



Health Policy Research

Bulletin

Complementary and Alternative Health Care: The Other Mainstream?

Research shows that, over the past several years, more and more Canadians have been turning to complementary and alternative health care (CAHC) and natural health products (NHPs) to treat illness and promote health. Now, legislators and policy makers are facing some difficult questions about how to assure the safety and effectiveness of such products and practices, while not unnecessarily restricting consumer access. This in turn raises questions about what constitutes an acceptable level of evidence for safety and effectiveness.

This issue of the *Health Policy Research Bulletin* explores these and other questions by:

- defining CAHC and NHPs and exploring how they are positioned among the array of health services and products available to Canadians
- presenting key utilization data on CAHC and NHPs and examining how and why consumers are using them
- discussing the evidentiary challenges that governments face in balancing safety and effectiveness needs with concerns about consumer access and informed choice
- chronicling how Health Canada addressed these concerns in developing the new regulatory framework for NHPs, which comes into effect in January 2004

Finally, the authors question whether, by addressing these challenges, CAHC and NHPs will become more integrated with conventional health care or whether they will remain the “other mainstream.”

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Some Commonly Used Terms

Complementary and alternative health care (CAHC); complementary and alternative medicine (CAM): diagnosis, treatment and/or prevention that complements mainstream medicine by contributing to a common whole, by satisfying a demand not met by conventional approaches, or by diversifying the conceptual framework of medicine.¹ Some common CAHC practices include: chiropractic services, massage therapy and traditional Chinese medicine. While CAM is the term most often used internationally, CAHC recognizes the diversity of practice areas, including medicine, and is the term most commonly used by Health Canada in a policy context.

Health: a state of complete physical, social and mental well-being, and not merely the absence of disease or infirmity.²

Health care: refers to all services, products and activities used by individuals for the purpose of promoting, maintaining, monitoring or restoring health.³

Health promotion: the process of enabling people to increase control over and to improve their health.⁴

Holistic health: physical, mental, emotional and spiritual components of health, and their interrelationship.

Informed choice: the ability of individuals and groups to make choices about their health based on their understanding of the evidence, facts, benefits and risks related to the issue, product or behaviour.⁵

Natural health products (NHPs): NHPs include herbs, vitamins, minerals, essential fatty acids and homeopathics, etc. These products are used to prevent, diagnose or treat disease, restore or correct function, or maintain or promote health. NHPs may be derived from plants, animals or micro-organisms.⁶

Self care: the decisions and actions that individuals take in the interest of their own health.⁷

@ [Click here for references.](#)

For More Information . . .

For more information on natural health products, the new Natural Health Product Regulations, or complementary and alternative health care, please go to the Natural Health Products Directorate (NHPD) website at: http://www.hc-sc.gc.ca/hpfb-dgpsa/nhpd-dpsn/index_e.html or e-mail the NHPD at: NHPD_DPSN@hc-sc.gc.ca or call toll free 1-888-774-5555.

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We welcome your feedback and suggestions. Please forward your comments and any address changes to bulletininfo@hc-sc.gc.ca. Electronic HTML and PDF versions of the Bulletin are available at: <http://www.hc-sc.gc.ca/arad-draa>

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Alternative Practices and Products:

A SURVIVAL GUIDE

Michael J. Smith and Joan E. Simpson, *Natural Health Products Directorate, Health Products and Food Branch, Health Canada*

Although many people are familiar with the terms “complementary and alternative health care” (CAHC) and “natural health products” (NHPs), they often mean different things to different people. The authors provide definitions for both terms and discuss how consumers’ understanding and use of these products and practices have been key factors in the quest for “integrated health care.”

Canadians are faced with a sometimes overwhelming choice of health care options. In addition to the many choices offered as part of conventional health care, they can also choose from among a range of CAHC therapies and NHPs. However, the choice is not always as simple as picking between option A — the conventional, or option B — the alternative. Increasingly, consumers are regarding CAHC and NHPs as useful tools in a comprehensive health care “toolbox” and are looking at ways to combine conventional and alternative therapies and products to achieve the best results.

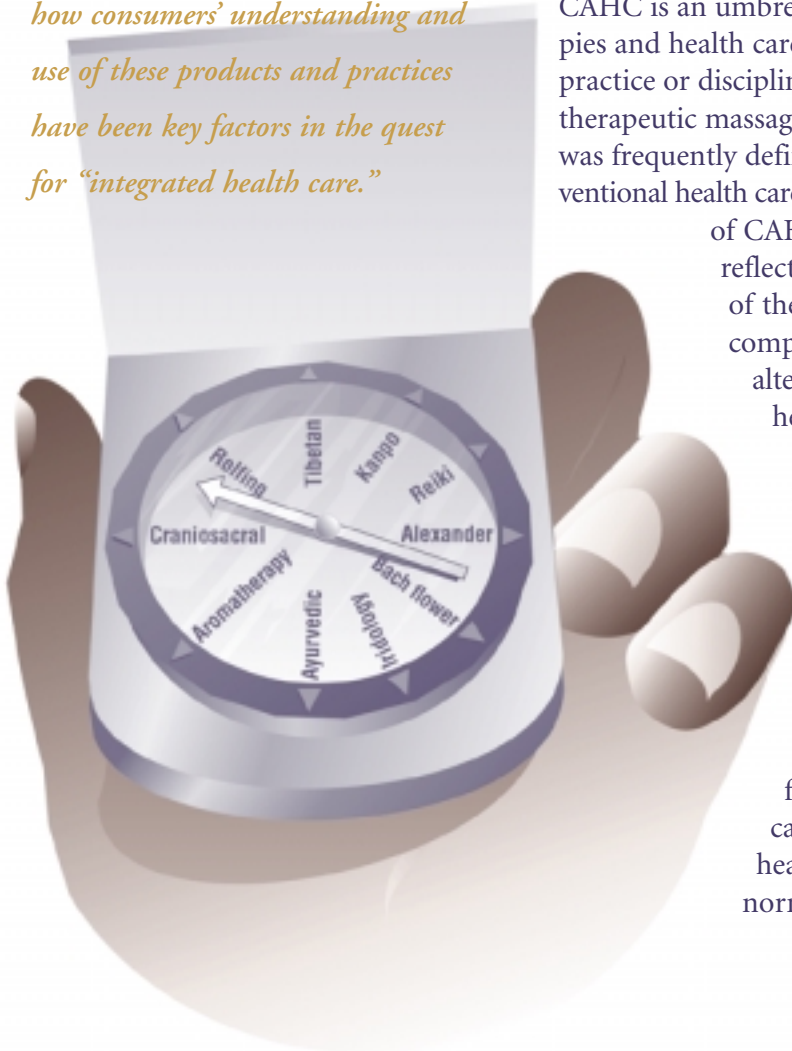
What Is CAHC?

CAHC is an umbrella term used to describe numerous individual therapies and health care approaches (see page 2). As many as 4,000 different practice or discipline areas have been catalogued, including chiropractic, therapeutic massage, homeopathy and herbalism.¹ Until recently, CAHC was frequently defined as alternative to conventional health care. However, the definition of CAHC is evolving to better reflect Canadians’ increasing use of these therapies, especially as complements — rather than alternatives — to conventional health care.²

CAHC therapies range in complexity from entire systems of medicine, such as Aboriginal healing and traditional Chinese medicine, to specific physical/spiritual/pharmacological interventions, such as reflexology, relaxation therapy and herbalism.^{3,4} The majority of CAHC therapies do not follow the biomedical model of conventional health care; instead, they are often based on paradigms of health and healing that are considered “outside the norm” in developed countries. ►

A Sampling of CAHC Therapies

- Alexander technique
- Aromatherapy
- Ayurvedic medicine
- Bach flower therapy
- Craniosacral therapy
- Iridology
- Kanpo medicine
- Reiki
- Rolfing
- Tibetan medicine



Although CAHC encompasses a diverse range of therapies (see box on page 3), they share some common characteristics. For example, they:

- work in conjunction with the body's own self-healing mechanisms
- are “holistic” — i.e., treat the whole person
- involve the patient as an active participant
- focus on disease prevention and well-being

These characteristics are not exclusively the domain of CAHC.³ In fact, many CAHC therapies have more in common with conventional care than with other forms of CAHC. For example, massage therapy is more similar to physiotherapy than it is to homeopathy.

Natural Health Products

Natural health products (NHPs) is a general term (see page 2) used to describe a variety of products, such as herbal medicines, homeopathic remedies and nutritional supplements. NHPs should not be considered a subset of CAHC therapies, as there are some important distinctions between the two. For example, NHPs are generally self-selected by the consumer, while practitioners typically play a key role in the use of CAHC therapies. Moreover, NHPs — like other health care products — are regulated by the federal government, while primary responsibility for CAHC — as for other health care services — rests with the provinces and territories.

Continuum of Product and Practice

It is useful to consider CAHC and NHPs on a continuum that positions specific products and practices in relation to each other, as well as to those in conventional care. For example, a product continuum could go from drugs to NHPs to food. In constructing such a continuum or

situating a specific product or practice along it, a number of factors should be considered, including:

- the potency of the pharmacological/therapeutic action
- the nature of the evidence base
- the degree of regulation
- the extent of cultural acceptance

Taking these factors into account, drugs are often placed at one end of the product continuum: their use is typically supported by rigorous scientific evidence; the products are of high quality; and access is generally restricted to mitigate any potential risk. Food products would fall at the opposite end of the continuum

because they pose low health risks and there is little need for supporting evidence of their effectiveness. Food quality is assured through regulation and consumer guidance (provided through informative labelling), and products are widely available. Generally, NHPs fall between food and drugs on the product continuum. The continuum approach ensures that specific categories of products are not classified as superior to one another, but are measured against appropriate parameters and standards of evidence (see article on page 23).

Where a product or practice is placed on the continuum would vary from country to country. For example, reflexology is a relatively minor therapy in North America, but is a major practice in Scandinavian countries.⁵ Similarly, while the evidence base for homeopathy is the same the world over, the therapy enjoys a much higher profile in Britain than in North America because of its widespread acceptance by British medical practitioners.⁶ In some countries, certain types of CAHC or NHPs are considered a dominant healing practice, for example, traditional Chinese medicine in China and Ayurvedic medicine on the Indian subcontinent.⁷

While the concept of a continuum is informative, it is also useful to

NHPs should not be considered a subset of CAHC therapies, as there are some important distinctions between the two. For example, NHPs are generally self-selected by the consumer, while practitioners typically play a key role in the use of CAHC therapies. Moreover, NHPs — like other health care products — are regulated by the federal government, while primary responsibility for CAHC — as for other health care services — rests with the provinces and territories.

keep in mind basic definitions, which are often influenced by regulations. For example, if new evidence supports a specific health benefit of a particular food, it is not automatically classified as an NHP. This particular food might be closer to the middle of the continuum than some NHPs, but it would still be a food. In the same way, CAHC therapies that are supported by scientific evidence — for example, acupuncture to treat nausea⁸ or chiropractic services for uncomplicated acute low back pain⁹ — are not necessarily regarded as conventional care.

Integrative Health Care

Since many of the same people who are using CAHC therapies and NHPs are also using “mainstream” medicine, links need to be established between the two types of health care options. Consumers have identified this need and are the driving force behind the current move toward “integrative health care.” Integrative care is more than using CAHC/NHPs and conventional care together. It is rooted in the belief that consumers should have the ability to make informed choices about all their health care options. This concept of integrative health care was explored at a recent workshop sponsored by Health Canada’s Health Policy Research Program (see page 35).¹⁰

Fundamental to integrative care is the notion that there must be effective communication among all involved parties, including the patient, the conventional health care provider, the complementary health care provider and government. Enhancing communication is particularly important as consumers



Since many of the same people who are using CAHC therapies and NHPs are also using “mainstream” medicine, links need to be established between the two types of health care options. Consumers have identified this need and are the driving force behind the current move toward “integrative health care.” Integrative care is more than using CAHC/NHPs and conventional care together. It is rooted in the belief that consumers should have the ability to make informed choices about all their health care options.

appear to be reluctant to discuss CAHC and NHPs with members of their conventional health care team. Until recently, it has fallen to consumers themselves to bridge the divide between alternative and conventional health care practitioners. However, as more and more people turn to alternative interventions to complement their conventional health care, practitioners from both sides are starting to communicate with each other, individually and through their organizations. Health Canada is facilitating such linkages by working with community groups, non-governmental organizations and educational bodies on initiatives aimed at better preparing family physicians to counsel patients on the use of CAHC and NHPs, and increasing research literacy among CAHC practitioners.¹¹

A Final Word

Many of the health care products and practices that consumers once considered to be alternative therapies are now viewed as complementary to conventional approaches. Moreover, consumers are recognizing the need for CAHC and NHPs to be “integrated” with mainstream health care options and are calling for action on this front. It has yet to be seen whether this vision of integrated use will be realized, or if CAHC and NHPs will remain distinct as the “other mainstream.” 🌱

@ [Click here for references.](#)

A Policy Challenge: Innovative Solutions

An interview with
Philip Waddington,
Director General of the
Natural Health Products
Directorate, Health Products
and Food Branch, Health
Canada, conducted by Nancy
Hamilton, Managing Editor
of the Health Policy Research
Bulletin.

Q An increasing number of people appear to be turning to complementary and alternative health care (CAHC) and natural health products (NHPs) as a way of treating illness and promoting health. Does the evidence support this observation?

Yes, as pointed out in the article on utilization trends (see page 9), the research shows that the use of CAHC therapies and NHPs has been on the rise over the past several years. However, the evidence also shows that while sales of NHPs increased substantially four or five years ago, sales have now levelled off and, in some cases, even declined.

Q To what do you attribute this recent decline?

While some of the decline is probably due to general economic downturn, the feedback we've received indicates that the decline may also be due to growing consumer dissatisfaction with the outcomes of products that have been available in a relatively unregulated marketplace. In other words, it could be a result of what we call "under-regulation." For example, if consumers tried a product based on a specific health claim and then found it did not deliver the expected effects, they may have turned away from NHPs entirely. I must add, however, that many manufacturers are making NHPs that work well and meet consumer expectations.

Q Your last point suggests a relationship between what you call "under-regulation" and consumer confidence.

To optimize consumer confidence, I believe governments need to find a balance between "under-regulation" and "over-regulation." With under-regulation, there are fewer barriers restricting consumer access, so consumers have access to a wider array of products and services. However, some of these are likely falling short in delivering expected outcomes to consumers. In the case of over-regulation, the market is more restricted. There are fewer products available, but these are supported by a very strong evidence base. Our consultations have shown that what people really want is a balance between these two extremes. They want assurances that products are safe and effective, but they also want access to as many options as possible.

Q *How are CAHC practices and NHPs regulated in Canada?*

CAHC practices are regulated at the provincial level, so I'll only make a few comments about them. Perhaps the most important point is that the provinces and territories are all moving forward at different speeds. Also, the regulatory environment varies from one practice to another. For instance, while some practitioners, like chiropractors, are regulated consistently across the country, others, like naturopaths, are regulated differently in each province. Although the federal government is not responsible for practitioner regulation, we are consulting with practitioners and provincial governments as they address issues related to scope of practice, training and accreditation.

Currently, NHPs must fit into either the “food” or the “drug” category under the federal *Food and Drugs Act* (FDA). According to the FDA, NHPs sold for their nutritional value are regulated as food while those making other health claims are regulated as drugs. However, there is widespread concern that the Food and Drug Regulations (FDR) are inappropriate for NHPs (see article on page 19) and that their application might lead to the removal of many NHPs from the marketplace.

Q *What approach did Health Canada take to resolve what appears to be a regulatory dilemma?*

The House of Commons Standing Committee on Health recognized that application of the FDR to NHPs served neither the consumer nor the industry. In its 1998 report, the Committee recommended that a new regulatory approach be developed. The Office of Natural Health Products — which later became the Natural Health Products Directorate — was established within Health Canada to oversee the development of a new

framework that would be more appropriate to the range of products in this sector.

A pivotal factor in this regulatory initiative has been the extensive consultations held with all major stakeholders, including consumers, manufacturers, practitioners and importers. I believe the time invested in the consultative process has paid off well. As a measure of its value, the new regulatory framework was approved with few amendments and will come into force in January 2004. It is important to clarify that this framework will apply only to NHPs sold over the counter. Products that require practitioner intervention or have a narrow safety margin will continue to be regulated as before under the FDR.

The two main pillars of the framework are, first, the good manufacturing practices (GMPs) and site licensing arrangements and, second, the standards of evidence (SOE). What makes the framework unique is that the GMPs and SOE have been developed with the specific characteristics of the industry in mind. Our goal was to ensure that the GMPs would maximize the benefits and minimize the negative impacts of the new Regulations.



Q *What are the main pillars of this new regulatory framework and what makes it unique?*

The two main pillars of the framework are, first, the good manufacturing practices (GMPs) and site licensing arrangements and, second, the standards of evidence (SOE) (see articles on pages 19 and 23). What makes the framework unique is that the GMPs and SOE have been developed with the specific characteristics of the industry in mind. Our goal was to ensure that the GMPs would maximize the benefits and minimize the negative impacts of the new Regulations. Unlike the pharmaceutical industry, which tends to be dominated by large-scale manufacturers, our Business Impact Test shows a relatively large number of small- to medium-sized NHP manufacturers. We also know that much of the innovation in this industry occurs in smaller companies because they are able to adapt more rapidly as new methods of processing or new products are developed. Imposing unnecessarily strict GMPs could have shut down many of the smaller operations, thereby limiting innovation. ▶

Q *How have the SOE been tailored to this sector?*

Two points are key. First, the SOE for NHPs call for an examination of the “totality of evidence.” For example, two Canadian randomized control trials are typically conducted before a new drug can be brought into Canada. But, under the new SOE, an NHP may not be considered new in Canada if it had been in use somewhere else. In that case, data from the other country could be used to substantiate safety and health claims for the product.

The second point relates to the different levels of evidence that are allowed under the SOE. The Committee recommended that the SOE be appropriate for a range of health claims. For instance, if a product makes treatment claims for a scratch or cut, then one level of evidence is required.

However, if the claims apply to a more serious condition, a higher level of evidence is necessary.

Q *What are some examples of the different levels of evidence provided for under the new SOE?*

As I mentioned, we consider the totality of evidence, including how the product is made and sold, the safety profile of the ingredients and how it is marketed in other countries, as well as evidence from those jurisdictions. We take into account both the traditional and scientific literature. If there are clinical trials, we look at those. We also consider non-randomized trials, as well as expert opinion reports (see article on page 23).

Another level of evidence focuses on whether there has been a history of traditional use. By this, we mean a practice of using that product which has been passed down within a community from one generation to the next. Under the new SOE, a minimum of 50 years is required to make a claim for traditional use. At the other end of the spectrum are products that are “globally” new — they have never

been used anywhere. In the case of a new product where the company provides insufficient evidence that the product can be used safely for the indicated conditions, additional testing or clinical trials are required.

Q *What will happen after the new NHP Regulations come into effect in January 2004?*

It will take six years to fully implement the new Regulations. During the first two years, we’ll focus on product safety by making sure that all manufacturers have site licences and are using the approved GMPs. Approximately 10,000 NHPs (of the estimated 50,000 to 60,000 on the market) currently have Drug Identification Numbers (DINs) issued under the FDR. These

products will have six years to transition to the new framework. The NHPD will be targeting compliance and enforcement actions on a risk-based approach to gradually bring the remaining products into full compliance throughout the first four years that the Regulations are implemented.

There is some uncertainty and a lot of work associated with implementing such a novel regulatory approach, but we’re committed to being vigilant in our follow-up activities so that consumers can realize the maximum benefits.

Q *In closing, how would you respond to potential critics who might say that support for CAHC and the new regulatory approach for NHPs is not sufficiently science based?*

I believe we *are* science based. In my view, science is the practice of observation, recording, making observation-based changes and then moving forward. This is the approach that has been taken by researchers, regulators and others working in the field to ensure that consumers have access to products and practices that are safe and effective. Our bottom line is about enabling consumers to make informed choices about their health care options. 🌟

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Utilization Patterns and Trends

Joan E. Simpson, *Natural Health Products Directorate (NHPD), Health Products and Food Branch, Health Canada*

Special thanks for the input provided by Sari Tudiver, Women's Health Bureau, Health Policy and Communications Branch; David Hoe, HIV/AIDS Policy, Coordination and Programs Division, Population and Public Health Branch; Nancy Lloyd, Centre for Chronic Disease Prevention and Control, Population and Public Health Branch; and Isabelle Caron, NHPD.

The popularity of complementary and alternative health care (CAHC) and natural health products (NHPs) is well documented. Drawing largely from recent studies prepared for Health Canada,¹⁻³ this article highlights current utilization patterns and trends, and examines how and why consumers are using these therapies and products. It also explores the challenges of gathering comprehensive information on consumer utilization.

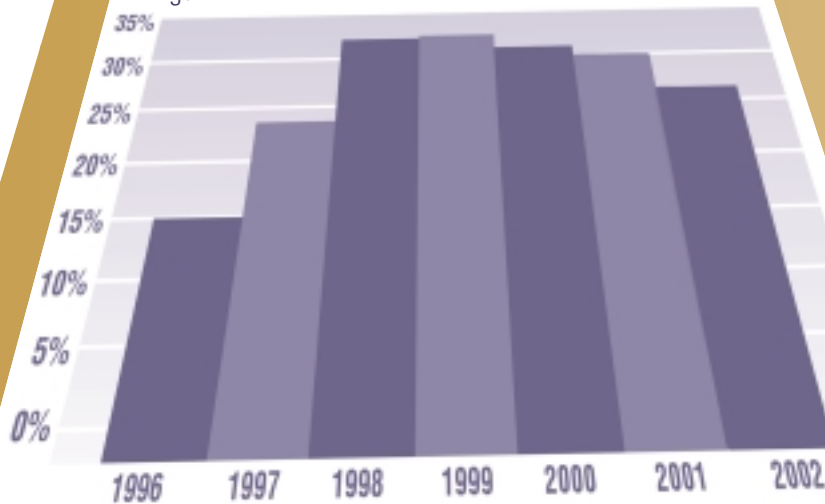
The Big Picture

There is strong supporting evidence that CAHC and NHPs are a large and generally increasing part of the Canadian health care reality.⁴ For example, the Berger Population Health Monitor recently reported that the proportion of Canadians using one or more NHPs in the previous six months rose from 70 percent in 1999 to 75 percent in 2001.⁵ Millar's 2001 analysis of National Population Health Survey data estimated that 19 percent of Canadians made use of CAHC practitioners in 1998 to 1999 (an increase of four percentage points from 1994 to 1995) for services ranging from chiropractic, yoga and massage to acupuncture, homeopathy and meditation.^{6,7} A 1998 survey by the Fraser Institute estimated that Canadians spent \$3.8 billion on CAHC and NHPs between 1996 and 1997.

Although utilization of NHPs increased significantly in the mid- to late 1990s, according to some measures there has been a slight decrease in the past few years. For instance, Figure 1 indicates that while the use of herbal remedies more than doubled during the period 1996 to 1999, there has been a subsequent levelling off since then. This drop may be due to lessened product demand (see interview on page 6), overall market reductions, or some combination thereof.

Figure 2 presents trends in Canadians' use of different types of CAHC practitioners from 1994 to 2001. ►

Figure 1: Use of Herbal Remedies, 1996-2002



Note: These data do not include vitamin and mineral usage.

Source: Nonprescription Drug Manufacturers Association of Canada, updated to 2002 from Hay Health Care Consulting Group's Berger Population Health Monitor, Survey #23 (R. Marles).

Overall, Canadians are making significant use of health care approaches that, until recently, were considered outside the scope of mainstream health care in North America.⁸

About Consumer Utilization Data

Information on consumer utilization offers insights into CAHC product and practice issues, and can help determine the agenda for future policy research. In his reports to Health Canada, De Bruyn^{1,2} describes relevant data sources and groups consumer utilization studies into three categories: research studies,⁹⁻¹² studies based on data from Canadian health surveys^{6,13-15} and public opinion polls.¹⁶

Gathering comprehensive information on the use of CAHC and NHPs presents many challenges, some relating to survey methodologies and others to the definitions of CAHC and NHPs employed in the studies. For instance, reports of CAHC use are affected by respondents' understanding of the terms, as well as their reasons for using a particular product or therapy. For this reason, researchers usually decide to ask about specific CAHC products, practice areas and practitioners in their surveys and define these clearly for respondents. Utilization responses can also be affected by consumers' views about whether a particular product or practice (e.g., prayer, meditation, use

of herbal teas) is a component of health care or just part of daily living. Another significant challenge is the need to appropriately represent Canada's ethno-cultural diversity in survey databases — clearly an area requiring further attention.^{1,17}

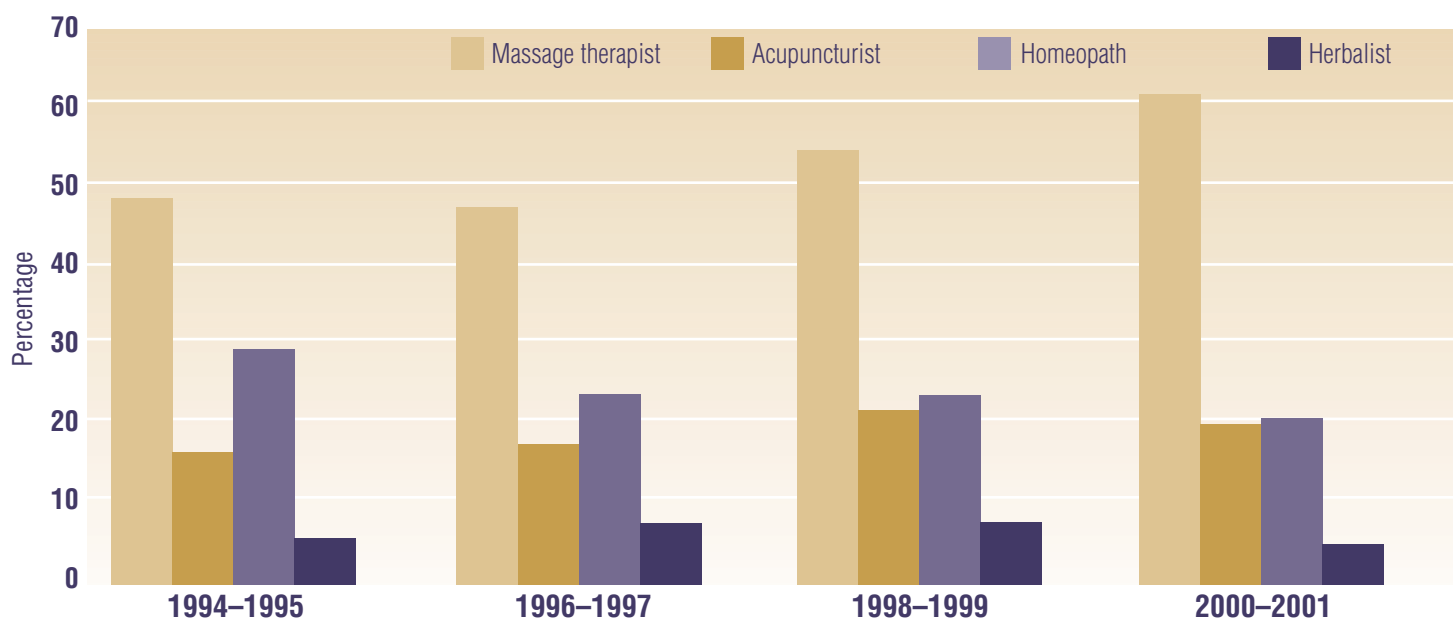
Similar to enhanced utilization studies, gathering information about the health outcomes of using NHPs and CAHC therapies has not been a major focus of health policy research to date.

Why the Widespread Use?

A number of factors may account for the increase in popularity of CAHC and NHPs, such as the rising prevalence of chronic diseases, greater public access to global health information, reduced deference for the decision-making role of conventional health care providers, and an increased sense of entitlement to quality of life.³

The reasons people give for using CAHC and NHPs range widely, from maintaining health and improving quality of life and well-being, to preventing disease, reducing stress, treating a condition or disease, and easing symptoms.³ Eisenberg et al.¹⁰ reported that 58 percent of CAHC treatments were used, at least in part, to prevent future illness or to maintain health and vitality, while 42 percent were used to treat existing illness.

Figure 2: **Use of CAHC Practitioners, 1994–1995 to 2000–2001**



Note: These data do not include visits to chiropractors, the most extensively used CAHC practitioners in Canada.

Source: National Population Health Survey, 1994–2000.

Normally, consumers themselves select an approach, with perceived effectiveness as the major reason for choosing between therapies. CAHC and NHPs tend to be used more often for chronic conditions, such as back pain and allergies, than for acute or life-threatening conditions.^{17,18} Moreover, most people cite positive reasons for choosing CAHC and NHPs, such as a desire to take control over their health, or compatibility with their belief systems, rather than negative reasons such as a fear of or disillusionment with conventional care.¹⁸ While CAHC and NHPs are sometimes used as an alternative to conventional medicine, they are generally employed as an adjunct to other therapies. According to current estimates, only 6 percent of Canadians use CAHC and NHPs to the exclusion of conventional medicine.¹⁷

Who Uses CAHC and NHPs?

Many consumer populations are using CAHC and NHPs, including:³

- the concerned well (who aim to enhance their health for the long term)
- people with specific health problems, ranging from minor to major (e.g., mental health concerns, infectious disease, acute illness or injury, mental illness, long-term disability, chronic disease)
- people with a life-threatening illness
- the terminally ill

Utilization can also vary by specific population groups or among people with different health problems.

Women

As Table 2 shows, women make greater use of CAHC and NHPs than men. In part, this is likely due to women's unique physiology and reproductive roles, which may lead them to seek alternative or complementary treatment, for example, to relieve nausea during pregnancy, induce or decrease lactation and relieve menopausal symptoms. As the "gatekeepers" of family health, women also tend to play a key role in decisions about the type of practitioner to be consulted and under what circumstances. Findings such as these indicate that women and men may have differing CAHC and self-care information needs.

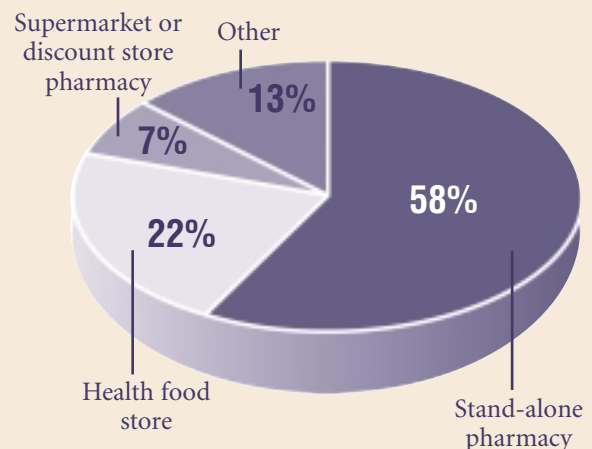
People Living with Chronic Illnesses

The use of alternative therapies by chronically ill populations has been the focus of several recent surveys. ►

Table 1: Use of NHPs*

Use of NHPs is highest in British Columbia and lowest in the Atlantic provinces: Forty-one percent of respondents in British Columbia reported using three or more NHPs in the previous six months, compared with 15 percent of respondents in the Atlantic provinces.

Pharmacies and health food stores are the main source of NHPs: Fifty-eight percent of respondents purchased their last NHP at a stand-alone pharmacy, 22 percent at a health food store and 7 percent at a supermarket or discount store pharmacy. Few NHP purchases were made on the Internet.



More people are consulting their physician or pharmacist about NHPs: Between 1998 and 2000, there was a substantial increase in the number of people discussing the use of NHPs with their physician (from 31 percent to 38 percent) or pharmacist (from 22 percent to 38 percent). Women were more likely than men to discuss NHPs with a conventional health care professional.

*Based on Hay Health Care Consulting Group's Berger Population Health Monitor, 2001.

Table 2: Use of Alternative Practitioners (APs)*

More Canadians are using APs than ever before: The use of APs among Canadians aged 18 or older increased from 15 percent in 1994–1995 to 19 percent in 1998–1999. Since use of chiropractors remained stable during that period, the overall increase may be attributed to the growing popularity of other types of APs (e.g., massage therapists, acupuncturists, homeopaths or naturopaths).⁷

Use of APs increases with education and income:

People with some post-secondary education are more likely to consult an AP than people with less than a high school diploma. People with a household income of \$50,000 or above consult an AP more often than those with a household income under \$20,000.⁷

Women are more likely than men to consult APs: Nineteen percent of women reported consulting an AP in the previous year, compared with 14 percent of men. However, men and women are equally likely to consult a chiropractor.⁷



Use of APs increases with education and income: People with some post-secondary education are more likely to consult an AP than people with less than a high school diploma. People with a household income of \$50,000 or above consult an AP more often than those with a household income under \$20,000.

Residents of Western Canada are more likely to use APs: The use of APs increases from east to west, with the highest rate of use in Alberta. Between 3 percent and 9 percent of people in the Atlantic provinces report consulting an AP, compared with 15 percent in Québec and Ontario, and 21 percent to 25 percent in the western provinces. The higher use in Western Canada may be a reflection of provincial health care plans, which offer some coverage for chiropractic services.⁷

Use of APs is greater among people with chronic conditions or chronic pain:

2001 survey data indicate that 59 percent of Canadians suffer from one or more chronic conditions.¹⁹ In 1998 to 1999, 25 percent of people with three or more chronic conditions consulted an AP, compared with 11 percent of those reporting no chronic conditions. Twenty-six percent of people who reported chronic pain consulted an AP, compared with 15 percent of those with no chronic pain. Use of APs was highest among people suffering from back problems.

**Based on the 1998–1999 National Population Health Survey.*

For example, surveys of people suffering from arthritis and rheumatism report prevalence rates ranging from 82 percent to 94 percent.²⁰⁻²² A British Columbia self-care study on the use of alternative therapies among adults aged 50 and older with arthritis, heart disease or hypertension concluded that “the illness context is critically important in affecting the propensity of individuals to use alternative therapies.”²³

People Living with HIV/AIDS

As discussed in the article on page 16, the use of CAHC and NHPs is particularly high for people living with HIV/AIDS.²⁴ Multiple reasons for this use are cited by consumers, most particularly to gain control over their health, boost immune function, delay and treat symptoms of the disease, help with side effects, relieve stress and improve general well-being.

People Living with Cancer

The 1998 National Population Health Survey indicates that 10 percent of Canadians with cancer report some use of alternative health care, while the related medical literature suggests that upwards of 60 percent of cancer patients use some form of CAHC.²⁵ The most commonly reported reasons are to boost the immune system, improve quality of life and prevent recurrences. Among those living with cancer, people with breast cancer, gastrointestinal cancer and lung cancer are the most frequent users of CAHC and NHPs (see “Who’s Doing What?” on page 28). As well, CAHC is commonly used for children with cancer; in one study, almost 60 percent of child patients were reported to have used one type of complementary or alternative medicine (CAM) during their cancer treatment.⁶

The 1998 National Population Health Survey indicates that 10 percent of Canadians with cancer report some use of alternative health care, while the related medical literature suggests that upwards of 60 percent of cancer patients use some form of CAHC. The most commonly reported reasons are to boost the immune system, improve quality of life and prevent recurrences. Among those living with cancer, people with breast cancer, gastrointestinal cancer and lung cancer are the most frequent users of CAHC and NHPs.

Assessing Products and Practitioners

Canadians using CAHC and NHPs may be doing so with or without the involvement of mainstream health care providers or any other practitioner.⁸ For this reason, it is critical that tools be provided to help consumers make informed decisions about how to access and use the various health care options (as discussed in the following article). Tables 1 and 2 highlight specific patterns and trends concerning access to and utilization of NHPs and CAHC practitioners, based on analyses of Canadian national population survey results.² Although not presented here, more in-depth analysis of user characteristics, for example, use of NHPs and CAHC by various ethnic groups, would be a valuable area for further study.

Moving Forward

Studies are needed to determine with greater detail the extent to which Canadians are opting for CAHC and NHPs. Enhanced studies on the utilization and health outcomes of these products and practices would assist in evaluating the potential for substantial health gains across population groups.

The demand for NHPs and CAHC has implications for health care delivery in Canada. As discussed throughout this issue, Health Canada’s attention has been directed at several key policy areas: developing

an appropriate regulatory framework for NHPs; assessing CAHC health system impacts; and exploring the needs of specific consumer populations for access to and utilization of holistic health care approaches. 🌐

@ [Click here for references.](#)



Did You Know? is a regular column of the Health Policy Research Bulletin examining aspects of health information, data and research that may be subject to misconceptions. In this issue, we investigate the perception that all natural health products and complementary and alternative health care therapies are safe.

It's Natural, So It Can't Hurt Me — Right?

Michael J. Smith and Robin J. Marles, *Natural Health Products Directorate, Health Products and Food Branch, Health Canada*

Many consumers and even some practitioners believe that natural health products (NHPs) and complementary and alternative health care (CAHC) therapies are always safe, no matter what the dosage is or how they are used (see Figure 1). Is this perception accurate? If not, how can we help people make informed, healthy choices, bearing in mind that the typical consumer of NHPs and CAHC is proactive about health care, inquisitive and well educated?

Natural Does Not Necessarily Mean Safe

Like most other things in life — including drugs, food and even motorcycle riding — the safety of NHPs and CAHC therapies depends on the amount or dosage, the characteristics of the user and the context in which they are used. More specifically, many of the risks associated with NHPs and CAHC fall into the following three categories:¹

Errors of Omission

Put simply, this means that by not doing the right thing, you are doing the wrong thing. For example, taking a herbal medicine that is inappropriate may cause consumers to ignore more proven or appropriate care (either

complementary or conventional). As a result, their condition may deteriorate.

Intrinsic Procedural Risks

These are problems that arise directly from using a product or practice. Because the body's organ systems and metabolic processes are complex and interactive, any health product is likely to have side effects. There is also the risk that NHPs may be adulterated with other substances (e.g., drugs), contain the wrong herb, or be contaminated as a result of poor manufacturing practices. NHPs may also interact with other substances, including conventional drugs, other NHPs or even foods.

Situational Amplifications

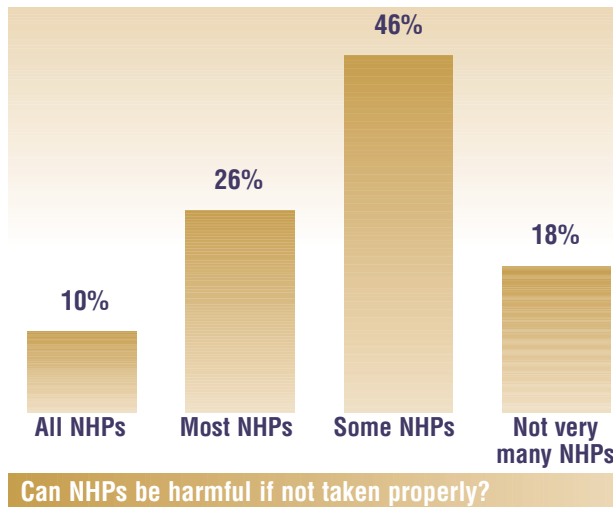
In this case, the condition worsens — usually temporarily — as a result of taking the “correct” NHP or CAHC. An example is the temporary and minor muscle aches some people experience after chiropractic manipulation.

Different Strokes (and Doses) for Different Folks

Not everyone responds the same way to conventional medications or NHPs. For example, children experience different growth and development characteristics as neonates (< 1 month), infants (1–12 months), toddlers (12–42 months), preschoolers (3.5–6 years), children (6–12 years), and adolescents (12–18 years). These stages of development affect how children absorb, distribute, metabolize and excrete drugs, as well as the product's actions. Children are also more susceptible than adults to the effects and toxicity of some products, but are better able to tolerate others.²⁻⁴

For many NHPs, documents describing traditional use provide little or no specific information on dosage for children, leaving parents and practitioners to either guess at or calculate the appropriate amount. (The situation is not much better for conventional drugs, since their

Figure 1: Perception of the Potential Risks Associated with the Misuse of NHPs, 1998



Source: Canada Health Monitor, 1998. Price Waterhouse Coopers National Survey Centre.

use in children is commonly “off-label” as well due to the lack of clinically-derived information on children’s dosage and pharmacology.) A number of dosing formulae for children have been proposed for use by health care practitioners, none of which is regarded as completely reliable.^{5,6}

Similarly, seniors often have special safety issues because of low body weight, coexisting health conditions and the use of multiple medications, including both conventional drugs (over-the-counter and prescription) and NHPs. As NHP use is not generally recorded in a patient’s history, it is difficult to watch for NHP-drug interactions in seniors, or in other groups with infectious or chronic diseases.⁷ Physicians are encouraged to start medications at a low dose and to monitor for side effects while increasing the dose to the lowest effective level, which may also help to minimize interactions.^{8,9}

Ginkgo Leaf Extract — An Example

Ginkgo leaf extract is an excellent example of how NHP use and dosage varies by population. Ginkgo extract contains a blood-thinning agent and has been clinically shown to reduce cognitive impairment in geriatric patients by improving blood flow throughout the brain.¹⁰ However, ginkgo may interact with other blood thinners to increase the risk of hemorrhage, emphasizing the importance of good patient–physician communication about the use of NHPs.

Advertisers have falsely extrapolated the benefits of ginkgo products by promoting them to young people as a way of improving their memory and cognitive functioning. Although these products are unlikely to help young people (as most have normal blood flow in the brain), ginkgo extract does have a potential use in children. Clinical evidence supports its use as an adjunct in the treatment of bacterial blood infections.¹¹ However, as children are not generally included in clinical trials, practitioners can only guess at an appropriate dose.

A Question of Communication

Effective communication between consumers, conventional and complementary health care providers, and government is critical in ensuring consumer safety. Results from several surveys¹² suggest that two thirds of people who use NHPs and CAHC do not tell their physicians they are doing so. Health Canada

is collaborating with partners such as the Association of Canadian Medical Colleges to improve physicians’ knowledge of CAHC and NHPs so they can better counsel their patients.

When something does go wrong, consumers are less likely to report the problem with an NHP than a drug, and are more likely to tell a neighbour or family member than their doctor or pharmacist.¹³ Effective reporting of adverse events is a major research priority and Health Canada is working with domestic and international partners to ensure proper reporting procedures, provide for effective risk communications with CAHC providers, and determine when an adverse event results from an adulterating substance or other factor rather than the NHP itself.

Communication between CAHC providers and conventional health care providers is a two-way process in which the responsibility lies equally with both groups to establish a good working relationship. For instance, conventional providers may not always be familiar with a specific NHP or CAHC therapy and, thus, they need to know when to refer a patient to a CAHC practitioner. Similarly, CAHC providers

may not always have the necessary training to make the best decision for a patient and must know when to make a referral to a conventional practitioner. Increasing consumer and practitioner understanding of the potential risks (and benefits) associated with CAHC and NHPs is vital in helping Canadians use them safely, effectively and respectfully. 🌱

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Finding the Balance:

Safety, Effectiveness and Access

David Hoe, HIV/AIDS Policy, Coordination and Programs Division,
Population and Public Health Branch, Health Canada

For some time, individual Canadians have been trying to balance concerns about safety, effectiveness and access as they use complementary and alternative health care (CAHC) and natural health products (NHPs) to maintain and improve their health. This article suggests that comprehensive frameworks and standards for the delivery, development and monitoring of CAHC and NHPs could promote consumer confidence by helping to ensure the safety and effectiveness of these products and practices. One case in point illustrates how people living with HIV/AIDS have successfully integrated CAHC and NHPs into their health care regimes.

Individual Balancing Acts

Canadians' considerable use of NHPs and CAHC suggests that they view these products and practices as an important complement to conventional health care and a valuable opportunity to improve their health.

When deciding whether to use a CAHC therapy or an NHP, each person performs a risk/benefit analysis. Among other factors, individuals must consider the product's or therapy's effectiveness and safety. Although a wealth of information exists about many products and practices, there are accuracy and reliability concerns. Furthermore, decisions must often be made without the assistance of an adequately informed practitioner. Consumers must also consider the financial costs because they pay "out of pocket" for the majority of products and practices. Currently, only selected practices are covered by third party insurers, most of them for a limited period.

While consumers of conventional health care interventions also perform risk/benefit analyses, mainstream health care has a well-established system or "orthodoxy" for balancing risk with benefit for an expected outcome. This orthodoxy encompasses components to help consumers assess the quality and safety of products and practices, and ensures training and standards for practitioners themselves, as well as for their use of drugs and medical devices. It is designed to assist consumers in making informed health care choices based on the best available evidence and to help practitioners provide safe and effective interventions.

Although the absence of such a comprehensive orthodoxy for CAHC and NHPs allows consumers access to a wide range of practices and products, it also has a variety of negative impacts. For example, consumers may not be fully informed, information about interventions may not be accurate or reliable, claims for effectiveness may not be justified and practitioner training may not be adequate. Many products and practices are well known and widely accepted; however, others give rise to a number of questions concerning their safety and effectiveness



(see box). Even though CAHC and NHPs may not pose some of the risks associated with certain mainstream health care interventions, such as surgery, these interventions cannot be assumed to be risk free (see “Did You Know?” on page 14).

A Role for Governments

In fact, concerns about the risks of using CAHC and NHPs have been associated with a possible decrease in consumer confidence that has contributed to recent declines in utilization (see the interview on page 6). If consumers are to be assured of the safety, quality and effectiveness of these practices and products, governments have a valid role to play in informing the consumer’s decision-making process by helping to identify the risks and benefits of CAHC and NHPs.

As with mainstream health care, governments’ primary tools for balancing access with assurances of safety and effectiveness are the regulation of products and practitioners, and the application of common law principles to practitioners. Jurisdiction in this area is divided, with the provinces and territories responsible for regulations concerning practitioners and the federal government overseeing product regulation. At this early stage, however, all levels of government can demonstrate leadership by guiding discussions on how CAHC and NHPs can be integrated effectively with mainstream health care. Specifically, governments can collaborate with each other, the scientific community, consumers, manufacturers, CAHC practitioners and policy developers to:

- develop standards of evidence for the safety and effectiveness of products and practices
- develop appropriate models of regulation that do not unnecessarily limit choice or access
- determine the role that CAHC and NHPs can play in helping Canadians maintain and improve their health

What Do We Know About Different CAHC Therapies and NHPs?

Some NHPs and CAHC practices are widely used, well accepted and raise few questions concerning their safety and effectiveness. For example, massage therapy is regarded as a credible therapy for helping to reduce stress and heal certain physiological conditions, while vitamins are widely used to improve nutritional balance. Many people turn to traditional Chinese medicine to treat a broad range of diseases. Similarly, Aboriginal people often integrate traditional healing methods with their health care regimens. It must be cautioned, however, that the field encompasses a vast array of products and practices, not all of which enjoy the same levels of use, evidence and consumer confidence.

- put in place necessary frameworks to prevent harm while respecting citizen autonomy
- strengthen professional bodies of CAHC practitioners to maintain training and other standards, and to conduct research designed to increase the effectiveness of their practices
- protect the environmental sustainability of natural resources used for healing, such as wild herbs used by Aboriginal healers

Government Action

Until recently, individuals and consumer organizations, such as people living with HIV/AIDS (see box on page 18), have been trying to balance concerns about safety, effectiveness and access in the absence of comprehensive frameworks and standards. However, governments at all levels have started to take action in this area. The article on page 19 highlights new federal activity aimed at providing a safe, evidence-based and appropriately regulated field for the production, consumption and monitoring of NHPs. Some provinces and territories have recognized education and practice standards for specific types of CAHC practitioners, though these approaches are not identical across the country. For example, chiropractic services and massage therapy are commonly recognized through regulation or registration, although many other CAHC practice areas are not.¹

Research Is Key

Although governments have made significant progress, there is still some distance to go to ensure that access to CAHC and NHPs is balanced with safety and effectiveness. Much work remains on expanding the evidence base to determine whether these products and practices achieve their intended health outcomes, which methods are the most effective, whether specific products and practices are safe, and under what circumstances they may not be safe and/or effective. ►

HIV/AIDS: A Case in Point

Over the past 20 years, people living with HIV/AIDS (PHAs) in Canada have developed substantial expertise in the use of CAHC and NHPs. Based on their experiences, PHAs have become vocal critics of this field, as well as of mainstream health care.

Greater Reliance on CAHC and NHPs

When the HIV/AIDS epidemic began, the conventional health care system did not have medications for the treatment and care of PHAs. On the other hand, alternative health care systems and providers offered literature on care of the immune system and suggested treatment options that could be accommodated into the daily lives of those affected by the disease. CAHC and NHPs provided relief through touch and energy work, addressed the issues of stress and pain reduction, and raised hopes of prolonged survival through improved self care in nutrition, physical movement, spiritual health and healing the immune system. The continuing use of CAHC and NHPs and their integration into the health care plans of many PHAs has led to a critical examination of the field and increased expectations for effective products and practices, and new frameworks that position CAHC and NHPs alongside conventional health care strategies.

While results vary across the country, several Ontario studies report that from 67 percent to over 90 percent of PHAs use complementary and alternative medicine.² This rate is approximately twice as high as that cited in a 1997 CTV/Angus Reid poll on the use of alternative medicines and practices by all Canadians (42 percent).

Integration with Conventional Care

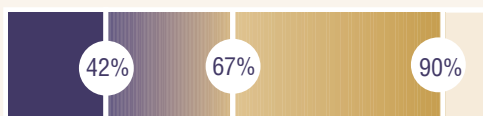
It is very common to find CAHC as part of the array of services available in community-based AIDS organizations. Massage therapy, Reiki therapy, nutritional counselling, relaxation and stress reduction are among the services offered to maintain and

improve the health of people affected by the disease. In their work to ensure Canadians living with HIV/AIDS have access to effective products and therapies, the Canadian Treatment Action Council places CAHC on an equal footing with conventional treatments and therapies. Moreover, NHPs — including nutritional supplements, vitamins and minerals — are widely used to help people manage the impacts of HIV and the medications used to treat the disease.

Although research on the use of CAHC by PHAs is limited, one in-depth qualitative study concluded that: “complementary therapies represent different things for these individuals — a health maintenance strategy, a healing strategy, an alternative to western medicine, a way of mitigating the side-effects of drug therapies, a strategy for maximising quality of life, a coping strategy, and a form of political resistance. . . . These meanings are neither mutually exclusive nor fixed. The therapies often appeal to individuals on different levels and their appeal may change over time.”³

An Impetus for Change

In integrating CAHC and NHPs into their health regimes, PHAs and their organizations have focused on how to ensure access to a range of options while providing the information needed to make informed choices. As a result, the experience of PHAs has become the impetus for further examination of this field and its place in the lives of people managing a serious health condition. Furthermore, it has highlighted a number of key issues such as: the importance of CAHC and NHPs to Canadians; the barriers that prevent access to informed choice of both products and practices; and the need for comprehensive systems that fully integrate CAHC and NHPs with contemporary health care approaches. 🌐



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@ [Click here for references.](#)

An Innovative Approach to Regulation

Sinéad Tuite, *Natural Health Products Directorate, Health Products and Food Branch, Health Canada*

In response to growing concerns about the regulatory environment for herbal remedies, Health Canada has developed a new regulatory framework for natural health products (NHPs). Scheduled to come into effect on January 1, 2004, this innovative framework is the product of extensive consultation with a range of stakeholders.

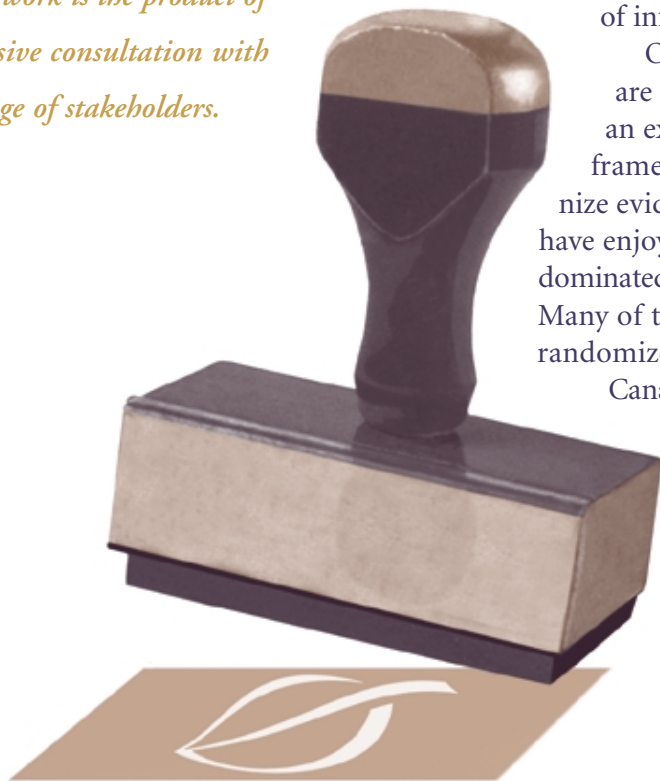
A Regulatory Dilemma

As pointed out in the interview on page 6, new NHP Regulations will come into effect in January 2004. Until then, NHPs will continue to be regulated as either food or drugs under the federal *Food and Drugs Act* (FDA) and Food and Drug Regulations (FDR). Under these Regulations, some NHPs are classified as foods, while other products carrying health or therapeutic claims are classified as drugs.

Neither of these classifications is appropriate for NHPs, however. For example, products classified as food cannot make health claims,* nor are they required to have full product use information on their labels or to undergo any type of pre-market approval. This has raised concerns about product safety and effectiveness, and the adequacy of information for decision making.

On the other hand, NHPs that are regulated as drugs are required to meet a very rigorous set of requirements. As an example, the standards of evidence for drugs consist of a framework based on clinical trials that does not readily recognize evidence based on a “history of safe use,” which many NHPs have enjoyed.† As Figure 1 illustrates, Canada’s NHP industry is dominated by small and micro firms with fewer than 20 employees.¹ Many of these firms could not support the considerable cost of randomized control trials. Furthermore, while the FDR use

Canada’s patent system to encourage innovation, the majority of NHP findings cannot be patented because the medicinal ingredients are found in nature, rather than being proprietary formulations. This limits the ability of NHP manufacturers to recoup the costs of developing new products or holding clinical trials. ►



*Recent changes to the FDA now permit a limited range of health-related claims for certain foods — for example, claims that position the food as part of healthy eating, or claims regarding the function or biological role of recognized nutrients.

†The Traditional Herbal Medicines Policy and Labelling Standards for Single Dilution Homeopathic Medicines do not require clinical trial evidence for these products.

Figure 1: **Number of Firms by Number of Employees**



Source: Health Canada, *Business Impact Test on the Natural Health Product Regulations, 2003*.

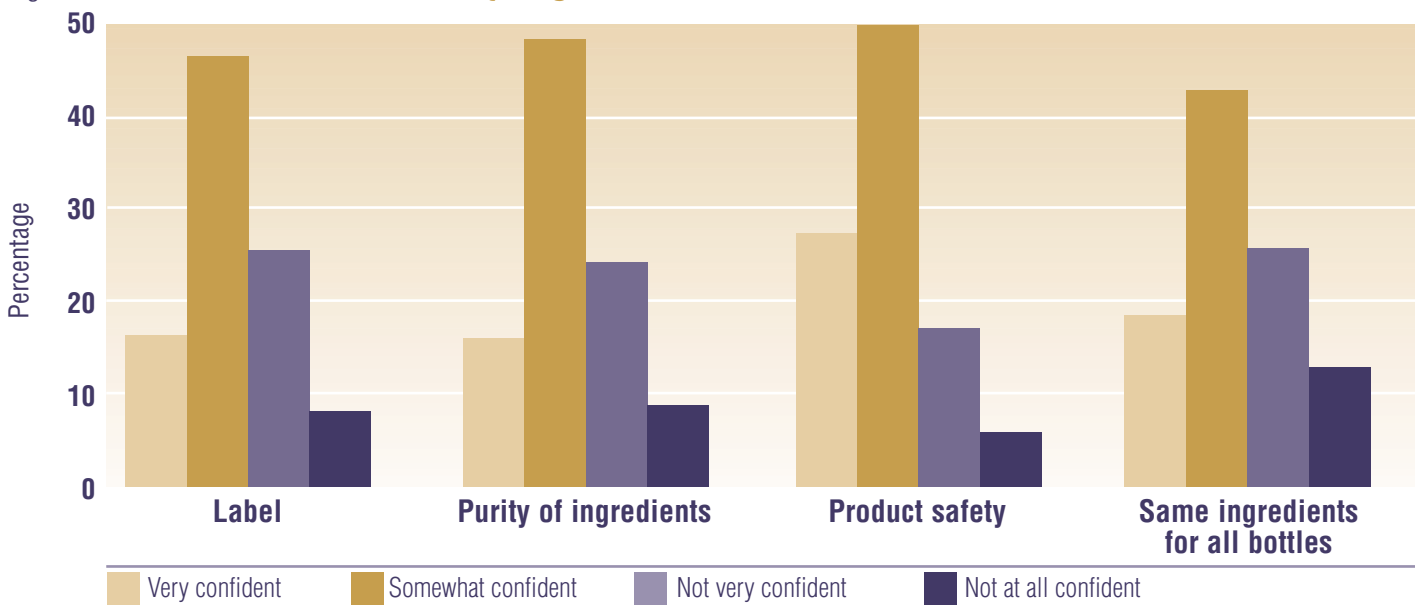
(For information on how the new regulatory framework encourages innovation through intellectual property rights, see page 27.)

The current regulatory environment has led to confusion in the marketplace as consumers attempt to choose between a substance labelled as a food (without health claims or full product use information) that sits on the shelf next to a similar or identical substance labelled as a drug (with health claims and adequate directions for use). As shown in Figure 2, this situation has not encouraged a high level of consumer confidence in the quality of NHPs.

A Catalyst for Change

By 1997, the growing dissatisfaction among consumers and the NHP industry had resulted in calls to re-examine the regulation of herbal remedies. Although many stakeholders viewed the regulatory regime for drugs as too rigorous for NHPs, there was also concern about whether all NHPs should be regulated as food products. Industry and consumers urged that the health benefits of NHPs be reflected in their labelling, while consumers also pressed for assurances about product quality and information on the health

Figure 2: **Confidence of Canadians in the Quality of NHPs**



Source: Hay Health Care Consulting Group, *Berger Population Health Monitor, Overview Report March 2001*.

What the Regulations Address

The new Regulations, which will also be under the *Food and Drugs Act*, provide direction in the following areas:

- definitions
- product licensing
- site licensing
- good manufacturing practices (GMPs)
- clinical trials
- labelling and packaging requirements
- adverse reaction reporting

benefits of individual products. Moreover, consumers indicated to Health Canada that they were willing to accept reasonable price increases in order to obtain these assurances.¹

Health Canada responded by establishing an Advisory Panel on NHPs and the Minister of Health announced a full public review of the regulatory regime for NHPs by the House of Commons Standing Committee on Health. The Committee heard from more than 150 individuals, associations and coalitions, and made 53 recommendations for a new regulatory framework. The Committee’s final report, *Natural Health Products: A New Vision*,² was presented to the House of Commons on November 4, 1998.

In March 1999, the Government accepted the recommendations as the basis of a broad policy framework for NHPs. In response, the Minister of Health created the Office of Natural Health Products — now the Natural Health Products Directorate (NHPD) — to oversee development of a new regulatory regime that would provide consumers with assurances of safe, effective and high quality products, while respecting Canadians’ freedom of choice, and philosophical and cultural diversity.

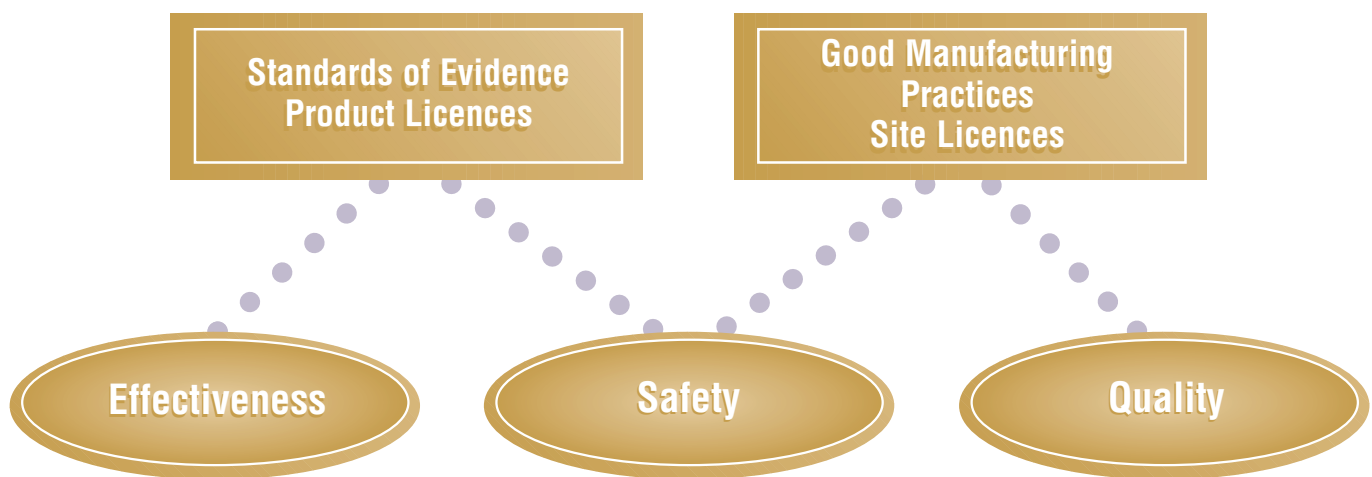
Best Practices in Stakeholder Consultations

The regulatory framework for NHPs was developed in extensive consultation with more than 2,100 stakeholders in 11 cities, including industry representatives, health care providers, academics and consumer groups. Once the Regulations were drafted, a series of working groups or “town halls” were convened to examine specific issue areas. Throughout the process, an expert advisory committee and industry working group provided input on relevant scientific, policy and operational matters.

A New Regulatory Framework

The new framework outlines standards of evidence that are more appropriate for NHPs than the standards of evidence in the FDR and sets out innovative approaches for achieving the Regulations’ objectives. ▶

Figure 3: **Specific Components Address Particular Concerns**



Under the new regime, NHPs can make claims related to structure and function, risk reduction, treatment and general nutrition. As outlined in the following article (page 23), the level of evidence required to support a product claim is graduated, based on the level of health claim. As proof of product effectiveness, Health Canada will accept a range of corresponding evidence, including traditional references, prior marketing experience, observational studies and clinical trials.

If applicants wish to conduct a clinical trial on an NHP, they must obtain authorization from Health Canada. To ensure that reviewers have the appropriate expertise, the Research Ethics Board that examines the clinical trial must have at least one member knowledgeable in complementary or alternative medicine.

Applications for Marketing NHPs

Under the new regulatory regime, all NHPs sold in Canada will require pre-market assessment and authorization of their safety and effectiveness. Using the standards of evidence, Health Canada will evaluate applications based on the totality of evidence available.

The new NHP Regulations also require product licence applicants to submit a listing of each product's medicinal and non-medicinal ingredients. To assist consumers in making informed choices, non-medicinal ingredients must appear on product labels along with medicinal ingredients.

Health Canada is developing a Compendium of Monographs outlining known safety and effectiveness information for the most



NHP Regulation in Other Countries

Regulation practices for NHPs vary considerably from country to country. Similar products are generally labelled as “drugs” in countries in the European Union.³ Australia recently classified many of these products as “complementary medicines” and made legislative and regulatory changes to regulate them as a subclass of “therapeutic goods.”⁴ In the United States, many NHPs are regulated as “dietary supplements,” which do not require pre-market review or proof of safety by the manufacturer and are not permitted to make treatment-cure claims.⁵ In Canada, NHPs will be classified as drugs under the FDA; however, they will be regulated separately under the new NHP Regulations.

commonly used ingredients on the market (see also page 26). Applicants will not be required to submit additional supporting data if their product's active ingredients meet the monograph specifications. The Regulations commit Health Canada to processing applications within 60 days, a timeframe that is designed to allow for efficient processing of a large volume of applications.

The regulatory framework also requires the manufacturer, packager, labeller and/or importer of each NHP to have a site licence. This will enable Health Canada to ensure that the products appearing on Canadian markets are of high quality and are made according to good manufacturing practices (GMPs) in licensed facilities (see also page 26).

As shown in Figure 3, the main framework components, such as the standards of evidence and GMPs, each address a need for safety, quality and effectiveness.

Looking Ahead

The NHP Regulations will come into force on January 1, 2004. A two-year transition period for site licensing and a six-year transition period for product licensing will allow the industry to adjust gradually to the new requirements (see the interview on page 6). Health Canada will conduct a full review of the regulatory framework at the end of this period and make adjustments based on experience and stakeholder and consumer feedback. 🌐

@ [Click here for references.](#)

The Evidence Base for Evaluating *Natural Health Products*

Robin J. Marles, Ph.D., *Natural Health Products Directorate,
Health Products and Food Branch, Health Canada*

H Health Canada has developed standards of evidence for evaluating licence applications for natural health products (NHPs). These standards were developed after extensive stakeholder consultation and harmonize well with international criteria. Applying these standards to the regulation of NHPs will allow consumers access to products that are safe and effective, and will facilitate consumers in making informed choices.

Regulating NHPs

One of the challenges in developing new Regulations for natural health products (NHPs) was to achieve an appropriate balance between generality and specificity. On one hand, the Regulations must be general enough to:

- encompass the more than 50,000 NHPs currently being sold
- allow for industry innovation in bringing new products to market
- respect freedom of choice, and philosophical and cultural diversity

On the other hand, the Regulations should be specific enough to:

- ensure that Canadians have access to NHPs that are safe, effective and of high quality
- enable consumers to make informed choices about personal health care

Responsible regulation requires that this balance be determined following a thorough examination of the evidence concerning NHPs.

Benefits of an Evidence-Based Approach

An evidence-based approach to regulating NHPs is expected to have a number of benefits:

- NHPs that fail to meet Health Canada's standards, or whose manufacturers do not apply for a product licence, will be removed from the market.
- Consumers will experience the health benefits of NHPs whose safety, effectiveness and quality are established by an evidence-based, pre-market approval system.
- Boosting consumer confidence that "what is on the label is in the bottle" will help create an increased demand for NHPs.
- Practitioners and pharmacists will be increasingly confident in making recommendations about NHPs.
- With a clear set of regulations specific to NHPs, industry participants will have a level playing field in which all products are required to meet the same set of standards. ▶



In addition, the cost of maintaining Canadians' health may decrease as consumers are better able to safely and effectively self-medicate. If this proves to be true, governments will benefit as well.

Standards of Evidence

Once the Regulations are in force in January 2004, every NHP sold in Canada must be issued a product licence, which registers it with Health Canada. As described in the article on page 19, the regulatory framework will outline newly developed standards of evidence (SOE) specific to the needs of NHPs. SOE are clearly defined criteria concerning the amount and type of evidence required to support each claim for safety, effectiveness and quality.

International Harmonization

Since Canada has active trade relationships with the United States, Europe, Asia, Australia, Latin America and Africa, Canadian NHP Regulations were also developed within the context of the international regulatory environment. Furthermore, Agriculture and Agri-Food Canada, the Canadian Forest Service and their provincial counterparts are exploring the possibility of expanding domestic production of NHPs to help diversify Canada's farm and forest product industry. Keeping these points in mind, Health Canada has established an evidence evaluation framework based on categories developed by the United States Agency for Healthcare Research and Quality¹ and adopted with minor modifications by the World Health Organization,² the European Agency for the Evaluation of Medicinal Products³ and the Australian Therapeutic Goods Administration.⁴

A Flexible Framework

An important feature of the new SOE approach is the recognition that a gradient of evidence strength exists and varying strengths of evidence can be used to support the claims of safety and effectiveness in a product licence application. As Table 1 indicates, the new regulatory framework incorporates a range of evidence levels. This is designed to allow considerable flexibility in the claims that manufacturers are permitted to make about an NHP. Simply put, the stronger the claim, the stronger the supporting evidence needs to be.

Effectiveness

Some of the major categories of health claims are described briefly in Table 2. To be allowed, a claim must correspond to the level and totality of the

Table 1: Evidence Levels

Level	Types of Evidence
I	well-designed systematic reviews and meta-analyses of randomized controlled trials (RCTs) or at least one well-designed RCT (preferably multi-centred)
II	well-designed clinical trials without randomization and/or control groups
III	well-designed descriptive and observational studies, such as correlational studies, cohort studies and case control studies
IV	expert opinion reports, peer-reviewed published articles, or conclusions of other reputable regulatory agencies
V	references to traditional uses

Table 2: Types of Claims

Claim Type	Explanation	Examples
Treatment	diagnosis, treatment or cure, mitigation, or prevention of disease, disorder, abnormal physiological state or its symptoms	treats upset stomach, relieves cramping and bloating due to indigestion, cures stomatitis
Risk reduction	reduction of a major risk factor for a chronic disease or abnormal physiological state	helps prevent infection and inflammation, promotes healing of wounds
Structure/Function	effects on a human body structure, a physiological or mental function	aids digestion

evidence of effectiveness which is available, meaning that higher level (i.e., stronger) evidence contradicting lower level (i.e., weaker) evidence will take precedence. As an example, scientific reports indicating that some comfrey products are toxic when taken internally would override claims about traditional uses of comfrey tea, unless evidence is presented that the product is free of these toxins.

As discussed in the interview on page 6, product claims may be traditional or non-traditional. The wording “traditionally used” may be applied to any of the claim types shown in Table 2 (except for conditions not appropriate to self care), if two independent references document at least 50 years of continuous traditional use within a particular culture or healing paradigm.

The herbs Roman chamomile, German chamomile and peppermint leaf can be used to illustrate how the SOE allow a variety of health claims to be made for a single NHP, based on the level of evidence supporting the product’s effectiveness and safety for each proposed purpose.

Roman Chamomile

Roman chamomile tea has long been “traditionally used to treat upset stomach” in Europe. Hence, this would be an acceptable claim supported by Level V evidence.⁵ As there is no clinical data (Levels I or II) to either support or contradict the claim,⁶ a stronger claim cannot be made. Texts on herbal safety (Level IV evidence) suggest that Roman chamomile is generally a safe product, except for pregnant women or people who are allergic to other members of the daisy family,^{7,8} a risk that can be mitigated by cautionary labelling.

German Chamomile

There is also Level V evidence that German chamomile, a distant relative of the Roman herb, is “traditionally used to treat upset stomach.” Moreover, there is clinical evidence (Level II) and further experimental animal and *in vitro* evidence (Level IV) supporting the treatment claim that it can be used effectively “for relief of cramping and bloating due to indigestion.” However, a claim that it can cure inflammations such as stomatitis would not be acceptable as there is only suggestive evidence (Level II) to support it, not conclusive evidence (Level I). Data on previous market experience could be used as additional sources of Level IV evidence. For example, despite a long history of high sales, there

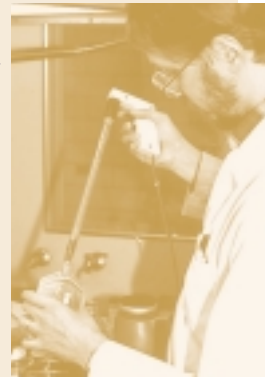
are few reports of problems resulting from consumption of German chamomile tea other than cross-reactivity in people allergic to other members of the daisy family.^{7,8} Levels I and III evidence support a risk reduction claim that German chamomile extracts applied topically “can help prevent infection and inflammation and promote healing of wounds.”⁹

Peppermint Leaf

Level V evidence about peppermint leaf tea supports the treatment claim that it is “traditionally used to relieve indigestion” and the structure/function claim, “traditionally used to aid digestion.” Furthermore, peppermint leaf oil in enteric-coated capsules could be marketed with a highest level treatment claim, ▶

Assessing Product Safety

- Are individualized instructions, practitioner supervision or routine lab monitoring required to ensure the safety or effectiveness of the substance?
- Is the substance used in treatment of a disease that is not appropriate for self care, e.g., a serious disease easily misdiagnosed by the public?
- Does use of the substance mask other ailments or their development?
- Does it have known adverse reactions at the recommended dose?
- Is there a narrow margin of safety between therapeutic and toxic doses, especially in seniors, children, and pregnant or nursing mothers?
- Has it demonstrated potential for addiction, abuse or severe dependency?
- Have experimental data shown that the substance induces toxicity in animals? Long enough to establish a pattern of toxicity in humans?
- Does it have known interactions with other NHPs, drugs or foods?
- Is it known to affect results of standard laboratory or other diagnostic tests?
- Is it likely to contribute to the development of resistant strains of microbes?
- Does the substance possess a high level of risk relative to expected benefits?



“clinically proven to provide symptomatic relief in irritable bowel syndrome,” because it is supported by a meta-analysis of clinical trials (Level I evidence).⁹

Safety

Evaluating the safety of NHPs is challenging because the full range of safety and toxicological data is often not available. Thus, it is particularly important that different types of evidence are recognized in the SOE, meaning that available information, such as history of use, can be used in evaluating product safety issues.

Some of the questions that will be used to assess product safety are presented in the box (page 25). For each “yes” response, Health Canada will assess whether the potential risk can be mitigated using such risk management tools as labelling.

All full product licence applications for NHPs must contain a “safety summary report” highlighting any safety issues identified in a thorough review of published scientific literature. For products that have never been used in humans, repeat-dose toxicity, genotoxicity and reproductive toxicology testing will be mandatory. Depending on the results of these baseline tests, further toxicity testing may be required.

Quality

Quality is a key issue in consumer protection. Many adverse effects initially attributed to NHPs have been traced to quality control problems such as contamination, adulteration or substitution with the wrong herb (e.g., contamination of the safe herb plantain with the heart drug digitalis leaf^{10,11}). To counter this concern, manufacturers, importers, packagers and labellers of NHPs will be required to submit evidence of compliance to NHP good manufacturing practices (GMPs),¹² in order to obtain a site licence.

GMPs set out requirements for places (premises, equipment), people (personnel, quality assurance staff), processes (sanitation program, operations) and products (specifications, stability, sterile product preparation, samples, records and recall reporting).

General specifications include tolerance limits for contaminants, while specifications unique to a particular substance may include chemical tests for markers to identify a particular species or variety of herb, or for levels of active or toxic constituents to support particular claims of effectiveness and safety. The variability inherent in products produced from nature makes

quality control more challenging for NHPs than for conventional drugs. However, without some assurance about the product’s quality (e.g., crop quality, potency), there can be no certainty about the quality of the evidence, for example, from a clinical trial.

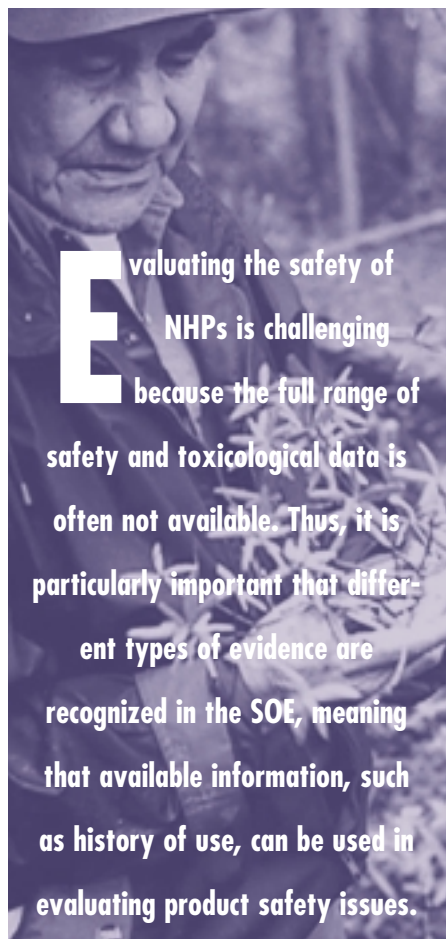
SOE in Action

Under the new Regulations, NHPs can obtain a product licence in one of two ways:

- **attestation** — the NHP conforms to the specifications of a product monograph in Health Canada’s Compendium
- **full assessment** — the NHP is submitted for a complete assessment, together with evidence to support its safety, quality and health claims

Product Monographs

A Compendium of Monographs is being prepared to assist in registering the safest and most commonly used NHPs on the Canadian market. Sources include monographs published by the World Health Organization,^{13,14} the German Commission E,⁶ the European Scientific Cooperative on Phytotherapy,¹⁵ the British Herbal Compendium,¹⁶ the American Herbal Pharmacopoeia,¹⁷ and other standard texts and peer-reviewed articles. As discussed in the article on page 19, Health Canada is evaluating almost 300 substances for possible product monographs, which will include the proper and common names of the source organism, source part (e.g., leaf, stem), recommended method of administration, dosage form, use or purpose, dose, duration of use, risk information and references.



Full Assessment

As all supporting evidence must be assessed according to the SOE, Health Canada will require considerably more time to process a full submission for a product licence application than to determine whether a product conforms to a monograph. However, one of the benefits of the full assessment procedure is that it will allow for industry innovation in the development of new single ingredient and combination products (see “Protecting Intellectual Property,” below).

While many NHPs have only one medicinal ingredient, almost 60 percent of NHPs currently sold contain a combination of medicinal ingredients. Moreover, this proportion may be on the rise as manufacturers vie for shares of a growing market. Although some combination products have a long market history and are therefore eligible to be monographed, there are an almost infinite number of possible combinations of medicinal ingredients. To address these concerns, a “Combinations Policy” has been developed that establishes clear industry guidelines concerning substances that can and cannot be combined, how medicinal and non-medicinal ingredients should be listed, how to adjust dosages, what evidence is required to support the combination of ingredients, and the rationale in support of the safety and effectiveness of a particular combination of substances.

Protecting Intellectual Property

Conventional drugs are generally given 20 years of patent protection so that manufacturers can recoup the considerable expense of preclinical and clinical drug development. Generic manufacturers wishing to make the same claim as the original patented drug must demonstrate the bioequivalence and/or pharmaceutical equivalence of their product. As most NHPs do not have the level of patent protection available for synthetic drugs, other incentives are needed to encourage industry innovation. To protect the intellectual property rights of the licence holder, proprietary data such as clinical trials submitted in support of a product licence application for an NHP will not be incorporated into monographs or otherwise released. Moreover, as the new NHP Regulations do not contain a bioequivalency clause, competitors making the same claim must submit their own evidence supporting the safety, effectiveness and quality of their product.

Regulation Versus Access

Since health care practice is subject to provincial rather than federal jurisdiction, the Regulations will not cover NHPs that physicians and complementary and alternative health care providers (e.g., Aboriginal traditional healers) prepare for their patients on an individual basis. Thus, the Regulations will not alter practitioners’ access to health products already within the scope of their practice. Furthermore, enforcing the Regulations may increase practitioners’ confidence in the safety, effectiveness and quality of registered NHPs and encourage them to recommend these products to their patients.

The NHP Regulations apply only to substances safe for over-the-counter use. Access to NHPs will be more uniform when the evidence-based approach to risk management is applied to exclude high risk products and to recommend mitigation strategies for self-care products. If Health Canada were to create a list of prescription NHPs, the right to prescribe them would vary from province to province. A registered health profession, such as naturopathy in Ontario, Manitoba, Saskatchewan and British Columbia, could be given that right by the provinces, but as yet no province has given naturopaths prescribing rights.

A Concluding Note

Health Canada’s evidence-based approach to regulating NHPs gives industry substantial flexibility in how they bring NHPs to the marketplace and also allows consumers ready access to a variety of products for self care. Harmonizing the SOE framework with the regulatory environment in other countries will help facilitate Canada’s international trade in NHPs. At the same time, consumer and practitioner confidence will likely increase as claims for safety, effectiveness and quality are evaluated according to clear criteria established with broad stakeholder input. 🌐

Thanks to Melissa Johnson, Yad Bhuller and Cicely Gu of the Natural Health Products Directorate for their assistance in assembling the information for this article.

@ [Click here for references.](#)



Who's Doing What?

Who's Doing What? is a regular column of the Health Policy Research Bulletin profiling key players, including Health Canada, involved in policy research in the current theme area. This issue profiles a sample of governmental and non-governmental organizations working in the field of complementary and alternative health care and natural health products.

Isabelle Caron and Joan E. Simpson, Natural Health Products Directorate, Health Products and Food Branch, Health Canada

Health Canada Showcase

The following activities illustrate the diversity of Health Canada's involvement with complementary and alternative health care (CAHC) and natural health products (NHPs). The following program areas are participating in an intradepartmental initiative to define policy issues and Health Canada's role in this area.

• CAM in Medical Curricula

The Department's Health Human Resource Strategies Division, Health Policy and Communications Branch, is working with the University of Calgary and the Association of Canadian Medical Colleges on a curriculum-related research initiative to facilitate the physician's role with respect to complementary and alternative medicine (CAM). Having agreed to include CAM content, Canadian undergraduate medical education programs are currently identifying and developing capacity-building tools in the areas of knowledge, skills and attitudes. With assistance from Health Canada, a national team of educators is working on curriculum implementation issues and held a workshop in the fall of 2003. Policy research issues include the recognition of CAM within the

conventional health care system and the role of physician information in decision making. For more information, e-mail: Frank_Cesa@hc-sc.gc.ca or Joan_Simpson@hc-sc.gc.ca

• Health Promotion and CAHC

The Health Policy and Communications Branch initiated policy research on a variety of CAHC health systems issues, including information, informed choice, educational approaches and product/practice issues. Building on this work, the Health Products and Food Branch incorporated health promotion as a component of the Natural Health Products Directorate's responsibilities in implementing an NHP regulatory framework. Current policy research activities include enhancing information provided to the public and practitioners, developing practitioner research capacity and contributing to departmental policy development (see: http://www.hc-sc.gc.ca/hpfb-dgpsa/nhpd-dpsn/research_e.html).

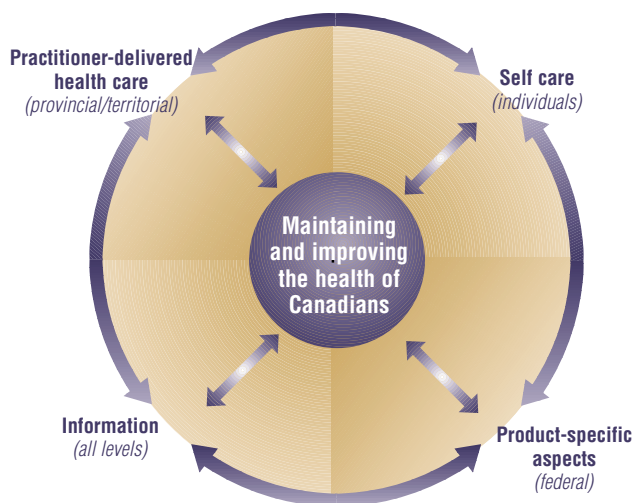
• Informing the Public

The Canadian Health Network, Population and Public Health Branch, provides multiple sources of credible and practical electronic health promotion and disease and injury prevention information to Canadians, including information on CAHC and NHPs. Policy research questions focus on, for example, assessing information source and quality, and balancing diverse perspectives (see: <http://www.canadian-health-network.ca>).

• NHP Research Program

Following up on the recommendations made by the 1998 Standing Committee on Health in its report on NHPs, the Natural Health Products Directorate will work with other Health Canada jurisdictions, the Canadian Institutes for Health Research and external partners to invest \$5 million

Integrative Health Care



Joan E. Simpson, July 2003.

over the next five years to support a variety of research initiatives in the area of NHPs. The research will focus on themes such as support of original product research, building research capacity, developing community infrastructure and partnerships, and enhancing knowledge transfer (see: http://www.hc-sc.gc.ca/hpfb-dgpsa/nhpd-dpsn/research_e.html).

Highlights of External Activities

- **Interdisciplinary Capacity Enhancement Network, Funded by the Canadian Institutes for Health Research**

The goal of the Complementary and Alternative Medicine — Interdisciplinary Capacity Enhancement Network (CAM ICE) is to create a sustainable, well-connected research community in Canada that is internationally recognized for its excellence and contributions to understanding CAM and its use. Led by researchers from the University of Toronto and the University of Calgary, the team will include professionals from various disciplines, including medical sociology, pharmacology, epidemiology, medicine, chiropractic, naturopathic medicine and ethics. Among the issues CAM ICE will focus on are: building a sustainable network that supports researchers studying CAM from a health services and policy perspective; developing research priorities, agenda and capacity; promoting knowledge transfer among researchers, health care practitioners, policy makers, research funders and the public; and linking with other relevant networks, organizations and educational institutions. For more information, contact: Dr. Heather Boon (heather.boon@utoronto.ca) or Dr. Marja Verhoef (mverhoef@ucalgary.ca).

- **Use of Complementary Therapies by Cancer Patients, Funded by the National Cancer Institute of Canada**

There are indications that interest in and use of complementary therapies is increasing among cancer patients. A new study led by the University of

Saskatchewan in conjunction with researchers from five other provinces will examine the prevalence, characteristics and use patterns of complementary therapies by cancer patients in six Canadian provinces during the first two years after diagnosis. The study, which aims to generate data currently unavailable in Canada, will provide information relevant to patients and their families, health professionals and the health care system. For more information, contact: Dr. Anne Leis (leis@sask.usask.ca).

- **CAM and Children and Youth: Legal, Ethical and Clinical Issues, Funded by the Hospital for Sick Children Foundation**

Although the use of CAHC and NHPs is growing rapidly in Canada, little is known about their use among children. Because of the vulnerability of the paediatric population, this application raises specific legal, ethical and clinical concerns. Plans are

Little is known about the use of CAHC and NHPs among children. Because of the vulnerability of the paediatric population, this application raises specific legal, ethical and clinical concerns. Plans are currently under way for an interdisciplinary research project that will develop the basis for a policy framework for consideration by hospitals, relevant professional organizations and government bodies.

currently under way for an interdisciplinary research project that will develop the basis for a policy framework for consideration by hospitals, relevant professional organizations and government bodies. Led by Osgoode Hall Law School at York University, Toronto Hospital for Sick Children, the University of Toronto and the University of Alberta, the project will involve researchers from the University of Alberta, York University, Toronto Hospital for Sick Children, Canadian College of Naturopathic Medicine and Harvard University. In the first stage of the study, researchers will collect and analyze Canadian and American data on legal, ethical and clinical issues raised by the use of CAHC and NHPs for children. In the second stage, case

scenarios will be developed to help identify gaps in information and generate recommendations for future health policies. For more information, contact: Dr. Joan Gilmour (jgilmour@osgoode.yorku.ca) or Dr. Christine Harrison (christine.harrison@sickkids.ca). ☎



Using Canada's Health Data is a regular column of the Health Policy Research Bulletin highlighting some of the methodologies commonly used in analyzing health data. This issue focuses on microsimulation modelling and illustrates how it can be used to determine the potential impact of various policy options.

Microsimulation Modelling: A Tool for Policy Analysis

Vishnu Kapur and Kisalaya Basu, *Applied Research and Analysis Directorate, Information Analysis and Connectivity Branch, Health Canada*

Policy makers are often faced with the task of choosing the most appropriate policy from an array of possible options. Typically, policy analysis tools such as macro-models help to inform decision makers about the impact that policies are likely to have on government finances and “average” Canadians. In many cases, however, decision makers also want information that will help them gauge how policies will affect different subgroups of the population including, for example, seniors, low-income families and single-parent families.

What Are Microsimulation Models?

Microsimulation models use micro data — i.e., household or individual level data — to show the distributional impact of policy changes on individuals or individual households, as well as on government finances. They do this by using a simplified representation of “real world” individuals or households to simulate the effect of policy changes. The data underlying the models — which can include hundreds or thousands of observations — embody a built-in population that often has the same distribution of characteristics as the actual population. Models such as these can also incorporate the rules of different expenditure and/or tax programs, allowing researchers to calculate the financial impact of policy changes on households or individuals in the database.

Microsimulation models are becoming increasingly popular among policy makers because they significantly enhance the evidence base for decision making by demonstrating the implications of policy options before they are put in place. The models work by imposing a policy change on individuals and households, and comparing the results to the status quo. The impacts are then “rolled up” to a level of aggregation useful for policy analysis. A sensitivity analysis can determine the “winners and losers,” that is, which types of households are better or worse off as a result of the policy change. These impacts are displayed in tables and graphs organized according to various socioeconomic factors, such as income level, education level and family type (e.g., seniors, two-parent, single-parent).

The PHARMASIM Microsimulation Model

Both the final report of the Commission on the Future of Health Care in Canada¹ (the Romanow report) and the Senate Committee Report, *The Health of Canadians — The Federal Role*² (the Kirby report), drew attention to rising drug costs in Canada. The Kirby report observed that many Canadians are becoming at risk for financial hardship due to the high cost of prescription drugs. To assess this hardship, policy analysts need information about the extent and degree of drug coverage in Canada. Health Canada's PHARMASIM microsimulation model not only provides this information, it also enables analysis of the fiscal and distribution effects of a wide range of options for enhancing drug insurance benefits.



Models Need Sound Data

One of the problems in building a reliable microsimulation model is the lack of a single data source containing information about all the necessary “real world” variables, for example, socioeconomic status,

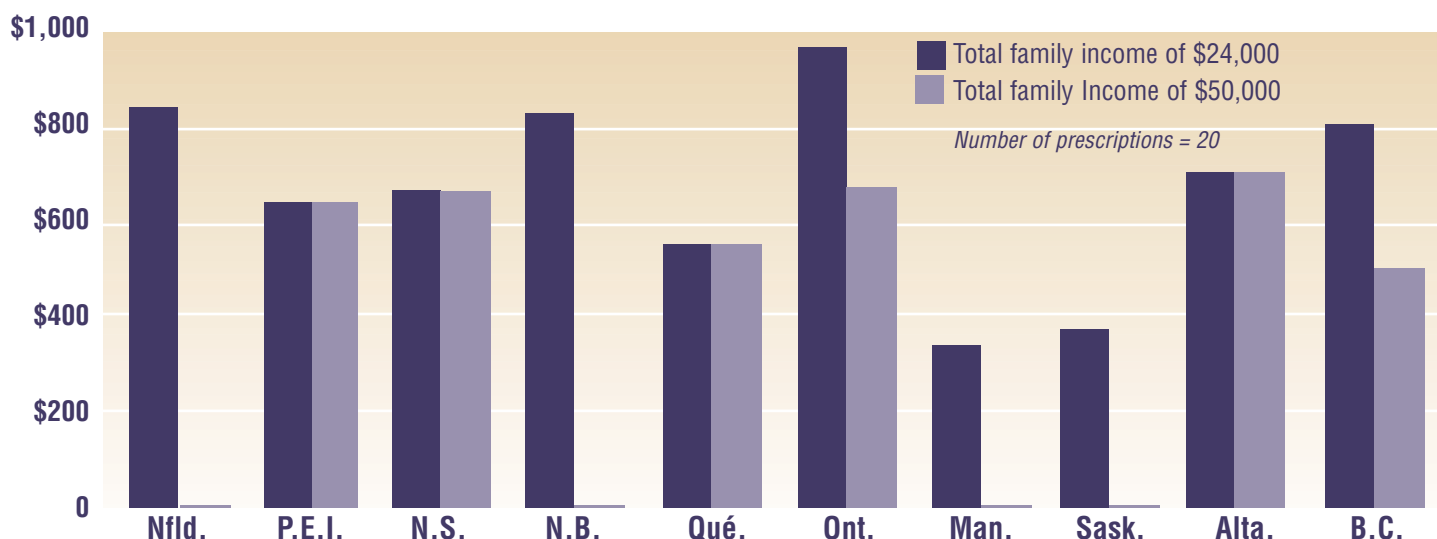
Table 1: **Data Sources and Available Variables**

Source Data	Variables Available			
	Socioeconomic	Drug Coverage	Tax Deductions	Drug Expenses
1. Survey of Consumer Finances (SCF)	Detailed	No	No	No
2. Survey of Household Spending (SHS)	Summary	Partial	No	Out-of-pocket only
3. Personal Income Tax System	Some	No	Yes	No
4. National Population Health Survey	Summary	Yes	No	No
5. Private Insurance Claims Data	Some	Not explicitly	No	Yes
6. Public Plan Claims Data	Some	Not explicitly	No	Yes

Table 2: **Extent of Coverage in Canada (% of Population)**

Province	Conventional and Catastrophic Plans (%)	Conventional Plans		
		Total (%)	Public (%)	Private (%)
Newfoundland and Labrador	67.8	67.8	20.5	47.3
Prince Edward Island	71.5	71.5	24.4	47.1
Nova Scotia	78.1	78.1	19.7	58.4
New Brunswick	75.1	75.1	17.9	57.2
Québec	100.0	100.0	43.3	56.7
Ontario	100.0	83.3	22.8	60.4
Manitoba	100.0	69.0	8.8	60.2
Saskatchewan	100.0	67.3	15.3	52.0
Alberta	80.1	80.1	16.5	63.7
British Columbia	100.0	76.8	21.6	55.2
All provinces	96.1	84.5	26.1	58.4

Figure 1: Comparison of Provincial Drug Benefits for a Typical Senior Couple with Annual Drug Costs of \$1,000



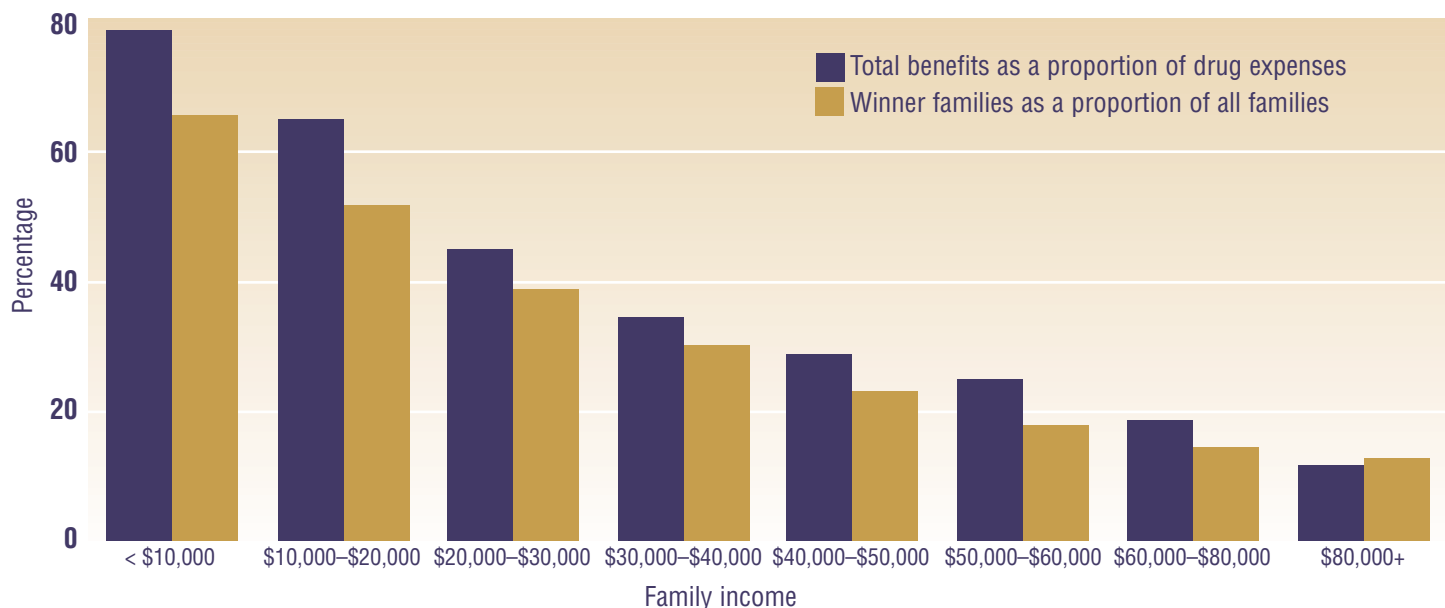
gross drug outlays, drug insurance coverage and out-of-pocket expenses. In the case of PHARMASIM, Health Canada researchers synthesized data from six different sources to develop a comprehensive database on drug expenditures and coverage. As Table 1 shows, each data source contains a unique “slice” of the information required for the PHARMASIM database. A number of statistical techniques were employed to meld data from these diverse sources, including statistical matching and imputation.^{3,4}

Understanding Current Patterns of Coverage

As indicated in Table 2, the new database can be used to illustrate the extent of drug coverage in Canada.⁵

Drug coverage can be analyzed along two dimensions — whether or not a household has any coverage at all, and the degree to which each household is covered. The data show that more than 96 percent of Canadians have some form of drug coverage. Almost 85 percent have a conventional (non-catastrophic) plan that compensates to varying degrees for a considerable

Figure 2: Impacts of Proposed Drug Subsidies



portion of prescription drug expenses. One quarter (26 percent) of Canadians are covered by a provincial (public) plan, compared to 58 percent that have a purely private plan (such as an employer-provided plan). In some cases, there is overlap between public and private plans.

Modelling the Status Quo

Using the new database and information on provincial drug plans, PHARMASIM can model existing provincial drug benefits for various Canadian sub-populations. Figure 1 illustrates the considerable provincial variation in drug insurance coverage for senior couples with low and average incomes. All provinces cover the drug costs of low-income households, for example, those on the Guaranteed Income Supplement (GIS) or social assistance. However, seniors with higher incomes are not provided with provincial coverage in New Brunswick, Newfoundland and Labrador, Manitoba or Saskatchewan (although the latter two provinces offer catastrophic coverage).

Econometric analysis models⁵ can provide further insights into patterns of coverage. For instance, the groups most vulnerable for lack of coverage generally include: people living in rural areas; young adults (under 35 years of age); adults aged 55–64; single people; people with no post-secondary education; self-employed or part-time workers; households in lower income brackets (\$10,000–\$30,000); and people living in Atlantic Canada, Manitoba and Saskatchewan. People in the 55–64 age group tend to have the highest out-of-pocket drug expenses because they have high drug consumption rates and relatively low rates of drug coverage. This group is not as well covered as the younger age groups because many people have left the work force due to early retirement or health problems. Neither is the 55–64 age group as well covered as seniors, who are eligible for provincial drug plans.

A Hypothetical Policy Change

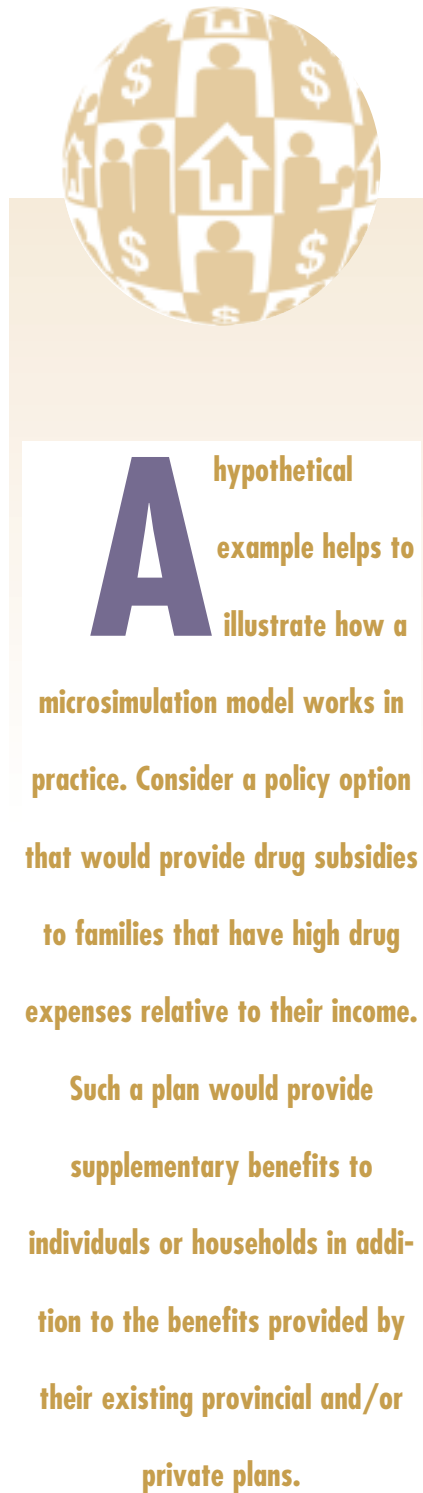
A hypothetical example helps to illustrate how a microsimulation model works in practice. Consider a policy option that would provide drug subsidies to families that have high drug expenses relative to their income. Such a plan would provide supplementary benefits to individuals or households in addition to the benefits provided by their existing provincial and/or private plans. Capped at \$1,500, the benefits would equal family out-of-pocket drug expenses above a progressive deductible of 1 percent to 3 percent of net family income. (It should be noted that this proposal is not made in either the Romanow or the Kirby reports, although some features from these reports were used to develop this example.)

According to PHARMASIM, the proposal would reduce family out-of-pocket expenses by a third (over and above expenses that are currently reimbursed). As Figure 2 illustrates, the proposal is progressive because it favours families with lower incomes. There are no “losers” under the proposed plan and the number of “winning” families declines with income, as does the average amount of gain.

Conclusion

Identifying the Canadians most likely to suffer financially from high drug costs can help policy makers design pharmacare programs that best meet the requirements of those who need them the most. By providing distributional and fiscal estimates of the impact of new programs and changes to existing programs, microsimulation models such as PHARMASIM can help ensure these programs balance affordability and effectiveness. 🌐

@ [Click here for references.](#)





New and Noteworthy is a regular column of the Health Policy Research Bulletin highlighting “up and coming” policy research in the health field.

Modelling Human Resource Needs

Working in collaboration with the Health Resourcing and Economics Branch of Alberta Health and Wellness, Health Canada’s Microsimulation Modelling and Data Analysis Division (MSDAD) has built a Health Human Resources (HHR) demand model that calculates the requirements for physicians and registered nurses in Alberta from 2000–2030. Completed in December 2002, the model simulates the relationship between the health characteristics of the population and the human resources required to meet its health needs. Such a model, when combined with MSDAD’s HHR supply models, can help Health Canada examine the implications of population aging for HHR supply and demand and identify potential gaps. The information can then be used to develop focused and informed policy responses at the national and provincial levels. For more information, e-mail: Gordon_Hawley@hc-sc.gc.ca

Climate Change and Health

The health and social impacts of climate change on Canadians within the context of the Kyoto Protocol was the focus of recent discussion at an Expert Panel Workshop on Climate Change and Health & Well-being in Canada. Organized by the University of Ottawa, the workshop will provide input to Health Canada’s Climate Change and Health Office (CCHO) as it leads the development of the health component of the next National Climate Change Impact Assessment. Canada is scheduled to complete the Assessment by 2005 as part of its commitment to the United Nations Framework Convention on Climate Change (UNFCCC). Updates on relevant policy research activities on climate change and health are available at: <http://www.hc-sc.gc.ca/cc>

Improving the Health of Canadians

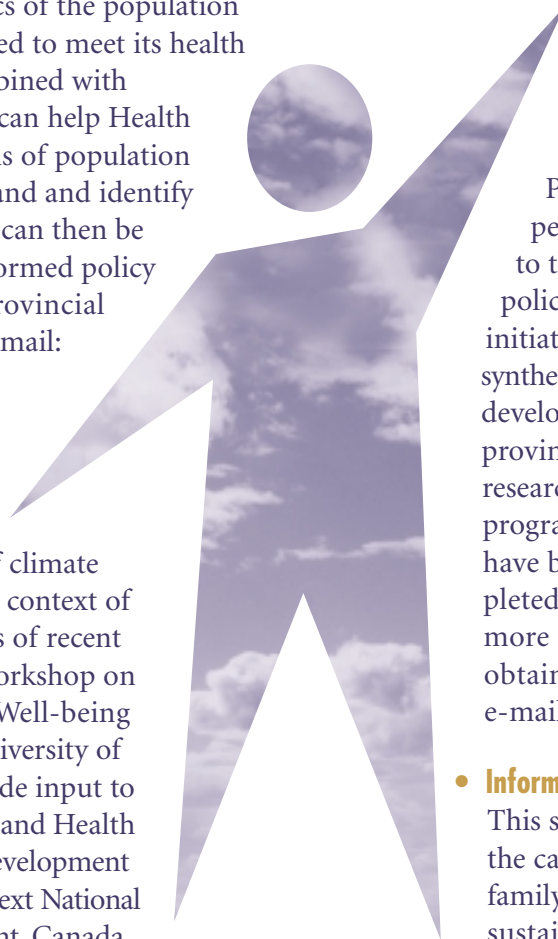
In December 2003, the Canadian Population Health Initiative (CPHI) of the Canadian Institute of Health Information (CIHI) will release a policy report entitled *Improving the Health of Canadians*. Part of CPHI’s strategy to provide information on population health issues and stimulate public dialogue on the determinants of health, the report will provide up-to-date information on the health of Canadians. Major topics include the health of Aboriginal people and the health effects of income distribution, early childhood development and obesity. More information can be found at: <http://www.cihi.ca>

Support for Health Policy Research

Health Canada’s Health Policy Research Program (HPRP) funds extramural, peer-reviewed research that contributes to the evidence base for the department’s policy decisions. HPRP supports a range of initiatives including: primary, secondary and synthesis research; policy research workshops; developmental contributions; and federal/provincial/territorial partnerships to fund research of national significance. Since the program’s inception in 2000, 22 initiatives have been funded; five of the projects completed to date are summarized below. For more information about the HPRP or to obtain summaries of the project reports, e-mail: RMDDinfo@hc-sc.gc.ca

- **Informal Care Networks for Seniors**

This study tested policy assumptions about the capacity of informal networks, such as family, friends and neighbours, to provide sustained care to frail, elderly Canadians. Using data from the 1996 Canadian General Social Survey, the study examined the characteristics of informal care networks for people aged 65 and over living with a long-term health limitation. The findings show that these networks are generally small in size,



female and kin dominated, and made up of young to middle-aged people who live in separate households from the care recipients. For more information on this study, e-mail: RMDDinfo@hc-sc.gc.ca

- **Integrative Health Care**

There is evidence that complementary and alternative health care (CAHC) is being integrated with conventional medicine, at least at the consumer level. However, the wide range of perceptions about what constitutes integrative health care (IHC) has made policy decisions in this area difficult.

This issue was the impetus for a workshop entitled “Integrative Health Care: Defining and Operationalizing the Fundamental Elements,” which aimed to develop a working definition of IHC and identify outcomes and indicators at the patient, practitioner and clinical levels. A report summarizing the results of the workshop may be obtained by e-mail: RMDDinfo@hc-sc.gc.ca



Hosted by the

Health Telematics Unit at the

University of Calgary, the

Telehealth Research Summer

Institute (TRSI) is an annual

event that focuses on advancing

policy and research through

evaluation of telehealth

programs and telelearning

initiatives in health care.

of health care services is now available in hospitals, homes, clinics, schools and the workplace. Understanding the challenges posed by health care that is geographically decentralized and technology mediated was the focus of a five-day research workshop at the University of Toronto in June 2002. Participants from research and public policy sectors in Canada and Sweden explored research on health care, technology and place, and the implications for diverse policy sectors — such as housing, social services and international trade — of providing geographically dispersed health care services. Several interdisciplinary, cross-professional, cross-national and cross-sectoral research and knowledge translation activities were developed during and after the workshop. To learn more about these activities or to access a copy of the final workshop report e-mail: RMDDinfo@hc-sc.gc.ca

- **Telehealth Research Summer Institute**

Hosted by the Health Telematics Unit at the University of Calgary, the Telehealth Research Summer Institute (TRSI) is an annual event that focuses on advancing policy and research through evaluation of telehealth programs and telelearning initiatives in health care. The third TRSI was held in July 2002 and issues concerning the socio-economic, technical and policy impacts of telehealth provided a framework for developing recommendations about future directions. Discussions at the fourth TRSI, which took place June 25–27, 2003, focused on a document entitled *Final Report for 3rd Annual Telehealth Research Summer Institute*. For more information, see: <http://www.ucalgary.ca/telehealth> or e-mail: RMDDinfo@hc-sc.gc.ca 📧

- **Enhancing Telehealth Services**

The 2002 National Telehealth Coordinators Workshop assembled guidelines and tools to assist in decision making, promote best practices and improve the consistency and efficiency of telehealth service delivery. Sixty telehealth coordinators from across the country participated in the workshop, which was held in October. A report summarizing recommendations on such issues as operational standards, skills and core competencies may be obtained by e-mail: RMDDinfo@hc-sc.gc.ca

- **Health Care Settings and Public Policy**

Recent health restructuring in Canada and Sweden has increased the number and type of settings in which care is delivered. As a result of fiscal and demographic pressures, technological advances, globalization and changes in social attitudes, a broad spectrum

Mark Your Calendar



What	When	Theme
Strengthening Foundations: Health Services and Policy Research — Canadian Health Care	November 22–24, 2003 Montréal, Québec http://www.ellisriley.on.ca/IHSPR	Role of health services and policy research in solving Canada's most pressing health care system and delivery issues
International Conference on Aging, Disability and Independence	December 4–6, 2003 Washington, DC http://www.asaging.org/icadi/03/index.cfm	Issues and key findings in research and development, practice, products, services and policies
International Microsimulation Conference on Population Aging and Health: Modelling Our Future	December 8–12, 2003 Canberra, Australia http://www.natsem.canberra.edu.au/	Microsimulation models and other modelling approaches used to examine population aging and health issues
San Diego Conference on Child and Family Maltreatment	January 26–30, 2004 San Diego, California http://www.charityadvantage.com/chadwickcenter/2004Conference.asp	Prevention, diagnosis, treatment and prosecution of child and family maltreatment
2004 National Health Policy Conference	January 28–30, 2004 Washington, DC http://www.academyhealth.org/nhpc/	Health policy scan to identify key health care issues confronting policy makers
18th National Conference on Chronic Disease Prevention and Control	February 18–20, 2004 Washington, DC http://www.cdc.gov/nccdphp/conference/	Investing in health: The dollars and sense of prevention
Preventive Medicine 2004	February 18–22, 2004 Orlando, Florida http://www.preventivemedicine2004.org/	Forum for policy makers, health care professionals and physicians focusing on four areas: public health care practices, clinical preventive medicine, health care quality improvement and prevention policy issues
International Conference on Emerging Infectious Diseases	February 29–March 3, 2004 Atlanta, Georgia http://www.iceid.org/default.asp	Exchange of scientific and public health information on emerging infectious diseases around the world, including infectious agents in farming and food production, and antimicrobial resistance
2nd World Congress on Women's Mental Health	March 17–20, 2004 Washington, DC http://womenmentalhealth.com/congress/default.htm	State-of-the-art developments in biopsychosocial aspects of women's mental health, psychology, psychopharmacology and other treatments
XVIIIth World Conference on Health Promotion and Health Education	April 26–30, 2004 Melbourne, Australia http://www.health2004.com.au/	Information in a range of areas, including health promotion, methodological issues, population groups and health care settings

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