Science, cynicism and scarcity

I recently visited the Soviet Union, where I purchased a therapeutic suction cup, a banka, at a pharmacy (Figure 1). When it was introduced perhaps several hundred years ago, it was the cutting edge of therapeutics, used to treat a variety of ailments, from musculoskeletal to respiratory. In traditional medicine, unfettered by the demands of clinical evaluation, without the impetus of innovation and the introspection of self-criticism, this remains a standard of therapy in Siberia.

The pivotal issue in clinical research in Canada today is whether it should be done. We are all painfully aware of the fiscal difficulties which Canada is experiencing. It has become fashionable among the media, both print and electronic, to talk of a crisis in health care. This gives the false impression of worsened outcomes of preventive and therapeutic measures. In fact, Canadians are living longer than ever. The crisis is in health care funding.

The cost of the health care business has grown rapidly. In Ontario, for example, the rate of increase has exceeded the rate of inflation for many years, and now represents one-third of the total provincial budget (1).

Canada’s population is young compared with that of other developed countries, and will age over the next while. The burden of chronic illness and debility will only increase. Economic scarcity will not go away after the present recession is over. We shall have to live with it, and attempt to reap some benefit from it.

The politically correct response to concerns about lack of funds has appropriately focused on prevention being more cost-effective than cure. Enormous efforts have been made to move medical care out of expensive institutions into the community. Along with these efforts has come a certain antitechnology, antidocline. Why invest huge funds in highly paid physicians and expensive drugs and devices, when a modicum of prevention could obviate the need for all of them? Condoms for all, and throw out the doctors and their antiretroviral therapies!

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The logical extreme of successful prevention is immortality of the patient. Many individuals in the community believe that if they avoid dietary cholesterol, cigarettes, alcohol, caffeine and stress, if they exercise regularly, if they avoid bad air and other pollutants, and are careful in their choice of sexual partners, they will live forever. Health care planners share some of this magical thinking, believing that they will be able virtually to eliminate medical services with good prevention. If they are lucky, they will delay the inevitable. If every Canadian became celibate today, it would take us years to eliminate the burden of the human immunodeficiency virus on our health care system and its users. Canadians will continue to get sick and demand medical services before they die. The last year of their lives will remain the most expensive. We must remember that the medicare system that people want is not simply a system of prolongation of life, nor of improvement of the quality of life, as conventionally measured. It is a system of someone being there when the public wants, when they perceive themselves to need the care.

Whatever the changes in society and in health care, it will remain unacceptable to the people of Canada for the medicare system to prolong life without providing the care at the time of need. We may be able to educate
Therapy produced a worse outcome than none (3). Adenine arabinoside (vidarabine), the next agent tested, would be criticized as a diversion of valuable funds from who participated in these studies incurred the terrible first plausible antiviral agent used to treat cause of death and severe disability in its victims. The dine, was found by clinical trial to be excessively toxic. improved mortality, but left an appreciable burden of vidarabine (5). In vitro testing identified potential thera-

Within months of diagnosis, is now cured in excess of 80%. Studies have shown the superiority of acyclovir over the public to reduce their demands of health care providers for trivial – ie, cheap – illness, but not for severe, potentially life threatening disease. What we must learn is how to treat illnesses more effectively and more cheaply. In order to innovate, we need solid clinical research.

There is uncertainty in the outcome of research; there may be delays before any success is achieved. A shining example of successful clinical investigation is acute lymphoblastic leukemia in childhood (Figure 2) (2). This malignancy, which used to be uniformly fatal within months of diagnosis, is now cured in excess of 80% of cases. This remarkable success came not after a breakthrough; rather, after years of painstaking clinical trial. There was early criticism of these studies. Results were modest, to say the least, and the children who participated in these studies incurred the terrible toxicity of their chemotherapy, in addition to the misery of their disease. Were these studies underway now, they would be criticized as a diversion of valuable funds from the delivery of health care.

Another example is herpes simplex encephalitis, a cause of death and severe disability in its victims. The first plausible antiviral agent used to treat it, idoxuridine, was found by clinical trial to be excessively toxic. Therapy produced a worse outcome than none (3). Adenine arabinoside (vidarabine), the next agent tested, improved mortality, but left an appreciable burden of long term neurological dysfunction (4). More recent studies have shown the superiority of acyclovir over vidarabine (5). In vitro testing identified potential thera-

We cannot judge value for dollar in investigative therapies with the same measure as in established management strategies. So long as there are new ideas, and imperfect therapies, we must continue to strive to improve our care. But there is no guarantee of success in clinical research.

We must continue to divert scarce funds from health services to research which offers us hope for the future. Particularly in times of economic slow-down, we are tempted to pursue the expedient, to get an immediate return on our investment. If there is merit in clinical innovation, there is merit during recessions as well as in boom times.

When we look at outcomes of studies with less spectacular results, we must not disregard them, nor downplay their importance. If one cumulates a sufficient number of modest improvements, one achieves great advance.

Appropriate use of new technologies, even apparently expensive ones, can both improve the quality of care and reduce costs. For example, intra-abdominal abscess is a life threatening condition which used to be difficult to diagnose, and which traditionally required major abdominal surgery for drainage. The surgery itself is a major cause of morbidity and perhaps mortality. On occasion the patient was deemed by one physician to be too sick to undergo surgery, and by another too sick not to. With the advent of ultrasound and computed tomography (CT), the ability to diagnose and localize intra-abdominal abscess has improved greatly (6), facilitating surgical management. Many patients are treated with percutaneous CT-guided catheter drainage, with less morbidity of the procedure, and, on occasion, shortened duration of hospitalization (7).

It is said that economies need downturns to exert some control on the products of the enthusiasm of the good times. During booms, companies and institutions expand. They can tolerate inefficiencies and minor misadventures. Their speculative investments are usually successful. In recessionary times, the fat is unceremoniously cut from any surviving concern, perhaps with a little meat as well. There is unceasing examination of every detail under the harsh glare of necessity, looking for anything whose excision the organism will survive, if not thrive on. Organizations which survive the bad times should emerge leaner, more efficient, with a clearer sense of purpose than how they entered them. Can the medical care system similarly benefit from the good times? I believe so. My colleagues and I are involved in endless scrutiny of our clinical practice, looking for new economies. There was little political will...
during the good times to promote our home intravenous antibiotic program in the Ottawa-Carleton area, the safety and economy of which had been well worked out in studies done in Manitoba years before. With that prior knowledge and with the economic necessity, the program came together and home intravenous antibiotic therapy is now a go. Likewise, there has been careful assessment of the necessity of hospitalization for surgical procedures and the desirable length of stay. New anesthetic agents of lower toxicity than old ones for surgical procedures and the desirable length of stay. New anesthetic agents of lower toxicity than old ones and of shorter duration of activity are a part of the technology which allows this. The harsh economic realities facilitate the political and administrative will for innovation.

How well does this jive with public cynicism? No incumbent head of state in the western world has been comfortably ensconced in power during the recent recession, and a number have failed in their attempts at re-election. The public perception of politicians in general is that they take advantage of any opportunity, fair or on occasion foul, that presents itself. Doctors too are perceived as greedy, although they are good to have on side when you’re sick. Their relationship with the pharmaceutical industry is suspect; witness the computers given to compliant physicians by one company. The border between the medical lobby and the pharmaceutical lobby is obscure to the public, and there is neither knowledge of, nor interest in, ethical guidelines of professional and industry associations.

Increasingly, the public is defining the right to set the agenda for issues of importance. More specifically groups particularly affected by matters at hand are demanding a seat at the agenda-setting table. In the medical arena, AIDS activists have won the right to discuss which clinical studies will be done, and how they will be performed. They have changed the entire regulatory process that sets the framework for research into new therapeutic agents, with ‘fast-tracking’. They have developed a new kind of clinical trial, the community-based trial, which has now left the AIDS arena and has been adopted into the realm of clinical research in general. Other lobbying groups have not only attracted considerable public interest, but also political power in the process: for example, women with breast cancer and the elderly. These groups, and others like them, will demand a say in what trials are done, and how they are conducted. We of industry, clinical medicine and academia will be wise to welcome them to the table, and to solicit their opinions. We will be wise to remember our own knowledge and experience in our discussions, and not be unduly swayed by their zeal or dogmatism. If we think they are wrong, we must be frank and clear in our response.

We live increasingly in a participatory democracy. The cynicism of which I spoke is directed against closed door dealings, of what are perceived to be self-serving groups in positions of power.

This is a time of the greatest opportunity to innovate. Economic scarcity demands that we rethink our systems of delivery of care, that we weed out the less effective or ineffective therapy. Further, it demands that proposed new therapies prove themselves not only in the dimensions of safety and efficacy, but also in cost and social utility. It is a time for a new social contract among the providers of care, the recipients of care and industry. The conflict is not between clinical care and research, but rather between expediency and long term gain. For my tax dollar, I'll support the long term.

REFERENCES

R Saginur, MD, FRCP
Ottawa, Ontario