *BMJ* 1999;**319**:312–15.
- 32 **Slavin RE.** Best evidence synthesis: an intelligent alternative to meta-analysis. *J Clin Epidemiol* 1995;**48**:9–18.
- 33 **Letzel H.** "Best-evidence synthesis: an intelligent alternative to meta-analysis": discussion. A case of "either-or" or "as well". *J Clin Epidemiol* 1995;**48**:19–21.
- 34 **Anello C,** Fleiss JL. Exploratory or analytic meta-analysis: should we distinguish between them? *J Clin Epidemiol* 1995;**48**:109–16.
- 35 **Clinical Journal of Sport Medicine.** *Guidelines for authors.* [www.cjsportmed.com/](http://www.cjsportmed.com/).
- 36 **Facione PA.** Critical thinking: what it is and why it counts. [www.calpress.com/pdf\\_files/what&why.pdf](http://www.calpress.com/pdf_files/what&why.pdf).
- 37 **Thompson SG,** Higgins JP. How should meta-regression analyses be undertaken and interpreted? *Stat Med* 2002;**21**:1559–73.
- 38 **Shrier I.** Stretching before exercise does not reduce the risk of local muscle injury: a critical review of the clinical and basic science literature. *Clin J Sport Med* 1999;**9**:221–7.
- 39 **Pope RP,** Herbert RD, Kirwan JD, Graham BJ. A randomized trial of preexercise stretching for prevention of lower-limb injury. *Med Sci Sports Exerc* 2000;**32**:271–7.
- 40 **Shrier I.** Does stretching help prevent injuries? In: MacAuley D, Best T, eds. *Evidence-based sports medicine.* London: BMJ Publishing Group, 2002:97–116.