Trends in Evidence Based Medicine for Herbal Remedies and Media Coverage

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Complementary and Alternative Medicines [*CAM*] are interventions that are not widely taught in medical schools and are not part of the usual arsenal of treatments and medications recommended and prescribed by physicians and available in hospitals.[1] CAM is big business ($30 billion in the US) with aggressive marketing. Their use in Europe and North America is increasing significantly.[2] For example, a 1998 phone survey of 1539 adults found that 42.1% in the United States had used at least one CAM within a twelve month period and that use had increased since 1990; the most used treatments were herbal medicine, massage, megavitamins, self-help groups, folk remedies, energy healing and homeopathy.[3] In 2003, 20% of all Canadians visited a CAM practitioner, up from 15% in 1994/5.[4]

Users of CAM are more likely to have higher education levels and report lower health status.[5] Common health problems treated with CAM are anxiety, back problems, chronic pain, and urinary tract problems. Use of CAM is dependent, not on dissatisfaction with conventional medicine as it is most commonly used in association with conventional medicine, but on philosophical orientations towards health and life, such as feminism, spirituality, and personal growth.[6] Other studies suggest that CAM use allows patients and consumers greater control over their health and a level of self-empowerment.[7] For these reasons, it has become increasingly important to understand the nature and impact of popular representations of CAM in this context.

The combination of educated and self-empowered users of CAM suggests a high degree of reliance on information sources outside of mainstream medical practitioners. Not surprisingly, coverage in sources including newspapers, television, magazines, other media, and the internet has increased to meet the demand for information. A vast quantity of information of varying quality exists in the media and on the internet.[8] There are concerns, however, that the media and internet provide too rosy a picture of CAM[9] and downplay adverse reactions to CAM, which can be dangerous and potentially fatal.[10] Such coverage augments the common misperception that CAM is natural and therefore, less harmful than conventional medical treatments.[11] Indeed, Barnes *et al*. (1998) found that users of CAM were less likely to report adverse effects than users of over-the-counter medicines.[12] These factors suggest that significant improvements need to be made to knowledge translation mechanisms for the public, healthcare professionals, and policy makers.

The response of the medical and scientific community has been an increasing interest in CAM issues. There has been an increase in the number and proportion of clinical trials of CAM, which suggests a trend toward an evidence-based approach. The cumulative number of clinical trial articles indexed on MEDLINE, however, remains small (0.4%), and more high-quality original research is needed.[13] Further, the proportion of those articles on CAM indexed as clinical trial-type studies is 2.1%, but rising.[14]

The lack of clinical trials may be due to a number of factors. There may be little incentive for commercial manufacturers of CAM products to run expensive clinical trials. However, the recent move to evidence-based health claims for CAM labeling and advertising in Canada[15] may drive an increase in CAM clinical trials in that country.

Some authors have suggested that there may be a publishing bias from mainstream medical journals during peer review or editorial process, in either rejecting CAM studies outright or favouring CAM studies with negative results.[16] However, others suggest that most CAM studies may simply be of insufficient quality to be published in high impact factor medical journals.[17] At least 50% of CAM articles were published in journals with no impact factor.[18]

Here we present preliminary data from a study that explores how knowledge is translated in the socio-economic-political context of CAM. This will have significant policy implications as Canada's new natural health product (NHP) regulations[19] were introduced on January 1, 2004 by the Natural Health Products Directorate (NHPD), Health Canada. The NHPD's mandate is to "ensure that all Canadians have ready access to natural health products that are safe, effective and of high quality, while respecting freedom of choice and philosophical and cultural diversity."[20] Specifically, we are interested in whether clinical trials and media coverage of herbal remedies, one of the predominant forms of CAM, are of sufficient quality to provide the public with information required for rational, informed and low-risk decision making.

Approach

We identified herbal remedy clinical trials reported in U.S., U.K. and Canada on Lexis/Nexis and Factiva from 1995 to the present, using the generic search terms "(herb or herbal) and remedy and 'clinical trial'". We sorted through these and isolated only those newspaper articles (281) that discussed the results of identifiable clinical trials. We then did specific searches on the two databases to locate all newspaper articles on each identifiable clinical trial using search terms in the form "(name of herbal remedy) and (study or trial) and ('author's name' or 'journal name' or sample size' or location of trial' or 'condition studies')" (N=389). We then located each clinical trial published in medical journals using PubMed (N=58).

Using a similar coding frame to that in Bubela and Caulfield (2004)[21], we compared newspaper articles with their published clinical trial to assess: the quality of the clinical trial (Jadad score)[22], claims and overall tone of the clinical trial, technical accuracy of media articles, and level of exaggeration in media articles. We also examined the overall structure, framing and treatment of risks and benefits, health claims and conflicts of interest in the newspaper articles.

Explosion in Number of Clinical Trials of Herbal Remedies Not Mirrored in Media

A search on PUBMED for "herbal" under publication type "clinical trial" from 1980-2004 showed a large increase in the number of clinical trials of herbal remedies (Figure 1). The early dearth of articles may be more related to the content of PUBMED and the number and type of journals covered. The vast majority of articles are published by researchers in Asia (mainly China) in specialised journals on Traditional Chinese Medicine.

Figure 1 also shows the number of media articles on herbal remedy clinical trials in newspapers in Canada, the United States and the United Kingdom. It is worth noting that there is no corresponding increase in the number of media articles on herbal remedy clinical trials, that is, the media is not reporting on the trend toward evidence-based medicine [*EBM*]. Given that many commentators note the high level of coverage of CAM in general in the media, this may indicate that most CAM stories are not based on EBM and instead are based on what one former CAM journalist for a women's magazine termed "feel good" and "lifestyle" articles.[23]

The lack of reporting on herbal remedy clinical trials may also be related to where the trial was conducted and published. Of the 58 clinical trials covered by the media in Canada, the U.S., and the U.K., only two were published in CAM specific journals. The majority (86%) were published in conventional medical journals, some with very high impact factors, such as the British Medical Journal (8), JAMA (8), and The Lancet (5). The clinical trials did, however, cover a range of herbs (e.g., Echinacea, Black Cohosh, Ginseng, Gingko, St. John's Wort, Saw Palmetto, Flaxseed) and medical conditions (e.g., baldness, obesity, skin conditions, sleep, pain, depression, menopause, colds, cancer). There also seemed to be a bias toward publishing trials where the lead institution was located in the U.S., the U.K., or Europe (Figure 2).

It is important to note, however, that unlike some other areas of research, this lack of reporting does not appear to be the result of a trend away from the reporting of negative trials. In pharmaceutical research, for example, there is emerging research that there is a strong bias in both scientific journals and the popular press.[24] This suggests that other socio-economic forces are at play in the context of CAM.[25]

Quality of Clinical Trials of Herbal Remedies and Media Reports

We used the Jadad score to calculate the quality of the clinical trials reported in the media.[26] The mean Jadad Score for the 58 clinical trials was 3.3 out of 5 (Figure 3). This is similar to the mean Jadad Score calculated by Linde *et al*. (2001) for clinical trials of herbal remedies. The slightly higher score in the present study may indicate that trials which receive media coverage are of higher quality than trials overall, especially since the majority of them are published first in high quality conventional medical journals.[27] Linde *et al*. also found that larger trials published more recently in journals listed in Medline and in the English language scored significantly higher than trials not meeting these criteria.[28] However, Linde *et al.* also found the majority had important shortcomings, especially the description of how subjects were blindly assigned to different treatments and the reporting of drop-outs and withdrawals.

The conclusion here is that newspapers are not reporting on the facts that the scientific or medical community, and increasingly, the educated and informed public, require to assess the quality of clinical trials.

This is similar to how newspapers handle the reporting of other biomedical research. For example, Holtzman, *et al.* (2005), recently found that the reporting of genetic discoveries often downplayed methodological limitations, such as the need for the replication of the study.[29] The short space available to newspaper journalists appears to be part of the problem.[30]

In our study, 78% of clinical trials were randomized and in 62.7% that randomization method was appropriate; 71.2% were described as double-blind and in 57.6% that method of double-blinding was appropriate; and 81.4% described withdrawals and dropouts. However, newspaper articles rarely described the methodology of the trial appropriately. The vast majority (over 80%) of newspaper articles did not describe methods of randomization or double-blinding and over 40% did not even mention the use of a "placebo". Of more concern, over 90% did not mention withdrawals and dropouts, while 40% did not mention the sample size; 57% did not mention the length of the trial and 75% did not mention the dosage. These were all errors of omission. When the newspaper articles actually reported technical facts, they did so accurately. The conclusion here is that newspapers are not reporting on the facts that the scientific or medical community, and increasingly, the educated and informed public, require to assess the quality of clinical trials.

Our preliminary results also indicate that the media significantly under-report risks associated with CAM, and that the media is more likely to report on clinical trials with negative results. It is difficult to ascertain whether this possible bias towards trials with negative results is a reflection of more negative trials being published in conventional medical journals, the main source of media articles.

However, our study is limited to newspaper stories that are directly related to peer-reviewed clinical trials and that do not reflect the majority of coverage on CAM. We did not consider television, the internet, women's magazines, and ad- vertising.

In conclusion, there is a welcome trend toward evidence-based medicine in the application of herbal remedies. This trend, however, is not necessarily reflected by mainstream news media in Canada, the United States and the United Kingdom. The coverage of clinical trials has a subtle negative trend and news articles do not provide readers with adequate information to assess the quality of the trial and its outcomes.

The next steps in this study on knowledge translation in a bio-medical context will be to compare media coverage of CAM with coverage of conventional pharmaceuticals used to treat the same medical conditions as those covered in the present study on CAM. We will also expand the media sources to include television, women's magazines and the internet and conduct surveys of Canadian CAM practitioners, pharmacists and the public on where they receive information about CAM and the quality of that information.

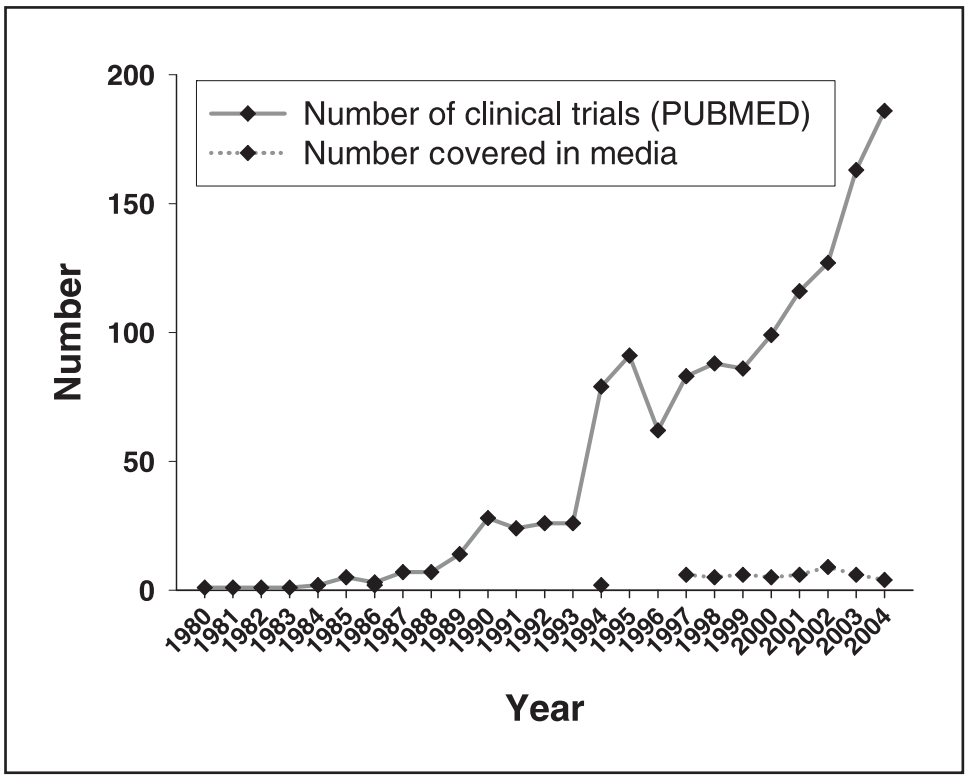

Figure 1.
Number of herbal remedy clinical trials on PUBMED using the keyword search "herbal" under publication type "clinical trial" from 1980-2004. The majority of articles are published by researchers in Asia (mainly China) in specialised journals on Traditional Chinese Medicine. This figure also shows (dashed line) the number of media articles on herbal remedy clinical trials in newspapers in Canada, the United States and the United Kingdom.

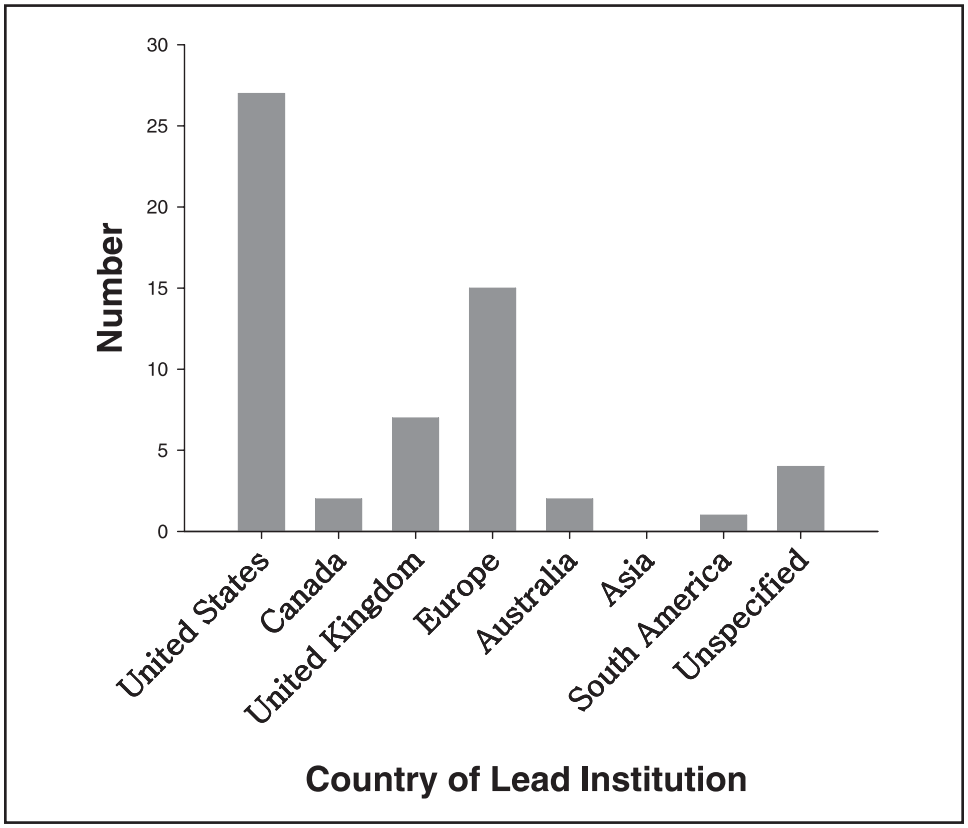

Figure 2.
Number of 58 published clinical trials of herbal remedies reported in 389 newspaper articles in Canada, the United States and the United Kingdom from 1995 to the present by country of the lead author's institution listed on the clinical trial.

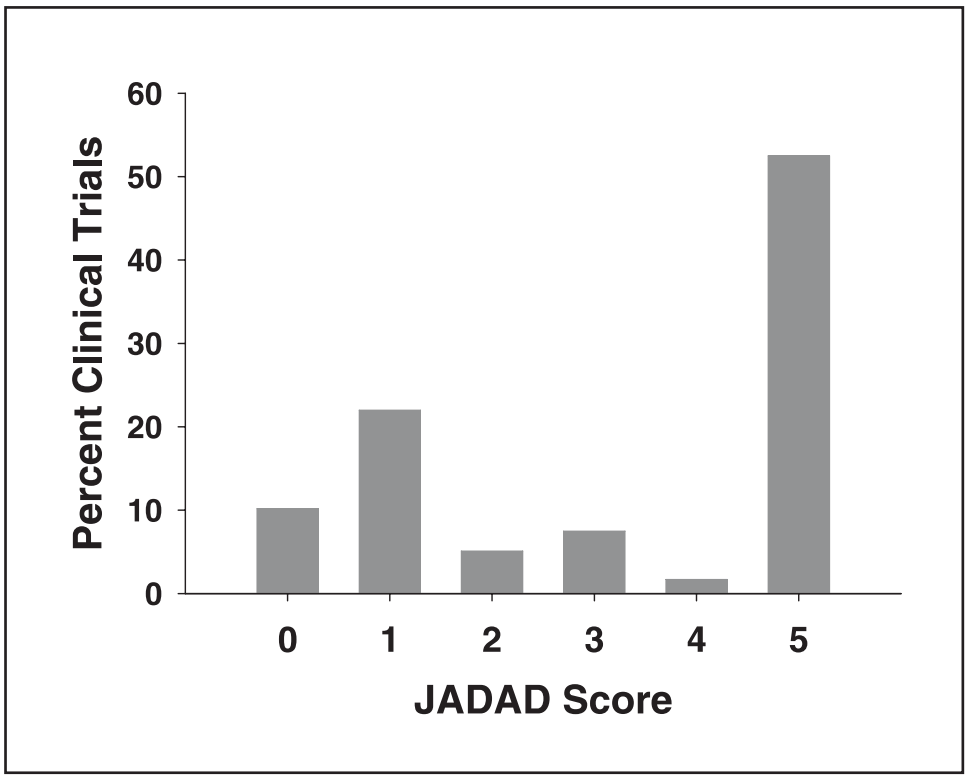

Figure 3.
Jadad score of clinical trial quality, with 5 being the highest score and zero the lowest, of 58 clinical trials reported in 389 newspaper articles in Canada, the United States and the United Kingdom from 1995 to the present.

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