Support of clinical trials

David Sackett suggests that the Medical Research Council (MRC) is neglecting clinical trials, a key area of health research.[1] In fact, MRC is improving support for clinical trials and correcting some of the problems identified by Sackett.

In fiscal year 1999/2000, MRC's investment in a total of 100 trials is $9.7 million, including 32 trials ($2.0 million) funded through the University–Industry Program. MRC provides $250 000 for trials methodology studies and awards training and career support to trials researchers, such as Michael Kramer of McGill University, an MRC Distinguished Scientist. Industry partner funding, leveraged through the University–Industry Program, provides a further $8.7 million. The total annual investment in MRC-sponsored trials research is therefore in excess of $18.7 million.

MRC's support for trials has more than doubled since 1997/98, while the overall grants budget has increased by 31%. The increase in support of trials is proportionately greater than for any other MRC program. Unfortunately, MRC's budget still cannot support all meritorious applications. Sackett noted that in the last 2 competitions 40% of deserving trial proposals could not be funded; for other grants, the figure was 59%. Financial constraints also force Council to cut budgets of approved grants by usually 10%–20%. In the last 2 competitions, Council has spared the budgets of approved trials, recognizing their unique nature.

MRC has launched a program to support international trials (www.mrc.gc.ca/proposals/proposals.html). We sponsored an evaluation of the outcomes of MRC-funded trials and a recent workshop where leading researchers debated the future of trials research, as MRC transforms into the Canadian Institutes of Health Research. The Canadian Institutes of Health Research's commitment "to excel in the creation of new knowledge and its translation into improved health for Canadians" will require substantial investment in clinical trials.

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If the WCB can do it, why not others?

If ever we need evidence of the failure of state-monopoly medicine, it is found in the emergence of special expedited care for injured workers.[1] Workers' compensation board (WCB) insurance schemes are founded on a sound accounting principle: Is it worthwhile paying more to get the service now, or should the worker wait (and be compensated by the board) until the public system can deliver the care the worker needs? In many cases workers would remain disabled for life if they waited for the public system to respond.

However, this same accounting principle is not carried over into the health care system the rest of us have to live with. It is hypocritical for politicians to turn a blind eye to this practice. Why should injured workers be able to jump the queue while all other citizens are forbidden from using their disposable income to purchase expedited care?

The call to government must be clear. Either fund the system properly or allow citizens to buy medical care privately, much the same as injured workers are now having their surgery paid for privately. The presence of privately funded WCB schemes will ultimately be the litmus test of inappropriate levels of government funding for medicare in Canada.

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Look beyond the skid-row image

By chance I came across an article in *CMAJ* by Deborah Jones[1] that misrepresented the Downtown Eastside of Vancouver in such an irresponsible way that I felt obliged to write even though the article was printed some time ago. An article with questionable research that demonizes Vancouver's oldest community and its diverse population of residents, most of whom are law abiding, does not reflect favourably on a medical journal dedicated to healing.

Jones suggests that some 7000 injection drug users live in the Downtown Eastside. This figure is wrong; many drug users come from outside the community to use the needle exchange. The Vancouver Injection Drug Users' Study (VIDUS; cfeweb.hivnet.ubc.ca), involving 1300 injection drug users over 4 years, reported that 68% of them live outside the Downtown Eastside.

Jones also states that the Downtown

Eastside has a "fluctuating population of 10 000 to 25 000 people." Most community leaders that I talked to agree that the population is from 10 000 to 12 000 if the single family homes in Strathcona are not counted, and from 15 000 to 16 000 if they are. All community leaders agree that the Downtown Eastside has a stable population base. Even residents who move from hotel room to hotel room often do not move out of the neighbourhood.

To label an entire community as "Skid Road" devalues both the local residents and their neighbourhood. When the only thing the media can see is the skid-row image, they cannot see the caring community that exists behind that negative façade.

The article carries an implied tone of contempt for some of the most ill and powerless people in our society and depicts local residents as losers with no redeeming qualities. Without doubt, contempt is the opposite of attention. One thing many residents have in common is poverty, and they live in that stressful condition with a dignity and caring that gives the neighbourhood surprising strength.

I am sure readers would agree with the Downtown Eastside woman who said, "I need to connect with someone who believes in me and helps me believe in myself."[2]

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Real-world effectiveness of antihypertensive drugs

James Wright and colleagues reported results of a meta-analysis of data on the effects of various antihypertensive drugs.[1] Their stated purpose was to assist physicians in choosing an initial antihypertensive drug by systematically quantifying the available evidence on efficacy, defined as lowering blood pressure and preventing adverse outcomes. They did not achieve this goal, however, because they focused exclusively on clinical trial data. Although they mentioned the importance of exercising treatment decisions on the basis of the best available evidence, they failed to remind physicians that the real-world effectiveness of antihypertensive therapies is also largely a function of patient compliance. Unfortunately, although Wright and colleagues included data for study withdrawals, they did not consider that real-world compliance cannot be studied under the conditions imposed by trials.[2]

If they had deemed results from studies that investigated compliance with antihypertensive therapies in actual practice as additional evidence worthy of consideration, physicians would also have been informed that class-specific patterns of persistence with initial antihypertensive drug therapy have emerged.[3–6] Persistence with antihypertensive therapy, for example, is generally poor, particularly for initial therapy with older agents such as diuretics and β-blockers. Therefore, to conclude, as the authors have, that physicians should select a diuretic in the absence of contraindications ignores the best available evidence. If the ultimate goal of antihypertensive therapy is to control hypertension and to avoid cardiovascular events, then physicians must consider *all* available evidence. An antihypertensive medication is only efficacious if a patient remains on therapy, and initial choice of antihypertensive therapy appears to be a significant factor in achieving this outcome.

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[The authors respond:]

We appreciate the letter by Jaime Caro and Krista Payne; however, we disagree with their conclusion. Before doctors consider choosing a drug on the basis of real-world compliance, they should ask 2 questions. Is the evidence suggesting a difference in compliance likely to be true? If there is a difference, what is the magnitude of that difference and is that magnitude likely to lead to a difference in morbidity and mortality? The answer to both questions in this case is No.

With regard to the first question, 2 studies[1,2] suggest that compliance is better with new drug classes than with old drug classes, and 2 studies[3,4] suggest that there is no difference in compliance. These 4 studies are observational and are subject to bias (i.e., patients prescribed drugs from different classes are not comparable). The most likely bias in the 2 studies claiming a difference is that patients receiving new drugs were more likely to have been given a drug sample in the doctor's office. Old drugs are not available as samples. This sampling would not be captured in the database and would bias the results in the direction seen. The authors should have been aware of this confounder but did not mention it. Lower compliance with the old drugs, thiazides and β-blockers, is highly unlikely to be true; a double-blind randomized controlled trial designed to test this hypothesis demonstrated fewer withdrawals with the old drugs than with the new drugs.[5]