## How patient outcomes are reported in drug advertisements

### Review of Canadian medical journals

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#### ABSTRACT

**OBJECTIVE** To examine how changes in outcomes are reported in drug advertisements in medical journals.

QUALITY OF EVIDENCE Advertisements from a convenience sample of 38 issues of Canadian Family Physician, Canadian Journal of Anaesthesia, Canadian Journal of Psychiatry, Canadian Medical Association Journal, and the New England Journal of Medicine.

MAIN MESSAGE Method of reporting changes in clinical outcomes (relative risk reduction [RRR], absolute risk reduction [ARR], number needed to treat [NNT]), name of product, and company marketing product were sought. In the 22 advertisements included in the analysis, 11 reported results as RRRs; two reported results as RRRs, but readers could calculate ARRs or NNTs from figures given in the advertisement; and nine gave no measure of results, but readers could calculate RRRs, ARRs, or NNTs from figures given.

**CONCLUSIONS** Most companies report changes in outcomes as RRRs, and this bias could influence the way physicians prescribe. Changes to the rules governing journal advertising and increased emphasis on critical appraisal skills would help mitigate this bias.

#### RÉSUMÉ

**OBJECTIF** Examiner la façon dont sont rapportés les résultats thérapeutiques dans les annonces publicitaires des revues médicales.

QUALITÉ DES DONNÉES Les annonces publicitaires d'un échantillon de commodité, tiré de 38 numéros du Médecin de famille canadien, du Canadian Journal of Anaesthesia, du Canadian Journal of Psychiatry, du Journal de l'Association médicale canadienne et du New England Journal of Medicine.

PRINCIPAL MESSAGE Nous avons relevé la méthode servant à rapporter les résultats thérapeutiques cliniques (une réduction relative du risque [RRR], une réduction absolue du risque [RAR], le nombre nécessaire dans l'essai du traitement [NNT]), le nom du produit et celui de l'entreprise qui commercialise ce dernier. Dans les 22 annonces analysées, 11 rapportaient les résultats comme étant une RRR; deux donnaient aussi des résultats qualifiés de RRR, mais les lecteurs étaient en mesure de calculer la RAR ou le NNT à partir des chiffres indiqués dans l'annonce; et neuf ne présentaient aucune mesure des résultats, mais les lecteurs pouvaient calculer la RRR, la RAR ou le NNT à partir des chiffres donnés.

**CONCLUSIONS** La plupart des entreprises présentent les résultats thérapeutiques comme étant une RRR qui, rapportés sous cet angle, sont susceptibles d'influencer la façon de prescrire des médecins. Des modifications aux règlements régissant la publicité dans les revues médicales et une plus grande insistance sur les compétences en évaluation critique pourraient contribuer à atténuer cette distorsion des faits.

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#### RESEARCH

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hanges in outcomes that result from drug and other therapy can be presented various ways: relative risk reduction (RRR), absolute risk reduction (ARR), and num-

ber needed to treat (NNT). An RRR is the percent reduction in the risk of targeted complications between two groups (eg, a drop in mortality from 50% to 25% would be an RRR of 50%). An ARR is the absolute percent difference in the risk of targeted complications between two groups (eg, a drop in mortality from 50% to 25% would be an ARR of 25%). The NNT is the number of patients that have to be treated to prevent one complication of the disease (eg, a drop in mortality from 50% to 25% would be an NNT of four [100 divided by the ARR]).<sup>1</sup>

Evidence suggests that physicians' enthusiasm for a treatment varies according to how results are presented; specifically, the inclination to use a particular drug therapy is greatest when results are given as RRRs and lowest when given as NNTs.<sup>2-4</sup> Journal advertisements are one source of information that physicians use to learn about medications. While physicians rate advertisements' credibility as low, more than half the 787 Canadian physicians surveyed had consulted advertisements during a single month.<sup>5</sup> The way results are presented in advertisements, therefore, could affect physicians' willingness to prescribe the medications featured in those advertisements.

This study examines how changes in outcomes were reported in pharmaceutical advertisements in a sample of Canadian medical journals.

#### **METHODS**

A convenience sample of 38 issues of medical journals from 1998 was reviewed: the first 18 issues of the Canadian edition of volume 338 of the New England Journal of Medicine, the first eight issues of volume 158 of the Canadian Medical Association Journal, the first four issues of volume 44 of Canadian Family Physician, volume 45 of the Canadian Journal of Anaesthesia, and volume 43 of the Canadian Journal of Psychiatry.

I chose these journals because the Canadian Medical Association Journal and Canadian Family Physician are the medical journals with the largest

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controlled circulation in Canada; the New England Journal of Medicine, arguably the most prestigious general medical journal in the world, has a Canadian edition containing advertisements directed at Canadian physicians; and the Canadian Journal of Anaesthesia and the Canadian Journal of Psychiatry are two relatively widely read specialty journals.

All distinct advertisements in the 38 issues were identified by manual search. A distinct advertisement was defined as one in which textual or pictoral content was different from any other advertisement. These advertisements were then examined to select those that reported changes in clinical outcomes as either RRRs, ARRs, or NNTs.

Some advertisements were not clear whether the percentage change cited referred to a change in the percentage of patients with a given outcome (an RRR) or a change in the number of events. For example, one advertisement said there was a 40% reduction in weekly anginal attacks. If this were an RRR, it could mean that 50% of the control group but only 30% of the treated group had anginal attacks during the week. But it could also mean a change in the number of events in the treated group from, say, five to three anginal attacks weekly. Because of this ambiguity, such advertisements were excluded.

For each advertisement I recorded the manner in which the changes were reported (RRR, ARR, or NNT), the name of the product, and the name of the company marketing it.

#### RESULTS

In the 38 journals, I found 130 distinct advertisements for 102 different products. These advertisements appeared a total of 571 times (range one to 12 appearances). Twenty-nine advertisements for 27 different products reported changes in clinical outcomes, but seven advertisements for seven products were excluded because it was unclear whether the numbers were RRRs or changes in the number of events. Therefore, a total of 22 advertisements for 20 products were included in the analysis. These advertisements appeared a total of 124 times (range two to 12 appearances); the products being promoted were made by 14 companies (**Table 1**).

**Table 2** shows how results were reported in the 22 advertisements. Eleven gave changes exclusively as RRRs. Two gave results as RRRs, but readers could calculate NNTs or ARRs from the figures given. For example, the advertisement for Coreg (carvedilol) quoted an RRR for mortality of 65% and

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also presented a graph that gave mortality in the conventional therapy group as 7.8% and in the carvedilol group as 3.2%, giving an ARR of 4.6% (7.8 minus 3.2) and a NNT of 22 (100 divided by 4.6). Nine advertisements did not give RRRs, ARRs, or NNTs, but results were presented in either graphs or tables from which readers could calculate RRRs, ARRs, and NNTs.

The specialty journals (Canadian Journal of Anaesthesia, Canadian Journal of Psychiatry) contained too few advertisements to determine whether there was a difference in the way results were reported in specialty medical journals and in general.

#### DISCUSSION

Results indicate that changes in clinical outcomes reported in advertisements in Canadian medical journals are usually reported as RRRs. Advertisements for almost all classes of drugs appear in family and general medical journals. Moreover, because the set of journals searched included Canadian Family Physician and the Canadian Medical Association Journal, there were large numbers of advertisements per issue. It is unlikely that using different journals, or using different issues of these journals, would have produced different results. There have been no relevant changes in the rules governing journal advertisements in recent years and, since recognition of the value of expressing results as ARRs or NNTs is a relatively recent phenomenon, ARRs and NNTs were probably used less frequently in the past.

Companies might choose to use RRRs for a variety of reasons. As Sackett and colleagues<sup>1</sup> point out, RRRs are usually given in the abstracts of articles, and companies might just be following the lead set by journals. Sackett and colleagues<sup>1</sup> also note that RRRs are "a quick and useful measure of clinical significance" and companies might include them for their informational value to doctors. Finally, there might be a commercial motive for using RRRs in preference to ARRs or NNTs. If RRRs produce more enthusiasm for a treatment and lead doctors to write more prescriptions for a product, it is to a company's commercial advantage to use RRRs.

The advertisement for carvedilol cited above is one case where it might be commercially advantageous to cite an RRR rather than an ARR given the large numerical difference between the two. Another example is the advertisement for simvastatin (Zocor), which cites an RRR of 42% in coronary mortality based on results in the Scandinavian

**Table 1.** Characteristics of advertisements

CHARACTERISTICS	NO. OF DISTINCT ADS	NO. OF PRODUCTS	NO. OF APPEARANCES
All advertisements (ads)	130	102	571
Ads reporting changes in clinical outcomes	29	27	154
Ads giving RRRs, ARRs, NNTs, or figures so readers can calculate these values	22	20	124

RRR-relative risk reduction, ARR-absolute risk reduction, NNT-number needed to treat.

**Table 2.** Use of RRRs, ARRs, or NNTs in advertisements

VALUES USED IN ADVERTISEMENTS (ADS)	NO. OF ADS (N = 22)	
RRRs only	11	
ARRs or NNTs	0	
RRRs, but readers could calculate ARRS or NNTs	2	
No value given, but readers could calculate RRRs, ARRs, or NNTs	9	

RRR—relative risk reduction. ARR—absolute risk reduction. NNT—number needed to treat.

Simvastatin Survival Study.<sup>6</sup> The ARR for the same outcome (not given in the advertisement) is 3.5% (8.5% deaths in the placebo group versus 5.0% in the simvastatin group).

Would differences of this sort between RRRs and ARRs change prescribing behaviour? Some evidence indicates that they might. In a study by Bobbio et al,<sup>4</sup> results of the Helsinki heart trial, involving another antilipemic drug, gemfibrozil,<sup>7</sup> were presented to physicians in various ways. When told the drug would lead to a 34% RRR in cardiac events, just under 80% of doctors agreed to prescribe the drug. When results were given as a 1.4% ARR, only 24% agreed to prescribe.

The finding that companies predominantly present results as RRRs also calls into question the adequacy of the Code of Advertising Acceptance from the Pharmaceutical Advertising Advisory Board (PAAB). The code governs the content of journal advertisements. Two of its provisions seem particularly relevant to the problem at hand: "APS [Advertising and promotion systems] must reflect an

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#### **Key points**

- Advertisements for drug therapy in medical journals do not often report changes in clinical outcome. Of 130 advertisements studied, only 29 reported changes in outcome, and seven of them used unspecified measures.
- More than half the 22 advertisements retained for the analysis reported outcomes in terms of relative risk reduction (RRRs). Absolute risk reduction (ARR) or number needed to treat (NNT) could be calculated for only half of the advertisements. Because physicians are more impressed by RRRs than ARRs, understanding the measure used to report outcomes is essential.

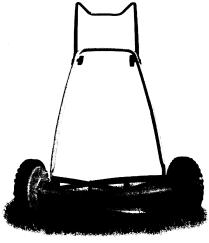
attitude of caution with respect to drug usage, with emphasis on rational drug therapy"; and "Statistics must be presented so as to accurately reflect their validity, reliability and level of significance." An argument can be made that use of RRRs alone to express clinical benefit distorts the value of a product, could lead to incautious use of that product, and therefore, detracts from rational drug therapy. The PAAB should seriously consider amending its code to require that, if results are given as RRRs, then either ARRs or NNTs must also be given. Making and enforcing such a change in the PAAB code would be easier if Health Canada's Health Protection Branch also required use of ARRs and NNTs in their Official Product Monograph because the content of advertisements has to conform to the information in the monograph.

Vigorous attention to teaching critical appraisal skills to medical students, housestaff, and practising physicians would also help doctors to appreciate the nuances of terminology and put them in a better position to evaluate information appropriately not only in advertisements but elsewhere also.

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# Used Regularly, It'll Trim More Than Just Your Lawn.

Thile it may not be commonly thought of as an exercise machine, the humble appliance pictured above is just one of several you probably already own that can contribute to a longer healthier life. In fact, regular yardwork like gardening, raking - or anything that gets you out and active - can improve a lot more than just your property value. Get active for 30 minutes a day, most days of the week, and before long you'll find you have more energy for all sorts of activities. Some of them even fun! After all, you're not the sort to let any grass grow under your feet.

