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Perspectives on Natural Health Products

Quality and Safety

Research

Population Groups
and Issue Areas

Information, Informed
Choice and Utilization

*A collection
of executive
summaries from
stakeholder
consultation
reports*

2001-2002

*A health promotion approach —
natural health products and
complementary and alternative
health care*

Prepared for the
Natural Health Products Directorate

Canada

Perspectives on Natural Health Products

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summaries from stakeholder
consultation reports
2001-2002*

December 2002

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provenant des rapports de consultation des intervenants
2001-2002*

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INTRODUCTION

Health Canada is committed to ensuring that Canadians have access to natural health products (NHPs) that are safe, effective and of high quality, while respecting freedom of choice and philosophical and cultural diversity. In developing an appropriate regulatory framework for NHPs, the Natural Health Products Directorate, Health Products and Food Branch, has maintained an open and transparent process of ongoing dialogue and consultation with stakeholders across Canada. This publication provides a collection of executive summaries from key documents created during the consultation process over the past two years. They are grouped under four central themes: Quality and Safety; Research; Population Groups and Issue Areas; and Information, Informed Choice and Utilization. Please visit www.hc-sc.gc.ca/hpb/onhp for an online version of this document as well as the complete reports.

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Drug Interactions with Natural Health Products: A Discussion Paper

*Heather Boon, BScPhm, PhD, Faculty of Pharmacy, University of Toronto, and
Tannis Jurgens, BScPhm, MSc, PhD, College of Pharmacy, Dalhousie University
November 2001*

Executive Summary

Almost half of all Canadians use complementary/alternative medicine (CAM), including natural health products (NHPs), in the management of their health. This widespread use means that many Canadians are using NHPs in conjunction with conventional medications, which raises concerns about potential NHP/drug interactions. The purpose of this report is to provide a broad overview of NHP/drug interactions from a Canadian perspective to facilitate discussion and identification of priority needs in this area. The report is structured around four main theme areas:

1. NHP/drug interactions from a biomedical perspective
2. clinical issues associated with identifying NHP/drug interactions and counseling patients about them
3. current health care system and policy issues, including a comparison of systems for reporting NHP/drug interactions in Canada, the United Kingdom and Australia
4. issues associated with transferring knowledge about NHP/drug interactions (from patients to practitioners to national reporting centres and back again)

At the end of the discussion, the authors identify the following priority needs:

- support for basic, clinical and epidemiological research about NHP/drug interactions
- communication with and education for health care practitioners (conventional and CAM), as well as Canadian consumers about NHP/drug interactions
- the development of a Canadian NHP/drug interaction reporting system that meets the needs of health care practitioners, researchers, patients, policy makers, the NHP industry and the pharmaceutical industry (This may involve changes to the current Adverse Drug Reaction (ADR) reporting system or the design of a new, separate system for reporting suspected NHP/drug interactions. In addition, discussion about who will be eligible to report suspected NHP/drug interactions – as well as what information will be required as part of each report – is necessary.)
- the development of an effective knowledge transfer system to facilitate the reporting of NHP/drug interactions and the ability of health care practitioners and patients to access information that has been reported in a reliable and timely manner

Drug Interactions with Natural Health Products: A Research Priority-Setting Conference

*Report prepared by Theodore de Bruyn
Ottawa, January 10-11, 2002*

Executive Summary

In 2001 and 2002, the Natural Health Products Directorate (NHPD) conducted a series of consultations to identify priorities for research on natural health products (NHPs). These consultations will guide the NHPD in its own research program and in its partnerships with other funders, such as the Canadian Institutes of Health Research (CIHR).

Interactions between NHPs and pharmaceutical drugs (NHP-drug interactions) is one area identified during stakeholder consultations as a research focus for the NHPD. An increasing number of Canadians are using NHPs, and many are taking prescription or over-the-counter drugs at the same time. This occurrence alone is reason to investigate potential or clinical NHP-drug interactions for both their positive and negative effects.

The Research Priority-Setting Conference on Drug Interactions with Natural Health Products involved approximately 70 participants drawn from many fields with an interest in NHP-drug interactions.

The objectives of the conference were:

- to identify, process and assess the current state of evidence related to NHP-drug interactions
- to explore the implications for: biomedical research; clinical research; research related to health systems, policy and legislation; and research related to communication and knowledge transfer
- to identify priorities, facilitate dialogue and foster collaboration between all relevant stakeholders to promote interest in research in this area

The primary objective of the conference was to assist in identifying research priorities concerning drug interactions with NHPs. This information will be used by the NHPD to work with other funders (such as CIHR) to advance research on these priorities and to issue requests for applications on these priorities.

This final report on the conference summarizes the outcomes of the conference at each of the following key points in the process:

1. two broad areas of research
2. a list of priorities in these two areas of research (with a description of each priority)
3. the top four priorities in these two areas of research, with a summary of considerations identified at the end of the conference

The research priorities identified by participants in the first day of the conference fell into two broad areas:

1. biomedical, clinical and epidemiological research on NHP-drug interactions
2. research related to reporting, dissemination and use of information about interactions.

In general, participants suggested that priority should be given to research dealing with:

- NHPs that are in high use
- populations that are at risk of NHP-drug interactions (e.g., populations defined by age, gender, diseases or conditions, genetic factors, etc.)
- interactions with drugs that have critical dose or plasma concentration requirements
- interactions with potential or known severe outcomes

The top four priorities in biomedical, clinical and epidemiological research on NHP-drug interactions were (numbered in order of priority):

- characterize NHPs being used
- identify pharmacologic actions of NHPs related to benefits, harms and interactions
- determine the clinical relevance of potential NHP-drug interactions
- determine the use of NHPs in the population

The four top priorities for research in relation to reporting, dissemination and use of information about NHP-drug interactions were (numbered in order of priority):

- research into early warning systems for NHP-drug interactions
- assessment of the needs of stakeholders (consumers, practitioners, regulators, distributors and delivery systems) regarding information on NHPs and NHP-drug interactions
- the use of a focused, population-based approach to determine areas of greatest risk for NHP-drug interactions and mechanisms for collecting information about NHP-drug interactions
- ways to facilitate the reporting of adverse drug reactions/drug interactions by all stakeholders

An Exploration of Current Issues in Botanical Quality: A Discussion Paper

Allison R. McCutcheon
February 27, 2002

Executive Summary

This report was commissioned by the Natural Health Products Directorate (NHPD) at Health Canada to provide background reading for participants invited to a two-day priority setting conference to discuss natural health product (NHP) standards and quality control, and to provide recommendations to the Directorate with respect to future initiatives in this area. The proceedings and recommendations from this conference will be available from the NHPD in the spring of 2002.

Throughout the entire consultation process on NHPs, from the Standing Committee on Health's hearings in 1997-98 to the present time, product quality has been consistently identified as one of the most critical issues. At the Natural Health Products Research Priority-Setting Conference in Halifax in 1999, sponsored by the Office of Natural Health Products (now the Natural Health Product Directorate), product quality was identified as a top priority in NHP research, especially with regards to botanical products. In consultations, stakeholders have urged the NHPD to take a leadership role in setting standards and facilitating research in this field. However, while there appears to be widespread agreement as to the importance of product quality based research and standards,

stakeholders' views on the specific research priorities vary substantially.

As a result, the NHPD invited stakeholder participation in the Quality Control and Product Standards Research Priority-Setting Conference in Vancouver, BC on March 8-9, 2002. This background document was written to lay a common groundwork for the conference discussions, by familiarizing participants with the diversity of issues and perspectives on the subject as well as some of the common themes. The contents of this discussion paper are based upon a survey of the literature and pertinent organizations, and the paper focuses on botanical quality as the area of greatest concern.

Since a key determinant of the scope of any discussion on product quality is how one defines the term 'quality,' some of the semantic issues surrounding the use of the word quality and related terms such as standardization are first explored. A brief overview of the criteria and methods that have been used to assess quality over the past 2,000 years provides an historical context for the subsequent discussion of existing and proposed new product quality regulations in Canada and the US.

In the survey of the scientific literature, no information specific to the quality of Canadian NHPs was found. Globally, three main issues were identified. These were the botanical identity of ingredients, product purity and potency. Reliable scientific data on product potency were especially

scant. In comparison, a substantial body of evidence on serious safety problems caused by incorrect botanical identifications and product impurities was found. The majority of reported adverse events were caused by the unintended or undeclared inclusion of a toxic plant, not the ingredients listed on the label.

Similarly, numerous examples of risks posed by non-botanical impurities were identified, including microbial contamination, heavy metal contamination and pesticide residues. The presence of heavy metals was the second most common cause of adverse events. Of equal or possibly greater concern was the high level of risk posed by adulteration with pharmaceutical drugs. A substantial number of both Canadian and foreign cases of herbal products containing pharmaceutical adulterants were found. These cases encompassed a wide range of drugs, including narcotics, stimulants, sedatives, corticosteroids and antibiotics.

Based upon this documentation of product quality deficits, some of the issues and challenges involved in assessing product quality are explored in this paper. For the assessment of product potency, some of the key issues include the selection of markers, validation of analytical methods, analytical competence and reference standards. For the assessment of identity and purity, many of the same key issues are identified, along with the lack of appropriate education and training, and the use of inappropriate technologies.

Throughout these discussions, several common themes clearly emerge, including methods

validation, reference materials and quality standards. Although Canada has the technical capacity, no constructive strategies for addressing these issues have been proposed to date. Other points include a lack of infrastructure and capacity needed to address the need for product quality assessment, the need for education and training of researchers, and the need for effective information dissemination and retrieval.

One of the key challenges in bridging these gaps is to obtain consensus on:

- research leaders and leadership roles
- the appropriate scope of research programs to address these gaps
- the appropriate balance between scientific rigor and practicality
- specific botanical priorities within each area
- the most effective strategies for facilitating the accomplishment of research goals

At the present time, research on product quality in Canada appears to be largely uncoordinated, with most projects conducted in isolation and the results often not widely disseminated. Knowledge transfer, especially from academia to industry and government, and information dissemination between industry members is quite limited. Fostering partnership and collaboration between stakeholders, possibly through the development of a cohesive quality research network, could make significant inroads in addressing these problems, and could generally assist in the successful execution of strategies to close quality research gaps.

Quality Controls and Product Standards: A Research Priority-Setting Conference

*Dennis Patrick O'Hara, DC, ND, PhD
Vancouver, March 8-9, 2002*

Executive Summary

On March 8-9, 2002, the Natural Health Products Directorate (NHPD) convened a conference to establish research priorities pertaining to quality controls and product standards for natural health products (NHPs) in Canada, especially with regard to botanical products. The Canadian participants included representatives from academia, industry, complementary and alternative health care practice, research, and various government agencies. Two participants from the USA, including a representative from the Office of Dietary Supplements at the National Institutes of Health, also contributed their expertise.

Through group and plenary discussions, the participants identified six research priorities as well as strategies and next steps that would advance these goals. The implementation of these recommendations would assist the NHPD in its mission to ensure that Canadians have access to safe, effective and high quality NHPs and to accurate and detailed information required to make properly informed choices.

Research Priorities, Strategies and Next Steps

1. **Develop methods for assessing botanical identity.** The inclusion of unintended or undeclared botanicals in a product represents a serious problem, as it is one of

the most common causes of adverse effects.

- a) **Develop a database.** Information concerning botanical identity, reference standards and various methods that may be used to assess identity should be collected in a database and critically evaluated to help identify research priorities.
- b) **Establish a hierarchy of methods.** Since there are a variety of methods that can be used to identify botanicals, it is necessary to establish a hierarchy of methods that are scientifically rigorous, cost effective and practical.
- c) **Develop a system to track identification.** A system must be developed to permit the identification of botanical products without ambiguity through all stages, from harvesting through manufacturing. A Certificate of Identity blended with Good Agricultural Practices (GAPs) is envisioned.
- d) **Construct a virtual network.** The construction of a virtual and comprehensive network of experts in botanical identification would aid these efforts.
- e) **Survey the industry.** A survey of the industry would also aid in the determination of the following specific identification needs: which botanicals are a priority; the range and most common types of preparation forms that require identification; and the capacity needs

pertaining to education, training and knowledge transfer.

2. **Perform research to inform the development of purity specifications.** Canadians want NHPs that are free from contaminants. While tolerance levels for many impurities have been established for food items, this is not the case for NHPs.
 - a) **Review existing data and develop a database.** It is necessary to review the existing data on botanical purity and to identify individuals and agencies with research expertise in this field. When other agencies or countries have studied tolerance levels and developed GAPs and good manufacturing processes (GMPs), this data will be critically evaluated.
 - b) **Identify gaps in knowledge and practice.** Presently, there are gaps in our knowledge and practices that permit contaminants to enter into NHPs. These gaps should be identified and prioritized so that effective efforts can be directed at limiting contamination.
 - c) **Develop Canadian GAP guidelines.** A project team should be formed to aid the development of Canadian good agricultural practices (GAPs) that would enhance product safety by reducing product contamination.
 - d) **Form a network.** A network of researchers with expertise in the field of purity specifications should be created to facilitate the efficient development of research initiatives and the effective transfer of information, thereby enhancing training and education.
3. **Perform research to identify and develop reference materials.** Reference materials are essential to the scientific evaluation of botanical quality because they are a critical component of identity, purity and strength

testing. Presently, reference materials are not readily available within Canada as there is no official source for authenticated reference materials.

- a) **Identify a lead agency.** There is a need to identify or designate a lead agency in Canada that can initiate and foster this initiative.
 - b) **Identify interested partners.** Research partners should be identified and research collaborations should be established both domestically and internationally.
 - c) **Establish protocols and programs.** Protocols for the identification and development of reference materials will need to be established by the research network. A program for the development and validation of methodologies for establishing and analyzing reference materials should also be initiated.
4. **Develop analytical methods to determine markers.** Marker compounds are constituents that naturally occur within an NHP and are often used to quantify the potency of a particular product or to standardize batches during manufacturing. However, many markers are not related to the biological activity of the product and, therefore, are not necessarily the best determinant of either quality or potency.
 - a) **Establish a national committee of experts.** A national committee with technical expertise would coordinate inter-laboratory studies for the creation of official analytical methods.
 - b) **Tasks of the national committee.** The national committee would prioritize the botanicals that will be the object of such research; compile and critically review the methods currently used to determine and analyze markers; and coordinate the development of officially validated methods to determine and analyze markers. The National Committee should work in

collaboration with the group that is overseeing the development of reference materials.

5. **Evaluate and identify biologically active components.** The potency of a product is usually determined by the quantity of the active ingredient present that will produce the desired therapeutic effect. For most botanical medicines, these biologically active ingredients have not been conclusively identified or understood.
- a) **Need for basic science research.** The mechanisms of action for NHPs and botanical remedies in particular need to be more thoroughly understood. Relevant biological assays are required to obtain meaningful measurements of potency and efficacy. Researchers should take advantage of the existing infrastructures that link producers, academia, government and industry. To avoid duplication, the latter should network with researchers developing methods for botanical identification.
 - b) **Establish a database.** A peer-reviewed database of existing bioassays and mechanisms of action should be established. This would also promote technology and knowledge transfer, help to avoid unnecessary duplication of research and increase the efficiency and progress of related research.
 - c) **Establish a virtual network.** Researchers in areas related to NHPs should be linked through a virtual network.
 - d) **Determine which NHPs should be researched.** The research priorities regarding biological assays and mechanisms of action would be influenced by the major health problems facing Canadians.

6. **Develop methods to monitor outcomes.** Is there 'value added' when regulations formally stipulate the quality controls and product standards that must be applied to the growing, production, distribution, marketing, and sale of NHPs?
- a) **Measure outcomes.** Measuring the effects of initiatives to improve quality controls and product standards for NHPs would determine the impact of these new regulations and practices on the safety, efficacy, accessibility and quality of NHPs. Such monitoring and measures would also review the ability of Canadian citizens and health care providers to make more informed choices.
 - b) **Establish baseline values.** Baseline values need to be established prior to the enactment of new regulations to determine current traits and patterns and the subsequent impact of new initiatives.
 - c) **Survey social attitudes.** A research project should be developed to measure the social attitudes of the Canadian population (or sub-populations such as the HIV/AIDS community, and/or paediatrics and youth) with respect to the safety, efficacy, and accessibility of NHPs, as well as the degree of informed choice and wellness.

During the working and plenary sessions, the participants shared their expertise and opinions with considerable enthusiasm and goodwill. Several of them noted a certain urgency for these research initiatives to be undertaken expeditiously, even as they acknowledged the various challenges that need to be overcome. They felt that the realization of these research priorities would help to address several concerns related to quality controls and products standards for NHPs in Canada. Consequently, advancing these research priorities would assist the NHPD with its goal of ensuring that Canadians have access to safe, effective, and high quality NHPs and to accurate and detailed information required to make properly informed choices.

Assessing Research Literacy in Complementary and Alternative Health Care Products and Practice: An Invitational Roundtable

*Heather Boon, BScPhm, PhD
Toronto, August 13-14, 2001*

Executive Summary

A lack of research literacy and capacity has been identified as a key barrier to complementary and alternative health care (CAHC) and natural health product (NHP) research. The primary objectives of this roundtable were:

- to identify and prioritize CAHC and NHP research infrastructure and training needs to facilitate CAHC and NHP research
- to identify strategies for meeting high priority needs

Four key CAHC and NHP research needs were identified:

1. a need for more awareness and understanding of the value of research
2. a need for mentors, role models and champions for CAHC and NHP research
3. a need for more CAHC and NHP research training
4. a need for more funding for CAHC and NHP research, training and infrastructure

Four strategies to meet these needs were identified as high priorities:

1. completion of a CAHC and NHP research needs assessment
2. support for a network of CAHC and NHP researchers and clinician investigators
3. development of CAHC and NHP research learning modules
4. development of CAHC and NHP research training support programs for faculty

Additional strategies were also discussed. These included:

- the development of a Centre of Excellence for CAHC and NHP research
- the identification of changes necessary within the current research funding and training program structures to allow CAHC and NHP researchers and clinician investigators to access current programs
- the establishment of an advisory group to continue the work started at this meeting
- funding for CAHC and NHP research knowledge transfer

The workshop discussions resulted in the following recommendations:

1. An advisory group should be established to follow up on the strategies and recommendations outlined during this workshop, and to advise Health Canada about future needs with respect to CAHC and NHP research literacy and capacity.
2. A needs assessment or environmental scan is necessary to ensure that future CAHC and NHP research literacy and capacity strategies meet the needs of a broad range of stakeholders. A Health Canada contract for this project may be the most effective way to complete this assessment.
3. Support for a network (or networks) of CAHC and NHP researchers and clinician investigators should be forthcoming to facilitate the development of CAHC and NHP research capacity.
4. Development of research learning modules and training support programs that can be accessed by a variety of CAHC institutions are recommended as ways to address the CAHC and NHP research literacy and capacity needs identified during this workshop. These programs should be designed and implemented following a broader needs assessment.
5. Health Canada should encourage the Canadian Institutes of Health Research to review current funding and training programs to ensure that CAHC clinician investigators, faculty members, and researchers are not unnecessarily excluded from applying for programs that clinician investigators, faculty members and researchers from conventional health care programs can currently access.
6. Support for one or more Centres of Excellence in CAHC and NHP research is recommended as a long-term strategy to enhance CAHC and NHP research capacity.
7. Funding for CAHC and NHP research knowledge transfer is recommended as a long-term strategy to enhance CAHC and NHP research literacy and capacity.

Reviewing and Assessing the Role of the Natural Health Products Directorate in Research: An Invitational Roundtable

*Dennis Patrick O'Hara, DC, ND, PhD
Ottawa, October 4-5, 2001*

Executive Summary

A diverse cross-section of stakeholders met to discuss what has been accomplished thus far by the Natural Health Products Directorate (NHPD) in the area of research, and to provide feedback and suggestions for future directions. More particularly, the group recommended specific objectives that the NHPD might accomplish by the end of its current fiscal year – i.e., by March 31, 2002 – and goals that would provide direction for the subsequent three to five years. The stakeholders at this roundtable included representatives from consumer groups, academia, research, industry, and patient care. While some participants had attended previous meetings hosted by the NHPD, others were new to these discussions. Accordingly, the advice that emerged reflected the breadth of experience of the participants. Some of the advice reinforced the direction and work that the NHPD has already chosen, while some proposed the next steps in the evolution of the NHPD as it continues to develop an infrastructure to meet its mandate.

Short-Term Recommendations

The following suggestions were emphasized during discussions:

- continue to ensure community and practitioner input at all levels
- avoid holding meetings that might repeat the work that has already been done; direct funds and energies to support the recommendations that were made at prior conferences and roundtables and that were reinforced during these discussions
- facilitate a process whereby leaders in complementary and alternative health care (CAHC) research and natural health product (NHP) research meet, discuss and choose worthwhile research projects that might be funded in part by the NHPD
 - when these projects are properly completed, they can serve as templates for future projects
- continue to forge partnerships and collaborations that
 - maximize the research dollars of the NHPD through leverage with other partners (such as the Canadian Institutes of Health Research – CIHR)

- encourage funders to become more receptive of CAHC and NHP research
- fund workshops that lead to the sharing of perspectives between conventional and CAHC/NHP researchers/practitioners, particularly in the area of research methodology
- fund workshops on research methodology in CAHC to develop a new paradigm for research
 - because of the methodological challenges currently facing CAHC and NHP research
 - because the funds available for NHP research are not, and will not be, at all comparable with the funds that have been spent on pharmaceutical research
- establish an effective network for information exchange and knowledge transfer so that efforts to increase the training capacity of CAHC researchers can be shared
 - the network will enable the dissemination of information and training materials across the country to those who cannot attend the workshops and minimize duplication while maximizing limited human and financial resources
 - fund the salary of a coordinator for the network, a software knowledge transfer consultant, and meetings to organize the network and train personnel
 - the network should be web-interfaced
 - the network will encourage cross-disciplinary dialogue and collaboration
 - the network will publish case studies and case series so that researchers do not feel limited to conducting only randomized control trials
- product related matters such as quality control and standardization remain a priority
- the work of the NHPD should include focus on wellness models
 - prevention and wellness models should receive more attention in contrast to the traditional emphasis on sickness models
 - consumers are using NHPs to stay well, not just to treat disease
 - determine if the use of NHPs helps consumers to move toward optimal health
 - there is a need to insert the holistic perspective into research
 - to date this has not been sufficiently emphasized in research recommendations and strategies
- form a central advisory committee or working group of perhaps 10 people with a variety of NHP/CAHC expertise/experience, and form sub-committees of interest groups or nodes feeding into this central working group
 - the focus of the individual nodes might include basic biomedical science; applied/clinical research and health systems; industry; quality control; research capacity and methodology; and information technology and knowledge transfer
 - while each node must have a majority of its participants selected from one specific field of expertise (e.g., a basic science research node would contain a majority of basic scientists), overall membership would be invitational and would include practitioners, consumers, industry, researchers and academics
 - linkages and feedback can exist among the nodes, the central advisory committee and consensus conferences that could be held as needed
 - linkages might also be fostered with CIHR, SSHRC, NSERC, etc.
- investigate the unique contribution that Canada can make to the international community; e.g.:

- aboriginal and multicultural use of complementary and alternative therapies
- indigenous botanicals and therapies

The priorities that are realized during the remainder of the fiscal year will not be done in isolation. They will be part of a general network of information sharing that will be established, and part of a general strategy to implement recommendations from previous conferences and roundtables.

Long-Term Recommendations

After March 2002 and beyond, the NHPD will:

- continue to build research capacity and to increase receptivity within funding agencies
- seed-fund the research priorities that emerge from the first group of interest group nodes

- fund workshops that cut across a number of nodes, and/or fund an annual conference that brings together a number of the nodes
- undertake a systematic review of the issues in CAHC and NHP research
- promote the unique contribution that Canada can make in the area of NHP/CAHC research at international dialogues. The unique contributions include:
 - aboriginal and multicultural contributions to health care
 - indigenous botanicals and therapies
 - the emerging blend of marketplace factors, publicly funded health care, diverse practitioners, and consumer needs
- support the establishment of database(s) of informed information that can be easily accessed by researchers, practitioners and consumers
 - objective, third party, evidence-based medicine research
 - monographs

Getting the Right Knowledge to the Right People at the Right Time: An Invitational Roundtable on Knowledge Transfer

Margaret Sampson
Ottawa, February 14-15, 2002

Executive Summary

On February 14-15 2002, Health Canada convened an invitational roundtable on knowledge transfer in the use of natural health products (NHPs). The participants at the roundtable included health care practitioners, information providers, academics, researchers, and government liaison, representing the Canadian perspective.

The objectives of the roundtable were:

- to explore how knowledge transfer/technology transfer is relevant to NHPs and the Natural Health Products Directorate
- to identify opportunities for using knowledge transfer strategies to enhance the flow of evidence-based information about NHPs to (and from) a variety of stakeholders.
- to identify strategies for facilitating high quality research in the area of knowledge transfer and NHPs

The roundtable focused on knowledge transfer challenges and opportunities associated with three stakeholder groups, each diverse within itself: healthcare providers, including

practitioners of both conventional healthcare and complementary and alternative medicine; the public; and policy makers.

Several general themes emerged from the discussion:

- ***Diversity within the stakeholder groups.*** Languages, education levels, world views and belief systems, and preferred medium for accessing information varied within and between the stakeholder groups, as did the types of decisions to be informed. Recognition and respect for such diversity would have to be central in any successful knowledge transfer strategy.
- ***Imbalance between volume of information and resources to take up that information.*** Challenges to be addressed by a knowledge transfer system include lack of time, complexity of material, and the ability of the user to discern the accuracy and relevance of information. Often the challenge is too much information, but sometimes (in the case of product or drug interaction, for example) too little information is the greater concern, and in these cases a system must also be capable of drawing in new information.
- ***The need for tools and techniques to guide the uptake of health information (including information on NHPs).*** Three broad

approaches were identified, and they are not mutually exclusive: systems that deliver information distilled from primary source material to a format suitable for the information needs, language, culture, location and time of the intended recipient; a seal of approval to certify that the information is sound; and opportunities for stakeholders to improve critical appraisal skills.

- ***Two-way knowledge transfer.*** Distinct from information dissemination strategies, any knowledge transfer system requires a bi-directional flow of information. It may require learning a client's information needs, and drawing information from the client that could be combined with other information to build new knowledge.

The following report provides a detailed summary of the participants' discussions concerning the challenges and opportunities associated with each stakeholder group, as well as suggestions regarding possible ways to move forward for two of those groups. The characteristics of the ideal knowledge transfer system are described, and a list of resources in knowledge transfer (existing systems) and potential partners in the research and development of knowledge transfer systems for NHPs is presented. This report also lists priorities and an action plan proposed by the group.

The action plan put forth consists of four major steps. First, a needs analysis should be commissioned by the Natural Health Products Directorate, possibly with partners, and performed as soon as possible. Second, a knowledge transfer strategy should be developed and implemented, informed by the needs analysis, and capitalizing on what currently exists. Third, the strategy should be marketed according to the principles employed by those already skilled at marketing information designed to change behaviour in the identified stakeholder groups

(such as the advertising agencies to pharmaceutical companies and federal lobby groups). Finally, an evaluation of the strategy was seen as essential.

A Note on Terminology

Early in the discussion, participants weighed the meanings and merits of the terms 'knowledge transfer' and 'knowledge translation,' (both abbreviated as KT). The roundtable decided that while knowledge transfer denotes the idea of a two-way exchange of information to create knowledge, and knowledge translation denotes the need to tailor information to intended recipients, both terms fit broadly within the scope of the day's discussion. Both are used in this report.

Building Complementary and Alternative Health Care and Natural Health Products Research Networks: A Discussion Paper

*Marja J. Verhoef, PhD and J.J. Jansen, RN, MPH
Calgary, June 17, 2002*

Executive Summary

The importance of complementary and alternative health care (CAHC) and natural health products (NHP) research has been a key topic in recent workshops and roundtable discussions supported by Health Canada's Natural Health Product Directorate (NHPD), Health Products and Food Branch and the Health Human Resource Strategies Division (HHRSD), Health Care Strategies and Policy Directorate. These discussions have repeatedly emphasized the need to network and to develop formal or informal networks in order to create and transfer knowledge, encourage research uptake, and build research capacity. This paper reviews the summary documents from these workshops and roundtable consultations to assess whether they have addressed the issue of networking and, if so, how this was done.

A review of the documents has resulted in four central themes, including the need and purpose for networking, forms of networking, and the role of Health Canada with respect to networking. Need and purpose evolve around leadership, coordination of communication, resource sharing, research capacity building, education and training, policy and standards development, and fundraising. Forms of networking include formal centralized

networks, virtual networks and networking (the development of networks). The role of Health Canada is seen as providing seed funding, collaborating with researchers to develop a strategic plan, sponsoring conferences, creating and supporting infrastructure, developing formal CACH/NHP interdepartmental and intergovernmental links, and initiating interagency links.

From the documents reviewed, it becomes clear that a comprehensive, holistic approach is now called for. The literature has identified the following characteristics that need to be considered when establishing a research network: a clear vision and goals, a clearly defined structure, open communication, appropriate leadership style, sustained support for network members and network activities, relationship building, the demonstration of accomplishments, and ongoing evaluation of network development.

Major challenges facing future network planning include establishing clear definitions and distinctions between CAHC, NHPs and integration; identifying the best form of networking; establishing an overarching network structure; and identifying critical success factors. We recommend the development of a conceptual framework; a national CAHC/NHP network, possibly consisting of different types of networks based on clear goals and objectives

and consisting of a well developed governance structure; and external relationships with the government, funding agencies and existing networks. Clearly, the need to strengthen connections, build trust and foster growth over the next five years will require a sustained and facilitated community development approach at all levels and layers of stakeholders. However, the

real question is not merely one of structural architecture, but of determining roles and responsibilities with regards to ownership (e.g., Health Canada, research funding agencies, researchers, etc.) of the building process and accountability for the intended outcomes.

Needs Assessment: Research Literacy and Capacity Amongst Complementary and Alternative Health Care Providers

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June 28, 2002

Executive Summary

The purpose of this project was to conduct a needs assessment/environmental scan of research literacy and capacity needs amongst complementary and alternative health care practitioners (CAHCs). The approach used was to interview 34 representatives from clinical practice, educational colleges and national associations for three specific disciplines (naturopathy, massage therapy and chiropractic), the results of which are presented in this report.

Although there was variation in the themes identified during the interviews of each of the three disciplines, there were more similarities than differences. The differences that did exist were a reflection of several variables, including:

- differing levels of prerequisite qualifications to enter the educational programs for the respective professions

- differing lengths of educational programs of each of the respective professions, impacting on the degree of focus on research
- differing levels of complexity within each of the disciplines, including the range and type of therapies offered and the potential for research
- differing stages of maturation of each of the disciplines

These differences would likely have been further exaggerated if other CAHC disciplines had been included in this study, reflecting the wide range and the complexity of the CAHC field.

Despite these differences, many of the themes identified during this needs assessment were similar across disciplines and were similar to those identified in previous surveys/workshops/forums. Common themes are outlined in detail in this report and are summarized below for each of the project objectives.

Current level and perceived adequacy of research training

Some level of research training is incorporated into the current curricula in each of the naturopathy, massage therapy and chiropractic training programs. As might be expected, the focus of research courses in the basic training programs is on accessing, understanding and applying – as opposed to conducting or disseminating – research. Chiropractic participants perceived the adequacy of their training to be the highest of the three disciplines, followed by naturopathy, then massage therapy. For all disciplines, representatives from the educational colleges perceived the adequacy of the training to be higher than that perceived by the practitioners. The majority of those interviewed indicated that while research training is improving, it is still lacking in many areas at all levels (undergraduate, graduate and post graduate).

Current level of perceived research literacy and capacity in practice

Levels of perceived research literacy and capacity differed amongst the professions, with the highest being perceived amongst the chiropractic profession. Similarly, the level of support provided by the literature to make treatment related decisions varied significantly between the disciplines, with the highest being reported by chiropractors and naturopathic physicians and the lowest by massage therapists. Interestingly, even those reporting that the literature provided support only infrequently changed treatment decisions as a result. The most significant barriers to accessing, understanding, applying, conducting and disseminating research were time and money. Dedicated research related funds are increasing but are still very limited for all CAHC disciplines.

Perceived research needs

Although research was reported to be highly valued by all participants, the level of understanding concerning what constitutes research varied, particularly with respect to qualitative research. The importance of cultivating a research culture beginning in the educational colleges with faculty and students, and continuing throughout practitioner careers, was unanimously endorsed by all participants (“professional socialization of research into the profession”). There was strong interest amongst all participants in all disciplines to acquire more research related skills (with a caveat of response bias). While the educational college participants were equally interested in increasing the knowledge level of their faculty in all topic areas, the practitioner participants were most interested in learning more about accessing research-based information, understanding research studies and learning more about research design and statistics.

Perceived willingness and opportunities to build bridges and share curricula

Given the commonalities of the responses from the different disciplines, there is likely significant potential to strengthen partnerships and potentially share at least some core research related content across undergraduate, graduate and continuing education programs (e.g., critical appraisal of research, statistics, research design and methodologies). Although the question about willingness to build partnerships and share research related content was not asked explicitly, the perception of the interviewers was that there would be (and has been) a willingness to do so. This perception was validated recently in the Research Literacy for Complementary and Alternative Health Care Practitioners report (CMTA, May 7, 2002).

Information resources

Although an intensive review of access to information sources was beyond the scope of this

project, a brief review suggests that access to multiple sources of information is available to CAHC practitioners, faculty, researchers, clinical investigators and students through the educational college libraries (for example, the libraries at the Canadian Memorial Chiropractic College and The Canadian College of Naturopathic Medicine). Despite the availability of information, comments from practitioner participants consistently pointed to the need to better co-ordinate and support delivery of information resources to practitioners. These libraries are well positioned to carry out this work but are generally funded to carry out mandates within educational institutions. A potential exists to build upon and expand services already available to promote, fund and provide equitable access.

Recommendations

Several recommendations arise from this needs assessment and are summarized below. Efforts are already underway to address many of these recommendations at local, provincial and/or national levels – for example, the establishment of a Centre of Excellence for natural health products, the creation of research related networks and the establishment of partnerships with various universities.

CAHC Research Infrastructure (priority no. 1)

1. Establish an advisory committee to follow up on strategies and recommendations arising from this report and earlier reports on promoting CAHC research. This group might include a combination of CAHC and conventional providers, all with an interest in CAHC research, and might include representative students, faculty, researchers, clinician investigators and practitioners.

2. Support the development of a network(s) of CAHC researchers and clinician investigators.
3. Support the establishment of a formal CAHC research foundation with appropriate funding.

CAHC Curriculum Collaboration (priority no. 2)

4. Identify desired core research competencies for CAHC students, faculty, researchers and practitioners.
5. Compare existing undergraduate, graduate, post graduate and continuing education programs to the core research competencies identified, and identify gaps and opportunities.
6. Develop common content that can be accessed by a variety of CAHC institutions – and regulatory bodies, national associations and other interested groups – to promote the development of core research competencies listed above for students, faculty, researchers and practitioners.

CAHC Continuing Education Collaboration

7. Support ongoing linkages with universities and ongoing collaboration with faculty within university settings.
8. Support the development of CAHC research training programs specifically for faculty, researchers and clinician investigators.
9. Assess the need for CAHC conferences/workshops and online courses (perhaps in modular format) as a vehicle for increasing research related skills (including application to practice) amongst CAHC practitioners.
10. Provide funding support for students, faculty, researchers, clinical investigators and practitioners to access research related educational programs (e.g., CIHR partnerships for faculty to advance their careers).

11. Identify ways to increase the profile and incorporate research into conferences and continuing education workshops on a regular basis.
12. Increase the availability and access to baccalaureate education for CAHC practitioners where it does not currently exist, and for graduate and post graduate programs for all CAHC practitioners.

Increasing the Availability of Research Funding

13. Identify ways to facilitate access to existing research funding sources by CAHC researchers and clinician investigators (e.g., CIHR grants).
14. Provide seed grants for students, faculty, researchers, clinical investigators and practitioners to develop research proposals and applications for external funding.

Increasing Access to Research Findings

15. Support the ongoing development of multi-disciplinary and discipline-specific research-based clinical practice guidelines.
16. Market the availability of, and provide funding support for, existing library access (physical and virtual access) to research-based information (e.g., CMCC and CCNM libraries).

17. Sort, consolidate and make available summaries of results of research-based studies on key topics (e.g., database of abstracts of review articles) for practitioners in each of the disciplines. Utilize professional journals and the internet/email as primary vehicles for disseminating this information.
18. Support the establishment of an electronic distribution list for the dissemination of research findings to practitioners, faculty and students.
19. Assess the need for a research focused web site with links to other professional web sites, which would include the following:
 - information on locations of existing sources of research-based information
 - content reflecting basic research skills (e.g., critical appraisal, research design and research methodology)
 - calendar of upcoming conferences and research-related events
 - database of results of research-based studies and abstracts on key topic areas applicable to practitioners
 - listing of research studies currently underway, including the principal investigator, a summary of the study and the funding source and amount

Developing a Research Agenda in Natural Health Products, Complementary and Alternative Health Care and HIV/AIDS: A Discussion Paper

*Theodore de Bruyn
February 27, 2002*

Executive Summary

This discussion paper provides a broad overview of issues concerning the development of a research agenda in the area of natural health products (NHPs), complementary and alternative health care (CAHC) and HIV/AIDS. The purpose of this report is to facilitate discussion and the identification of priority needs at the Invitational Roundtable on the Role of Natural Health Products and Complementary and Alternative Health Care: Developing a Research Agenda. The roundtable is being convened in March 2002 by the Natural Health Products Directorate, in collaboration with the Health Human Resources Strategy Division and the HIV/AIDS Policy, Coordination and Programs Division of Health Canada.

The objectives of the roundtable are:

- ***to assist in the further development of a research agenda in the area of NHPs, CAHC, and HIV/AIDS***, building on the priorities first established in the document “Towards Integrative Care: National Strategic Planning Meeting on Complementary Therapies and HIV/AIDS.” This report, along with others referred to in this discussion

paper, have set out the main lines of a research agenda. The purpose this roundtable is to develop this agenda further by suggesting specific steps.

- ***to build capacity to conduct research in Canada in NHPs and CAHC***, with HIV/AIDS serving as an area with readiness to explore ways to accomplish this. There is widespread recognition of the need to build research capacity – to increase the ability and readiness of individuals and organizations to identify, develop and conduct research – in NHPs and CAHC in Canada. What is needed now are specific steps to do this in areas where there is sufficient readiness. HIV/AIDS is one such area.
- ***to contribute to the NHPD’s process of identifying and advancing research priorities in NHPs and CAHC within the national arena***. The NHPD is seeking to identify and advance research priorities both through its own funds (intended primarily for developmental purposes) and in collaboration with other funders (such as the Canadian Institutes of Health Research, the Hospital for Sick Children Foundation, and other funders).

The groundwork for the roundtable began in previous consultations within the HIV/AIDS field and the CAHC/NHP field. Drawing from these consultations, this discussion paper:

- summarizes key aspects of the use of CAHC/NHPs by people with HIV/AIDS
- summarizes research priorities that have been identified in the area of NHPs, CAHC and HIV/AIDS
- summarizes the outcomes of Health Canada's consultations on building research capacity and advancing research priorities in CAHC/NHPs
- outlines a process for considering next steps

Next Steps

There is growing momentum in Canada to build research capacity and to advance the research agenda with regard to CAHC and NHPs. Researchers, practitioners, consumers, information providers, industry, government, and research funders are actively looking at specific and concrete ways to move forward.

In this context, there is a potential for synergy between the HIV/AIDS field and the broader CAHC/NHP field. With their considerable experience in the use of CAHC/NHPs, research,

community organization, industry relations, and consultation and lobbying, people and organizations in the HIV/AIDS field have much to contribute to CAHC/NHP research.

At the same time, the momentum in the broader CAHC/NHP field may help to strengthen the capacity of the HIV/AIDS field to identify, participate in, and advance research on CAHC and NHPs, particularly research that is of special relevance to people with HIV/AIDS.

The roundtable on March 10-11, 2002 is intended to explore the potential for mutual strengthening and collaboration in the following areas:

- building research capacity
- methodological development
- NHP research
- health services research
- knowledge dissemination and uptake
- building and strengthening liaisons

In HIV/AIDS consultations and/or in CAHC/NHP consultations, these areas have been identified as areas for action. The overall objective of the roundtable is to identify and select top priorities and opportunities for each of these areas and to identify strategies to move forward in advancing these priorities.

The Role of Natural Health Products and Complementary and Alternative Health Care in HIV/AIDS – Developing a Research Agenda: An Invitational Roundtable

*Theodore de Bruyn
Vancouver, March 10-11, 2002*

Executive Summary

A roundtable on developing a research agenda on the role of natural health products (NHPs) and complementary and alternative health care (CAHC) in HIV/AIDS was convened by the Natural Health Products Directorate (NHPD), in collaboration the Health Human Resources Strategies Division and the HIV/AIDS Policy, Coordination and Programs Division of Health Canada. This roundtable was one of several meetings on research priorities being held with populations known to use CAHC and NHPs.

Objectives

The objectives of the roundtable were:

- to assist in the further development of a research agenda in the area of NHPs, CAHC, and HIV/AIDS
- to build capacity to conduct research in Canada in NHPs and CAHC, with HIV/AIDS serving as an area with readiness to explore ways to accomplish this
- to contribute to the NHPD's process of identifying and advancing research

priorities in NHPs and CAHC within the national arena

Process

The roundtable focused on six aspects of research on CAHC and NHPs:

1. NHPs research
2. health practices/services research
3. building research capacity
4. methodological development
5. research dissemination and uptake
6. building and strengthening liaisons

In light of potential synergies between the HIV/AIDS field and the broader field of CAHC and NHPs, the instructions to the participants were, for each of the above six areas:

- to identify priorities or opportunities for research or research-related activities
- to select the top three priorities or opportunities
- to identify strategies to advance the top three priorities or opportunities

An Overarching Principle

Participants agreed that consumers need to be involved at all stages of the research process (the design and implementation of the project, and the analysis and dissemination of the results) and in each of the priorities identified below. This overarching principle of access to, and ownership and control of, the research process – which is central to research involving Aboriginal peoples, traditional Aboriginal healers and Aboriginal healing practices – has been endorsed in general by people with HIV/AIDS.

Priorities

Participants identified the following priorities in each area under discussion:

NHP research

Priority #1: research on beneficial and detrimental interactions: interactions among NHPs (NHP-NHP interactions) and interactions between NHPs and drugs used by people with HIV/AIDS (NHP-drug interactions)

Priority #2: focus on NHPs used in treatment and support of HIV/AIDS-related conditions (side effects, toxicities, opportunistic infections, etc.)

Priority #3: prioritize the NHPs to be researched first

Health practices/services research

Participants identified an overarching theme for research in this area: research to advance integration across the continuum of health care practices and services, with a special focus on CAHC and NHPs. Participants also identified guiding principles for the research and possible research projects.

Priority #1: funding and capacity building of integrative research teams working on CAHC and NHPs with a focus on HIV/AIDS

Building research capacity

Priority #1:

- a) training in conducting research and using research findings for CAHC practitioners, educators, students and community members
- b) funding for CAHC practitioners to write up case reports
- c) a focus on Aboriginal access to, and ownership and control of, the research process

Priority #2: leveling the playing field to gain equal access to research funds

Priority #3: funding for training awards, research projects and research infrastructure in CAHC and NHPs research

Methodological development

Priority #1: establish standards of evidence and research

Priority #2: education and training in standards of evidence and research for CAHC practitioners and educators and for conventional practitioners and researchers

Priority #3: foster research skills in CAHC and NHPs among practitioners and researchers

Priority #4: educate funding review panels and research ethics boards about CAHC and NHPs research, methods and standards of evidence

Research dissemination and uptake

Priority #1: reviews of research on CAHC and NHPs

Priority #2: assessment of information needs of target audiences

Priority #3: dissemination and uptake strategies

Building and strengthening liaisons

Participants identified the sectors in which awareness of and involvement in CAHC and NHPs research need to be strengthened – researchers, funders, community organizations, hospitals and clinics, practitioners, professional associations, educational institutions, information providers and the media – and discussed ways to do this.

Priority #1: time, resources and institutional support to work specifically on building partnerships and promoting research on integrative health care

Final Recommendation

To develop research on CAHC and NHPs in the field of HIV/AIDS, it is necessary to have the time and resources to build partnerships, explore opportunities and increase the profile of CAHC and NHPs in existing HIV/AIDS networks and programs.

There was overwhelming consensus that funding for a dedicated staff person is necessary to undertake activities to build research on CAHC and NHPs in the field of HIV/AIDS. The following activities were identified but were not prioritized:

- Build on existing HIV/AIDS observational databases (British Columbia Centre for Excellence in HIV/AIDS, the HIV Information Infrastructure Project) to gather information about the use of CAHC and NHPs among people with HIV/AIDS in relation to conventional health care and treatments.
- Identify and build relations with partners in research on CAHC and NHPs (funders, industry, HIV/AIDS researchers and practitioners).
- Increase the awareness in the HIV/AIDS field of research on CAHC and NHPs at the annual conferences of the Canadian Association of HIV Research and at the XVI International AIDS Conference to be held in Toronto in 2006.
- Disseminate information through existing HIV/AIDS networks about research opportunities and share information about research initiatives in CAHC and NHPs.
- Liaise with broader networks and evolving initiatives in CAHC and NHPs.
- Facilitate the development of research on Aboriginal healing practices in relation to HIV/AIDS.

Natural Health Products Research in Children and Youth: A Priority-Setting Conference

*Dennis Patrick O'Hara, DC, ND, PhD
Toronto, March 17-18, 2002*

Executive Summary

As part of its mandate to facilitate the research of natural health products (NHPs), and in keeping with its objective to foster collaboration and partnership building, the Natural Health Products Directorate (NHPD) at Health Canada continued its relationship with The Hospital for Sick Children Foundation by co-hosting a second conference on NHP research in children and youth on March 17-18, 2002. The participants included academics, researchers, paediatricians, practitioners of complementary and alternative health care (CAHC), parents and hospital administrators, as well as representatives from the NHP industry and various government agencies.

The conference objectives were:

- to identify the current state of NHP-based research relative to children and youth;
- to facilitate dialogue and promote networking within and between the conventional and CAHC communities; and
- to establish a research agenda and identify priorities to assist in the development of the evidence base that will provide Canadians with information required to make informed decisions about NHPs and their use with children, and will also support the regulatory framework proposed by the NHPD.

Through group and plenary discussions, the participants identified four research priorities to address the objectives.

1. ***Create a usage database and evaluate current data on NHPs relative to children.*** It would be helpful to identify the NHPs that are most commonly used by Canadian children and the conditions for which NHPs are most frequently used in the treatment of children, as well as to determine what research has already been done in this area.
 - a) Undertake a national survey to determine who is using what products to treat which conditions, and to determine when and why they are using these products.
 - b) Piggyback the national survey onto existing surveys such as the national census, the National Longitudinal Survey of Children and Youth (supported by Human Resources Development Canada), and similar existing surveys.
 - c) Identify, synthesize and evaluate existing data on NHPs. Existing databases on NHPs should be evaluated to ascertain if they can provide useful information on NHP use by children. This evaluation might involve the use of systematic reviews and meta-analyses.
 - d) Work with the Cochrane Collaboration, an international organization that prepares and

maintains systematic reviews that the general populace can use to make more informed decisions about various healthcare therapies and products. The Cochrane Collaboration may be helpful since it already has fields or networks that pay particular attention to complementary medicine and child health.

- e) Establish a National Centre of Excellence (NCE) for NHPs and CAHC, with nodes established by geography and expertise. Local geographical needs and sensitivities would be considered, as would the expertise of various specialities and practices. Paediatrics would be one of the top three priorities for this NCE.

2. **Explore both basic and clinical science issues.** There are broad gaps in our knowledge of NHPs and their use by children and youth that can only be bridged by basic science and clinical research.

- a) Identify areas of high need and/or high prevalence of use. The health conditions that are most commonly encountered in paediatric care and the NHPs that are used most frequently by children should be the primary focus of preliminary research. Possible areas of investigation could include the pharmacokinetics of NHPs as well as drug-NHP interactions and NHP-NHP interactions.
- b) Build a basic science knowledge base. After identifying the diseases that should be the focus of research, the studies will seek answers to similar questions about the use of NHPs to treat specific diseases so that a matrix of information can be constructed.

- c) Collaborate, co-operate and communicate with existing networks, practitioners and NHP experts. Researchers studying NHPs and children should work with existing networks (e. g., the Canadian Paediatric Clinical Pharmacology Network) or partner with the Canadian Institutes of Health Research (CIHR) where research into NHPs and their use by children could fit into existing programs.

3. **Set priorities for knowledge translation and transfer to consumers.** Consumers want accurate and intelligible information on NHPs, especially when using these products with their children. They want to have confidence in both the products they take (with respect to efficacy, safety and quality) and in the information they receive (about product claims and content).

- a) Identify quality information on the Internet. Websites that provide monographs informed by the most recent evidence-based medical research on the more commonly used NHPs could appear on a list of approved sources of information. This could be part of an initiative, facilitated by the NHPD, to establish a central clearing house for information dissemination.
- b) Identify professionals who are knowledgeable about NHPs. While many people offer information and advice about NHPs, there is a wide range of expertise and competence. Only those who are knowledgeable should be dispensing and providing advice about NHPs.
- c) Accredite pharmacies and health food stores. Pharmacies and health food stores that have properly trained personnel onsite can be accredited as centres that provide quality information on NHPs. However, the impression must not be fostered that the NHPD is trying to regulate in an area of provincial jurisdiction.

- d) Educate the end consumer. To provide consumers with more and accurate information about NHPs, pamphlets and posters could be available in pharmacies, health food stores and the offices of health care professionals; curricula in high schools could be expanded, and public forums could be hosted.

4. ***Research ethical questions related to the healthcare of children and research methodologies for the study of NHP use in children.*** Policies that guide ethical research involving children need to be better developed. There is also a need to establish guidelines for NHP research that respect both accepted scientific methods and the various paradigms of NHP use.

- a) Review the Tri-Council Policy Statement. After a review of the Tri-Council Policy Statement governing the conduct of ethical research in humans, a companion document could be developed that would specifically address ethical concerns about research involving children.
- b) Review international law and policy. Since other jurisdictions may have already undertaken the task described above, a review of international law and policy could avoid unnecessary duplication and identify uniquely Canadian needs.
- c) Determine potential barriers to NHP research in children. Through consultation and surveys of paediatric

research ethics boards (REBs) and various research councils (such as CIHR), potential barriers to NHP research with children could be identified. Having identified possible barriers, it would be possible to design strategies to resolve them.

- d) Start with the research methodologies that are known. There are accepted scientific research methodologies that could be applied to the research of NHP use in children, including randomized clinical trials. In addition, observational studies and epidemiological studies are both accepted methods and adaptable to NHP research.
- e) Establish clinical trial research guidelines for children and youth. NHPs are often used in a specific cultural or paradigm context, and/or as part of individualized treatments that are not always easily adapted to randomized trials. The levels of evidence that have traditionally been accepted in CAHC research are often not the same as those for conventional medicine.

During the working and plenary sessions, the participants shared their expertise, experiences and opinions with considerable enthusiasm and goodwill. It was noted that research on NHP use in paediatric populations should also include the fetus, since the NHPs that a mother may take could also affect the unborn child. Several participants stressed that children and youth populations are often ‘forgotten populations’ in healthcare research. Too often, results from research completed on adults are simply extrapolated to this younger population.

Information and Informed Choice in the Use of Complementary and Alternative Health Care and Natural Health Products: An Invitational Roundtable

*Theodore de Bruyn
Vancouver, October 21-22, 2001*

Executive Summary

On October 21-22, 2001, Health Canada convened an invitational roundtable on information and informed choice in the use of complementary and alternative health care (CAHC) and natural health products (NHPs). The meeting was one of several convened in 2001 and 2002 by the Health Human Resource Strategies Division, Health Care Strategies and Policy Directorate, Health Policy and Communications Branch, and the Natural Health Products Directorate, Health Products and Food Branch, on issues related to CAHC and NHPs.

The participants in the roundtable included conventional practitioners, complementary and alternative practitioners, information providers, manufacturers and providers of NHPs, academics, researchers and policy analysts. To include an international perspective, participants were invited from the United Kingdom and the United States in addition to Canada.

The objectives of the roundtable were:

- to provide a multisectoral forum for discussion
- to identify key challenges with regard to providing information and supporting informed choice in the use of CAHC and NHPs
- to suggest ways to address these challenges
- to produce a report on the roundtable for public distribution

The roundtable focused on four broad areas of concern:

- 1 sources and systems of expert information
- 2 the collection, evaluation, selection and presentation of accessible information for practitioners and consumers
- 3 public and professional education in receiving and using information
- 4 improving connections, consistency, and integration in providing information

Several general themes emerged from the discussion:

- ***Working interactively with many systems.*** Many systems are involved in providing information and supporting informed choice: research development, professional education, manufacturing standards, regulatory systems, health intermediaries and consumers' groups. Changes often occur when several of these systems interact (often through personal contacts and in local settings) so as to make established systems more responsive to complementary and alternative therapies.
- ***Recognizing the role of complementary and alternative therapies.*** The health system – conventional practitioners, professional associations, regulatory authorities, health departments and agencies – is an important source of information about health and health care for Canadians. It is essential that people who work in the health system (especially nurses, pharmacists and primary care physicians) gain a better understanding of complementary and alternative therapies, so that they can provide information about these therapies and support informed choice in their use. What is needed is greater recognition of the role that complementary and alternative therapies can and do play in health promotion and health care, and more effort to create a place for complementary and alternative approaches, practices or products within or alongside the health system.
- ***Approaching therapies in a holistic way.*** When gathering information about complementary and alternative therapies or providing information about them, it is essential to approach the therapies and their use in a holistic way. There is a danger of reducing complementary and alternative approaches simply to a specific practice or of reducing a practice simply to a single intervention.
- ***Developing standards and coordinating systems.*** It would be helpful if government agencies, professional associations and information providers in Canada could arrive at common standards for the evaluation, selection and presentation of information about complementary and alternative therapies, and could coordinate their work in promoting and implementing such standards.
- ***Helping people find and understand information.*** There are tools that would make it easier for people to find and understand the information they are seeking. They include such things as resources in multiple languages and in plain language, a bilingual (English and French) thesaurus of terminology of complementary and alternative therapies, a directory of complementary and alternative practitioners, and an inventory of agencies and resources that provide information about complementary and alternative therapies.
- ***Improving skills in evaluating and applying information.*** It is impossible to control the quantity and quality of information available to the public and practitioners. Nevertheless, steps can be taken to help the public and practitioners improve their skills in evaluating and applying information. This could involve such aids as checklists on what to look for in an information item, guidelines on when to seek professional advice or when to refer, or listings of recommended sources of information.
- ***Meeting people where they are.*** Communication and learning take place when information providers meet people where they are. It is important to remain abreast of current trends among consumers of complementary and alternative therapies, and to recognize the diverse interests and needs among consumers. More understanding is required of how people make decisions, and how to work with the informal networks upon which people rely for

information. It is essential to provide access to sources of information in the communities where people live (e.g., primary care providers, community clinics, libraries); in a variety of formats (e.g., audio, electronic, print); and in the person's own language and at the person's functional level of literacy.

- ***Respecting diversity and choice.***

Diversity is an overall theme: complementary and alternative therapies are diverse, consumers of these therapies are diverse, and so are the reasons that people use them. It is important that initiatives and systems to gather and provide information about complementary and alternative therapies are capable of representing this diversity, and that they do not present a limited view of a given therapy by focusing only on a specific aspect (e.g., its usefulness in treating a certain condition).

This report provides a detailed summary of the participants' discussion of the four broad areas of concern, describing the challenges that participants identified and the ways forward that they suggested.

A Note on Terminology

During the roundtable, participants at times addressed their remarks generally and inclusively to all aspects of complementary and alternative health, including an overall approach to health, the practices employed in that approach and the products employed in that approach. In this report, the phrase complementary and alternative therapies is used to refer to all of these aspects: overall approach, practices and products. The terms practices and products are used to refer to more specific aspects of complementary and alternative health, as required by the discussion.

Health Law and Ethics in Relation to the Use of Complementary and Alternative Health Care and Natural Health Products: An Invitational Roundtable

*Theodore de Bruyn
Toronto, December 1-2, 2001*

Executive Summary

On December 1-2, 2001, Health Canada convened an invitational roundtable on health law and ethics in relation to the use of complementary and alternative health care (CAHC) and natural health products (NHPs). The meeting was one of several convened in 2001 and 2002 by the Health Human Resource Strategies Division, Health Care Strategies and Policy Directorate, Health Policy and Communications Branch, and the Natural Health Products Directorate, Health Products and Food Branch, on issues related to CAHC and NHPs.

The participants in the roundtable included lawyers, ethicists, practitioners, academics, manufacturers of NHPs and policy analysts. To provide an international perspective, a participant was invited from the United States.

The objectives of the roundtable were:

- to provide a multisectoral forum for discussion
- to identify key legal and ethical issues related to the use of CAHC and NHPs
- to suggest ways to address these issues

- to produce a report on the roundtable for public distribution

The roundtable considered four broad areas of concern:

1. practitioner-related legal and ethical issues
2. product-related legal and ethical issues
3. legal and ethical issues related to persons who use CAHC and NHPs
4. general legal and ethical issues

Participants identified issues and challenges in each of these areas of concern. Several general themes emerged from the discussion:

Balancing Interests

Complementary and alternative health care, like conventional health care, is beset by conflicting or competing interests. Principles and procedures developed over time in health care to disclose and manage such conflicts of interest should and can be applied to CAHC.

The Value of Ethical Frameworks

When dealing with issues raised by increasing interest in and use of complementary and alternative therapies, ethical frameworks help to contextualize the problems raised by an issue, lend coherence to the direction taken on the issue, and mediate differences of views on the issue. Several current ethical frameworks could help to address issues raised by the use of complementary and alternative therapies. It is important to draw on these frameworks.

The Importance of Public Information and Informed Choice

When people are well informed about complementary and alternative therapies, they are better able to make informed choices about the products they might use or the procedures they might consent to. What is needed is an environment that provides robust support for informed choice. This requires, for example:

- that practitioners be knowledgeable about the range of options available to people and that they advise people about the risks and benefits in a respectful way
- that labels of products convey the information people need in clear and simple language
- that providers of products provide good information about their use
- control of direct-to-consumer advertising

The Importance of Professional Formation

The formation of practitioners – which includes not only education and training in an area of practice, but also the development of professional character and ethical awareness – is key to their ability to provide information to people and to deal with the ethical questions

that might arise in clinical practice.

It is important that conventional practitioners become sufficiently knowledgeable about complementary and alternative therapies, and that complementary and alternative practitioners become sufficiently knowledgeable about conventional medicine. However, the formation of attitudes and behaviours is needed in addition to the development of knowledge.

Access to Products and Services

There are ongoing concerns about constraints on access to products and services. These constraints include:

- lack of public insurance coverage for complementary and alternative therapies
- inadequate knowledge among practitioners about the products and services that might be helpful to people
- delays in uptake of new knowledge into clinical practice guidelines
- inequities between the regulations for drugs and those for NHPs or between the regulations for NHPs and those for functional foods
- prohibition of making claims with regard to diseases listed in Schedule A of the Food and Drugs Act

While these concerns need to be addressed, the goal is not necessarily unlimited access to products and services. There is a role for regulatory controls and professional judgement.

The Person-Provider Relationship

The relationship between the person seeking care or service and the provider of care or service varies according to the circumstances of the person seeking care or service, and the nature of the care and service provided. It is difficult to settle on language to describe this relationship. Each of the terms commonly used – ‘patient,’ ‘client,’ ‘consumer’ – has

its connotations with respect to the disposition of the person seeking care or service, and the disposition of the provider of care or service.

However, it was generally agreed that health care is not a commodity like other commodities. While it might be appropriate to call people who buy NHPs ‘consumers,’ it would be misleading to suggest that the relationship that people have to health care providers is the same as the relationship they have to other goods and services.

Ongoing Ethical and Legal Deliberation

Several observations can be made about the need for further ethical and legal deliberation in relation to the use of CAHC and NHPs.

First, the increasing use of complementary and alternative therapies is bringing about, and will continue to bring about, changes to the health system in Canada. Some of the changes identified by participants in the roundtable included:

- changes in the formation of practitioners
- evolving policy regarding the use of complementary and alternative therapies in health care institutions
- assessment of evidence regarding the effectiveness of complementary and alternative therapies
- changes to clinical practice guidelines
- reconsideration of products and services covered by public and private health insurance plans

Such changes will need to be accompanied by ethical and legal reflection. While it might not be necessary to develop entirely new ethical or legal frameworks, there will be adjustments and perhaps comprehensive reconsideration. This is an exciting prospect, but also one that

requires sustained and thorough attention from all participants.

Second, a key relationship in health care is the relationship between the person receiving care or service and the provider of care or service. There are many ways in which this relationship can and should contribute to informed decisions in the use of complementary and alternative therapies. The fact that it does not always do so should be a subject of ethical and legal deliberation. It is important to identify, from an ethical and legal perspective, how the person-provider relationship – whether in conventional health care, CAHC, or in some form of joint or integrated health care – should contribute to informed decisions in the use of complementary and alternative therapies. It is also important to identify any justifiable conditions on or limits to the provider’s responsibilities to the person using complementary and alternative therapies.

Third, many people use complementary and alternative therapies as a form of self-care. This means that access to safe and effective products and services, as well as access to clear, easy-to-understand, and reliable information about these products and services, will continue to be a central concern. Undoubtedly, there will be differences in perspective among regulators, practitioners (both conventional and complementary/alternative), manufacturers, policy makers and people who use complementary and alternative therapies as to how to address issues regarding access to products and services in self-care. The discussion at the roundtable suggests that ethical and legal reflection should be a part of the process of clarifying or resolving such differences in perspective.

A Note on Terminology

*During the roundtable, participants at times addressed their remarks generally and inclusively to all aspects of complementary and alternative health care, including an overall approach to health, the practices employed in that approach, the services provided, and the products used. In this report, the phrase **complementary and alternative therapies** is used to refer to all these aspects: overall approach, practices, services and products. The terms **practices**, **services** and **products** are used to refer to more specific aspects of complementary and alternative health care, as required by the discussion.*

A Summary of National Data on Complementary and Alternative Health Care – Current Status and Future Development: A Discussion Paper

*Theodore de Bruyn
March 2002*

Executive Summary

Canadians are making more and more use of complementary and alternative health care (CAHC). This growing use includes natural health products (NHPs), complementary and alternative practices, as well as consultations with complementary and alternative practitioners.

Despite its increasing role in the health care of Canadians, there is relatively limited national data on CAHC for a number of reasons. Since CAHC is not integrated into established health care delivery systems, data on the use of complementary and alternative practitioners, products, and services are not generated by regulatory bodies, health care institutions, and public health insurance plans. Health Canada only recently established a regulatory authority for NHPs – the Natural Health Products Directorate (NHPD) – and is now in the process of establishing a regulatory framework for NHPs. Many, but not all, CAHC professional associations are in relatively early stages of development and currently have limited capacity to provide national data. Furthermore, a significant proportion of people who use complementary and alternative practices or products do so as a form of self care, and this usage is not readily captured by information systems focused on health services.

In recent years, there has been a concerted effort by the federal and provincial/territorial

governments to obtain better information about the health of Canadians and health care in Canada. At the national level, Statistics Canada has been gathering population data about health and health care through the National Population Health Survey (NPHS) and, more recently, through the Canadian Community Health Survey (CCHS). In an effort to provide a more complete picture of health care in Canada, the Canadian Institute for Health Information (CIHI) has been leading numerous projects under the Roadmap Initiative to develop or enhance data systems on health and health care, to develop and implement more complete indicators of health and health care, and to consolidate and analyze all available data. A series of labour market sector studies have been conducted or considered by Human Resources Development Canada (HRDC) among a number of health care sectors and professions including nursing, physicians, oral health practitioners, pharmacy, home care, and CAHC practitioners.

The following report summarizes national data currently gathered on CAHC in the context of these initiatives and suggests possible opportunities for gathering more complete data. The report focuses on national initiatives, specifically the population health surveys administered by Statistics Canada, the health information projects led by CIHI, and the employment sector studies facilitated by HRDC. A discussion of local studies is beyond the scope of this report.