

**The Naturopathic Medical Research Agenda:
The Future and Foundation
of Naturopathic Medical Science**

**A report produced through a grant from
the National Institutes of Health – National Center for
Complementary and Alternative Medicine**

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The Naturopathic Medical Research Agenda

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Foreword

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The completion of the Naturopathic Medical Research Agenda is an historic occasion. I very much enjoyed participating as one of the “conventional” scientists on the Naturopathic Medical Research Agenda (NMRA) Workgroup. It was a great pleasure to meet and work with the intellectually stimulating, intelligent, and socially committed individuals who were assembled for the NMRA Workgroup. I enjoyed speaking with naturopathic medical students, naturopathic clinicians and researchers, with the impressive group of outside advisers that were assembled, and with the naturopathic medical college faculty and leadership. I commend the NMRA Core Team for their wisdom and courage in including researchers from other disciplines, many of whom gave feedback that challenged some long-held assumptions and provided the NMRA Workgroup with valuable insights into the ways of thinking that are more conducive to successful scientific research in naturopathic medicine. Though honest and direct, NMRA Workgroup discussions were always respectful and collaborative. I learned a great deal during this two-year process and I am grateful and honored to have been included.

Despite being what might be considered a “conventional” scientist working within a conventional medical research setting I share many important values with the naturopathic profession. I believe that the current medical approach to illness and disease in our country is irrational, inequitable, often ineffective and wasteful, and definitely unsustainable. I also believe that there is more to healing than medications and invasive procedures and that the art of healing in this country has often been supplanted by the technology and business of medicine. While naturopathic medicine may not have all the answers, I do believe that there is much to learn from its emphasis on the whole person and on its use of less toxic and less invasive approaches to healing.

Research is always a challenging and demanding endeavor. The exciting research sound bites on the 11 o’clock news tell nothing of the enormous amount of sustained effort that teams of researchers expend over several years to successfully complete a project, much less the years of frustration often required to obtain grant funds to begin the project in the first place. Obtaining research funding is particularly difficult for new researchers entering new areas of research, including complementary and alternative medicine. However, with the completion of the NMRA report, the naturopathic profession has taken a large step forward. You are wisely focusing your enthusiastic but limited energies and resources on collaborations with colleagues both within and outside the naturopathic medical profession. You are also painstakingly and methodically laying the groundwork that will be necessary to prepare you to conduct the large scientifically rigorous randomized controlled trials that will ultimately be required in order to have a major impact on clinical care in the United States.

Research is a difficult business, demanding patience, passion, and perseverance. But like all well-prepared pioneers you now know where you are headed, you have a map, you have your teams assembled, and you will follow the stars to your dreams. Congratulations on your pioneering efforts in establishing a research agenda for naturopathic medicine. Your agenda is truly a milestone in the development of the profession and will shape the future of research in naturopathic medicine for years to come.

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EXECUTIVE SUMMARY

This report documents the process and findings of the Naturopathic Medical Research Agenda, a project funded by NIH-NCCAM through a grant that ran from August 1, 2002 through August 31, 2004. The goals of this project were:

- Goal 1: To bring together naturopathic physicians and conventional research scientists in order to establish the Naturopathic Medical Research Agenda Workgroup;
- Goal 2: From this process, to produce a document entitled “The Naturopathic Medical Research Agenda” that includes a prioritized list of research questions and areas, coupled with appropriate research design methods for each.

Participants in the project included over 1200 individuals, representing a broad range of scientific and clinical backgrounds. Input from the naturopathic profession itself was substantial, involving participants from the naturopathic medical colleges and the national professional association, and encompassing many of the profession’s leading faculty, researchers, clinicians, and writers. Conventional physicians and scientists also participated broadly and made significant contributions through the NMRA Workgroup.

A series of meetings was held during the project period to elicit, discuss, analyze and prioritize feedback on the direction of the Agenda, and on the criteria by which decisions would ultimately be made. Articulation of the following guiding principles emerged:

The Agenda should be designed to test **three fundamental hypotheses**:

- Naturopathic medicine is safe and effective for health promotion and for the prevention and management of a broad range of common conditions.
- Increased availability of the services of naturopathic physicians will improve patient health in a cost-effective manner.
- The scientific exploration of naturopathic medical practices and principles will yield important, perhaps even revolutionary, insights into the nature of health and the biology of healing.

The Agenda should use the following **prioritization criteria** in determining the specific focus of future research efforts:

- Study conditions with the highest burden of illness
- Study problems of existing and emerging public health significance
- Study those naturopathic treatments thought to be most effective
- Study naturopathic approaches with real potential to make significant advances in patient care
- Foster the development of needed methods and infrastructure
- For initial studies, focus on near-term feasibility

The Agenda should reflect the following **goals**: first, to improve the health of patients; second, to improve naturopathic medical practice; third, to focus primarily on populations, not diseases; fourth, to conduct research on the whole practice of naturopathic medicine rather than on single agents.

Research Recommendations

Consistent with the emphasis on studying people and populations, and with the prioritization criteria stated above, two populations were identified for the initial focus of naturopathic medicine research: the first is defined by a diagnosis (type 2 diabetes) and the second by a stage of life (elderly).

The significance of diabetes can scarcely be overstated; the Centers for Disease Control recently estimated that one in three children born in the year 2000 will eventually become diabetic. Demographics make studying the elderly an extremely high priority – as the baby boomers age, a major impact on costs and suffering can be achieved by reducing the incidence of serious chronic disease, of secondary complications from chronic disease, and of debility associated with aging.

Healthy aging, of course, must begin with infants and children, and the development of habits and physiological predispositions from childhood on will be important future priorities. Rising rates of conditions such as asthma, allergies, attention disorders, obesity, and type 2 diabetes in children do not bode well for a healthy older population in those who are at the beginning of their lives. Therefore, research on a pediatric population was identified as an important future priority.

The NMRA calls for systematic reviews and the collection of preliminary clinical data in preparation for a large randomized controlled trial assessing the effect of individualized **naturopathic medical care in comparison to conventional care in a population of individuals with type 2 diabetes**. Outcomes of whole-practice research on a diabetic population will include biomedical disease markers, including assessment of co-morbidities, and health and health services indicators.

Controlled studies of **naturopathic medical care for the preservation and the promotion of optimal health in geriatric populations** are specified in the Agenda. The NMRA also recommends the collection of data from demonstration projects with health plans that include naturopathic physicians, as these are clinical sites where outcomes and cost of service can be studied. Neurogerontology and diabetes prevention and treatment in the elderly have been identified as an initial focus of NMRA gerontology/geriatrics research.

The NMRA can help naturopathic medicine be part of the healthcare solutions our nation clearly needs by doing excellent research in critically important areas. Through the NMRA process, the following recommendations were made regarding the **priorities for how to approach naturopathic medical research in the two populations**:

- Design and execute **whole-practice research** protocols, with a focus on naturopathic medicine as a primary care practice for the two populations (diabetics and the elderly);
- Continue research on the **components of naturopathic medicine** (e.g., single agents for a particular diagnosis, mechanism of action studies); and
- Perform **contextual research**, examining important aspects of the practice of naturopathic medicine (e.g., the patient-practitioner interaction) or its relationships with the larger health system (integration) through **observational studies**.

Most research to date on naturopathic medicine has been component research. As yet, little work has been done in the areas of whole-practice and context research.

Finally, there was strong support for women's health research among naturopathic physicians in the field, especially component research on natural hormone replacement therapy for women in their peri- and postmenopausal years. At the 2004 annual national meeting of the Association of Naturopathic Physicians held in Portland, Oregon there was widespread agreement that the evaluation of the safety and efficacy of bio-identical steroid hormones for the treatment of menopausal women was of high priority. A group of naturopathic physicians specializing in women's health met with NMRA leadership at this national meeting. From these meetings this physician group committed themselves to organizing research trials on bio-identical estrogens and progesterone.

Research Readiness

In order to consolidate naturopathic medical research, the team and institutions that developed the NMRA will form the basis for an ongoing collaborative network. Each of the naturopathic institutions represented on

the Workgroup Core has already committed to, and is engaged in, lines of work related to at least one of the populations of interest. Collaborative partnerships with researchers in conventional medicine, public health, and other disciplines will be actively pursued or strengthened where they currently exist. Many of the consulting scientists in the Workgroup have also committed to participate in the areas discussed in this report. More formal consortia are expected to arise around each specified research direction.

In addition, certain methodological challenges inherent in researching the whole practice of naturopathic medicine were identified and must be resolved. These include notably:

1. Standardization of treatment substances such as botanical medicines and practices such as mind-body interventions;
2. The identification and study of non-specific healing effects and the use of health outcomes and measures, as well as disease outcomes, to evaluate effectiveness;
3. Study designs (including the use of controls and blinding) that will accommodate individualization of treatment and the use of combination therapies, both of which are established naturopathic practices.

Finally, the infrastructure that will enable collaborating NMRA institutions and individuals to respond with excellence to these research goals is growing but needs further support. The NMRA identified four research methods and strategies for which infrastructure development is needed:

- high validity randomized controlled trials (RCTs) of whole-practice naturopathic medicine for the evaluation of efficacy of “best” protocols;
- observational studies and health services research to assess safety, cost, and effectiveness of current practice and integration;
- laboratory studies to establish standards and investigate critical effects and mechanisms; and
- basic and clinical capacities for the exploration of naturopathic medical principles.

Implementation

Four tracks have been identified to foster diverse research leadership and broad participation in research initiatives among the participating naturopathic medical colleges:

- **Publications and Information Dissemination Track** (Canadian College of Naturopathic Medicine, Bastyr University, and Australian Centre for Complementary Medicine Education and Research),
- **Diabetes Track** (Southwest College of Naturopathic Medicine; Bastyr University; National College of Naturopathic Medicine),
- **Gerontology Track: Health of the Elderly** (Bastyr University; National College of Naturopathic Medicine), and
- **Whole Practice and Methods Track** (National College of Naturopathic Medicine).

These Tracks will allow each institution to appropriately focus its infrastructure development, as well as assist faculty, clinicians, and researchers to develop skills in specific areas of interest.

Other implementation steps include:

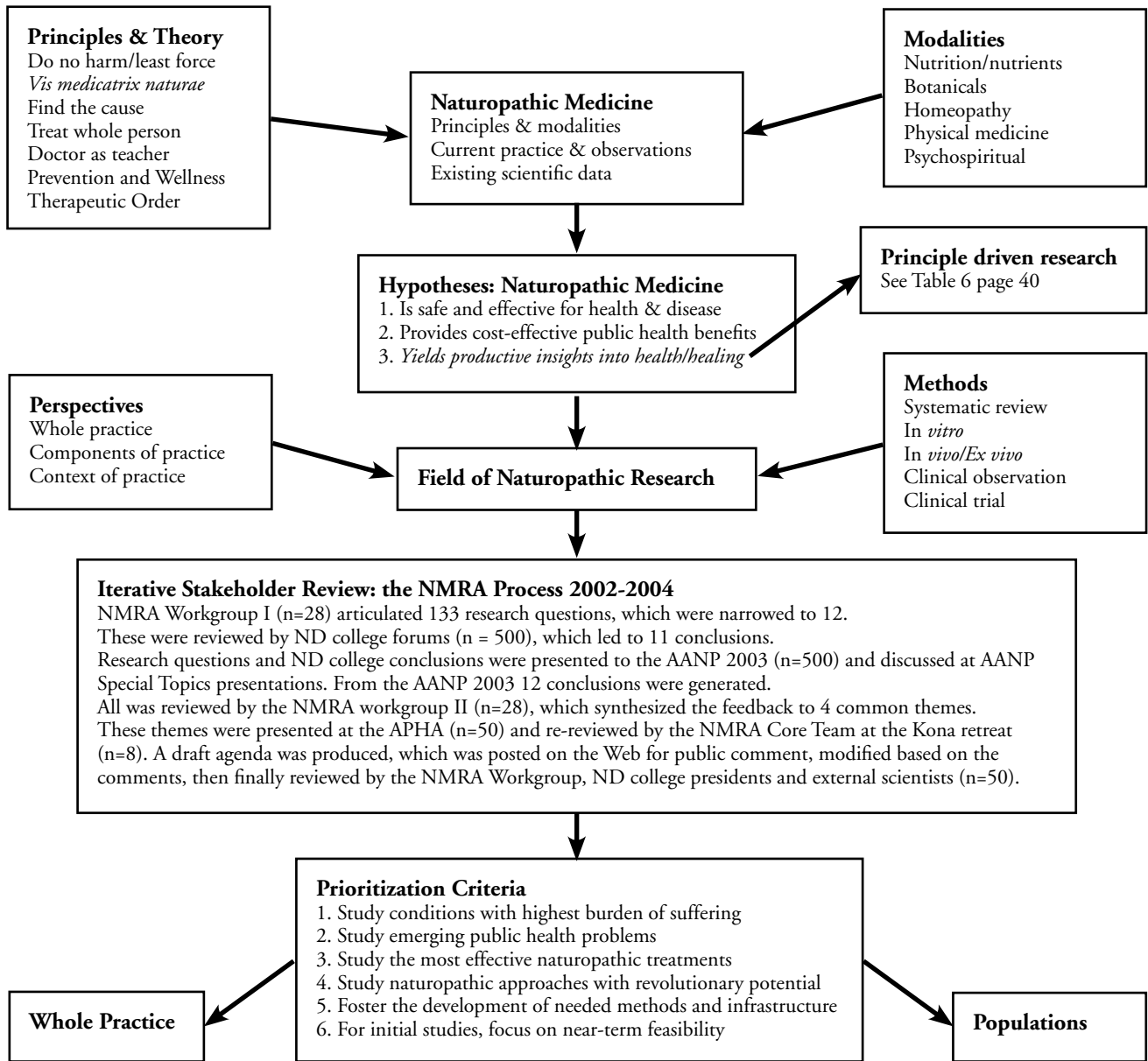
- Preparation of grant proposals to both government agencies and private foundations to fund the activities recommended by this report;
- Development of a Web-based network and annual meetings to facilitate communication about the ongoing work, and to enable institutions and individuals that are geographically distant to collaborate effectively and efficiently;
- Establishment of a mentorship program to match inexperienced naturopathic physician researchers with senior ones, and to disseminate information about training opportunities; and
- Submission of papers based on work arising from the NMRA project to peer-reviewed journals in order to more formally analyze many of the suggestions that emerged and disseminate the findings.

Tangible and immediate outcomes of the NMRA included the production of one NMRA book, three NIH grant proposals, and facilitation of the start-up of the peer-reviewed journal, the *International Journal of Naturopathic Medicine*.

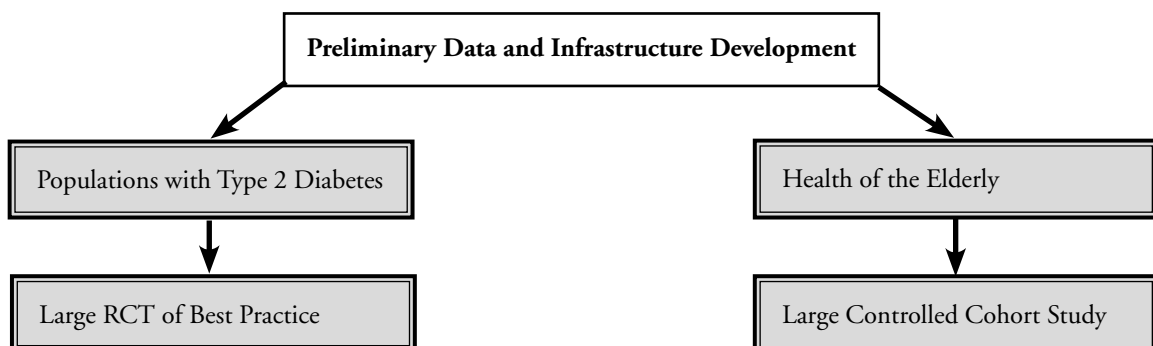
A visual overview of the the Naturopathic Medical Research Agenda 2005-2010 is presented in Figure 1.

Figure 1. The Naturopathic Medical Research Agenda

VISION & VALUES: HEALTHY PEOPLE ~ HEALTHY COMMUNITIES ~ HEALTHY WORLD ~ DISCOVERY



THE NMRA WILL FOCUS ON PEOPLE, NOT DISEASES, USING WHOLE PRACTICE RESEARCH METHODS WITH BROAD ASSESSMENT OF HEALTH, SAFETY, DISEASE MARKERS, AND HEALTH SERVICES OUTCOMES



THE GRANT

On June 1, 2001 Drs. Standish (Bastyr University) and Calabrese (National College of Naturopathic Medicine) submitted an R21 application to the National Center for Complementary and Alternative Medicine (NCCAM) entitled “The North American Naturopathic Medical Research Consortium.” Naturopathic research directors from the five North American naturopathic medical colleges assisted Drs. Standish and Calabrese in developing the grant application. The directors included Dr. Kail (Southwest College of Naturopathic Medicine), Dr. Mills, (Canadian College of Naturopathic Medicine), and Dr. Mattie (University of Bridgeport). Dr. Snider (Bastyr University) joined Drs. Standish, Calabrese and the core team in October 2002.

The initial application requested funding for development of a naturopathic medical consortium, and was subsequently revised to request two years of funding in order to develop a prioritized and systematic naturopathic medical research agenda for the five accredited four-year naturopathic medical colleges in the United States and Canada. The \$250,000 grant was funded with Leanna Standish, ND, PhD as principal investigator at Bastyr University, and work began August 2002. The purpose of the grant was to bring together the research directors from the naturopathic medical colleges with medical scientists from conventional academic research institutions to form the Naturopathic Medical Research Agenda (NMRA) Workgroup. In January 2003 the University of Queensland/Southern Cross University’s college of naturopathic medicine and its director, Stephen Myers, PhD, BMed, ND, were added to the NMRA workgroup. Dr. Traub (Chair of Scientific Affairs for the American Association of Naturopathic Medicine) also joined the Workgroup in January 2003.

The charge of the NMRA Workgroup was to consider the scientific potential and methodological issues inherent in the investigation of naturopathic medicine and to develop a research agenda to be implemented through the collaborative efforts of the naturopathic medical colleges along with collaborators from conventional academic medical settings. The goal of two years of meetings, retreats, and electronic conversations was to produce a document entitled “The Naturopathic Medical Research Agenda.” This document is a prioritized list of research questions, along with the appropriate research infrastructure, design and methods for each.

The goals of the grant were met. The NMRA Workgroup selected key areas of research and articulated the research methods, the research infrastructure, and collaborations needed for each area. Even before the completion of the grant period in August 2004 collaborative work has already begun at the naturopathic medical colleges in the US, Canada, and Australia in the high priority areas of diabetes and gerontology.



Workgroup Session II Participants, November 2003

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THE BACKGROUND

This report on the Naturopathic Medical Research Agenda (NMRA) is the result of a two-year process (2002-2004) of meetings, debate, retreat, and review, funded by an R21 grant from the NIH National Center for Complementary and Alternative Medicine (NCCAM). The twenty-eight Workgroup members were asked by the investigators of the grant to represent diverse views and interests from inside and outside the naturopathic medicine community. They served for two years, and provided input and decision-making advice and strategies at every key point in the process. Over the two years, more than 1200 scientists and physicians from both conventional and naturopathic medical institutions and organizations participated. The generous contributions of nationally respected scientists and physicians from conventional medical science are deeply appreciated by the naturopathic profession. Final decisions about focus and content were made by the investigators in conjunction with the core team.

Our work began with the definition of naturopathic medical research and the formulation of three hypotheses:

1. Naturopathic medicine is safe and effective for health promotion and for the prevention and management of a broad range of common conditions.
2. Increased availability of the services of naturopathic physicians will improve patient health in a cost-effective manner.
3. The scientific exploration of naturopathic medical practices and principles will yield important insights into the nature of health and the biology of healing.

We spent two years deciding the best way to evaluate these hypotheses, developing the criteria for selection, and then selecting the population and condition foci for the NMRA to study through appropriate, feasible, and efficient research methods.

The NMRA Workgroup decided (1) that whole practice research methods are an essential approach to evaluate the efficacy of naturopathic medicine, and (2) that study end-points must include sensitive measures of health and well-being as well as a broad array of clinical, laboratory, and quality-of-life markers. We selected two groups in whom to evaluate the effects of naturopathic care: those with type 2 diabetes and the elderly. Pediatric populations were identified as an important future priority.

After the NMRA was presented at the AANP 2003 Convention in Seattle, WA, significant discussion developed among the members of the AANP about the need to form a focus on women's health research. As a result, a task force on the safety and efficacy of natural hormone replacement therapy was established.

We have organized this document so that the needs of readers seeking varying levels of depth can be accommodated. The process and key outcomes are summarized in the Executive Summary and Figure 1 (pages 1-4). For those readers wanting greater depth, the body of the report provides a

...whole practice research methods are essential to evaluate the efficacy of naturopathic medicine...

detailed narrative. The Appendices contain more detailed information about naturopathic medicine and the NMRA participants and process.

The goal of the NMRA Workgroup's process was to fit naturopathic clinical practice and theory into an achievable research agenda for systematic evaluation of key health benefits. In pursuing this goal, the Workgroup has attended carefully to the national health goals of the US Department of Health and Human Services, especially the health promotion and disease prevention goals of Healthy People 2010 and STEPS to a Healthier US. The NMRA calls for the application of rigorous and well-accepted research methods to answer a set of research questions in a manner that preserves the integrity of the practice under study, while performing replicable studies that will provide practical and transferable clinical and health services insights.

The goals of the project were achieved. The report describes a plan for systematic investigation of naturopathic medicine over the next five years. It is intended to be a map for the cooperative activities of naturopathic and conventional research institutions and potential funders in pursuing specific lines of investigation. It may also serve as a guide for the development of the necessary methods and infrastructure to carry out a systematic evaluation of naturopathic medical practice.

Using a broad-based data gathering process, seeking consensus where possible and appropriate, and incrementally improving upon the content with each successive level of input, we have developed an agenda to collect data that can shape changes in the naturopathic profession and contribute substantively to health science policy discussions at the national level. The work inspired by the NMRA has already begun through the mobilization of collaborations and resources that resulted from this project. Through the implementation of this Agenda, naturopathic medicine can contribute to more effective patient care and help to expand solutions for the growing economic, environmental, and psychosocial problems confronting our current health care system. Our commitment going forward is to perform the research that will generate reliable evidence that will guide us on how these important goals may be best accomplished.

...naturopathic medicine can contribute to...solutions for the growing economic, environmental, and psychosocial problems confronting our current health care system.

The Naturopathic Profession

Naturopathic medicine is a worldwide profession with concentrations in the US, Germany, Canada, UK, Australia, and India. In these countries, naturopathic medicine is a primary health care profession that functions to promote health and to prevent, diagnose, and treat acute and chronic disease. There are differences among various regional traditions, but the approach to development of a research agenda would apply to any of them. Textbooks of naturopathic medicine exist and serve as core teaching tools in medical education (Pizzorno and Murray's *Textbook of Natural Medicine*, 1999). The NMRA Workgroup includes naturopathic physicians and researchers representing institutions from the US, Canada, and Australia, where practice and regulation are similar.

In North America, a naturopathic physician must be licensed to practice in fourteen states, four Canadian provinces, the District of Columbia, the US territories of Puerto Rico and the US Virgin Islands. The license typically is broad, allowing naturopathic doctors (NDs in some jurisdictions, NMDs in others) to diagnose any disease and treat using any natural means. In Arizona and British Columbia, acupuncture is a part of the regulated practice; elsewhere, naturopathic physicians must obtain an additional license to practice acupuncture. Legend drugs are permitted in some jurisdictions, and minor office surgical procedures and midwifery are permitted in most. The term "naturopathic physician" or "doctor of naturopathic medicine" is used to describe a practitioner in licensed jurisdictions. In these jurisdictions, naturopathic doctors are required to graduate from an accredited naturopathic medical school that requires four years of full-time study, and to pass an extensive postdoctoral board examination (NPLEX) in order to receive a license. Licensed naturopathic physicians must fulfill state-mandated continuing education requirements annually. They have a specific scope of practice defined by their state's law. Naturopathic physicians also practice in at least 28 states that have no licensure laws (Hough et al., 2001).

According to the University of California San Francisco's *Profile of a Profession: Naturopathic Practice*, in 2001 the American Association of Naturopathic Physicians reported having about 1800 members and the Canadian Naturopathic Association reported about 300 members (Hough et al., 2001). Figures obtained by Hough et al. from state licensing boards in the 12 jurisdictions licensed at that time showed that 1300 NDs were licensed in the US, and 500 were licensed in Canada. It was estimated overall in the UCSF report that there were approximately 2,000 licensed naturopathic doctors in the U.S. who have been trained in accredited four-year post-baccalaureate institutions. There may be several thousand more naturopathic physicians unable to be licensed whose training is highly variable (Hough et al. 2001).

According to Cooper and Staffet (1996) in their report *Trends in the Education and Practice of Alternative Medicine Clinician*, there were 1800 naturopathic physicians in 1994 (0.7 per 100,000), 870 of whom were licensed in at least one of the states offering licensure (4.1 per 100,000 in only those states that offered licensure). However, Cooper and Staffet predicted significant growth in the numbers of licensed naturopathic physicians: "We project a doubling in the number of alternative medicine clinicians over the next 15 years...." The per capita supply of alternative medicine clinicians will grow by 88% between 1994 and 2010, while [conventional] physician supply will grow by 16%. Alternative medicine clinicians were defined to include licensed NDs, chiropractors and acupuncturists (Cooper and Staffet, 1996). Enrollment data at accredited naturopathic colleges from 1990 to 2001 support Cooper's assertion. According to the Council on Naturopathic Medical Education (CNME), there were 319 students enrolled in US naturopathic colleges in 1990. This number grew to 1523 by 2001 (Loft, 2001). During the same period the approximate number of accredited CAM schools graduating licensed CAM providers tripled from 50 to 149, with the number of naturopathic colleges doubling from two to four in the US (Snider and Petty, 2002).

Naturopathic practice. Licensed naturopathic physicians are broadly trained in complementary and alternative (CAM) practices and are well prepared for integration into the mainstream health care system. Their education in the basic and diagnostic sciences of biomedicine, as well as their training in primary care and their competencies in health promotion, prepare them for participation in integrated care delivery, public and community health settings, as well as individual practice.

The naturopathic doctor's initial visit focuses on learning as much as possible about the patient using thorough history and review of systems, physical examination, laboratory tests, radiology, and other diagnostic procedures. The patient's diet, environment, toxic burden, exercise, stress, and other lifestyle elements are also evaluated. As a better understanding of the patient's health and disease status is established, the doctor and patient work together to develop a treatment and health promotion program that works for the patient. Treatment modalities include, among others, botanical medicines, diet, nutritional supplements, homeopathy, physical medicine (physiotherapy, hydrotherapy, manipulation), and psychological and lifestyle counseling. (While some states license NDs to practice acupuncture, the first NMRA will not address this modality. Rather, we will focus on naturopathic medicine as a system in itself.) A naturopathic physician, as part of a vitalistic medical tradition, arrives at a functional and constitutional assessment as well as a disease diagnosis. Treatment is individualized for the particular patient's condition, environment, and capacities as well as for the specific disease entity. Typically, a combination of treatments is applied and continuously adjusted over time as the patient's condition changes. Naturopathic physicians work with both acute and chronic conditions in all populations, and provide patient education and counseling to enhance wellness and healing, prevention of the onset of illness, and coordination of care.

Naturopathic physicians practice as primary care clinicians and may also choose to specialize in patient populations (e.g., women, the elderly, pediatrics), modalities (e.g., homeopathy, botanical medicine, counseling), or areas of clinical emphasis (e.g., environmental medicine, cardiology). Some may offer a special emphasis in treating people with certain conditions (e.g., diabetes, cancer, infectious disease). See Snider 1996 for a review.

"We project a doubling in the number of alternative medicine clinicians over the next 15 years...."

Naturopathic physicians practice as primary care clinicians ... in both acute and chronic conditions in all populations.

Using Washington State medical insurance claims data, Lafferty et al. (2004) concluded that CAM treatment did not appear to be replacing conventional treatment but instead is integrated into overall care. Cherkin et al. (2002) studied practice patterns and patients seen by four types of CAM providers, including licensed naturopathic physicians. Data indicated that “of the four CAM professions, acupuncturists and naturopathic physicians saw the broadest range of conditions; children comprised 10% of visits to naturopathic physicians; and that at least two thirds of visits resulted from self-referrals.”

Cherkin et al. (2002) collected data in Connecticut and Washington State on naturopathic medical visits. They reported “...about one-third to one-half of visits to naturopathic physicians were for problems that the practitioner believed were concurrently being cared for by a conventional physician” (p. 466). However, naturopathic medicine is often practiced as an alternative rather than a complement to conventional medicine, especially in primary care.

In Australia...5% of the population had visited a naturopathic physician.

...a significant percentage of cancer patients seek out naturopathic medical care.

Naturopathic medicine and chronic disease. The experience of NDs in practice is that patients with serious chronic disease commonly seek out naturopathic medical care; thus, how the ND integrates with the conventional care team and the value to patients of having an ND on the care team seem to be issues well worth exploring. In Australia, McClennan et al. (2003) demonstrated that in the past year, 5% of the population had visited a naturopathic physician. While only a small percentage of Americans have received medical care from naturopathic physicians, a disproportionately higher percentage of seriously ill people, especially those with cancer, seek out this type of CAM care. A 2002 nationwide survey of insurance data (National Health Interview Survey, CDC 2004), found that only 0.2% of surveyed Americans reported receiving health care from a naturopathic medical provider. Lafferty et al. (2004) analyzed insurance claims data and found a higher naturopathic physician utilization rate of 3% among Washington state residents. Analysis of year 2000 claims data from two large Washington State insurance companies indicated that a significant percentage of cancer patients seek out naturopathic medical care. Of 357,709 claimants, 7,915 (2.3%) had a cancer diagnosis. Among cancer patients 7.1% had a claim for naturopathy, acupuncture, or massage and 11.6% for a chiropractor during the study year. In some groups, such as women receiving chemotherapy, use of naturopathic medical providers was as high as 13%. Use of naturopathic medicine and acupuncture was more common (OR 2.0, $p < .001$, OR 1.4 $p < .001$ respectively), and use of chiropractic was less common (OR .9, $p < .001$), for cancer patients relative to those without cancer. Billed amounts for alternative services comprised less than 2% of the overall medical bills for cancer patients. Lafferty et al. concluded that a substantial number of insured cancer patients would use alternative providers if given the choice. The cost of such treatment is modest in comparison to conventional care charges. For individuals with cancer, CAM providers do not appear, in most cases, to be replacing conventional providers but are instead integrated into overall care. Data show that patients with cancer who utilize naturopathic medicine report high satisfaction with that care (Lafferty et al. 2004). However, the impact of such care on mortality and morbidity is still unknown. The need for prospective outcomes studies and RCTs of combined conventional and naturopathic cancer care is an important priority; fortunately, some studies by naturopathic physicians are now getting underway.

Brief History of Naturopathic Medicine

The term “naturopathy” was coined in 1895 to describe a health care system based on the integration based on the integration of diverse medical and health disciplines. While individual therapies may or may not have been shared among these disciplines, the philosophical thread of health promotion and support of the body’s intrinsic healing processes permeated these early schools of thought in the United States. Naturopathic medicine was brought to the U.S. in 1905 by Benedict Lust as an outgrowth of the European water cure tradition, which had deep roots in traditional world medicines. Lust’s founding of the American College of Naturopathy in 1902, purchasing of the name naturopathy and founding of the American Naturopathic Association were elements of the process of establishing the profession. Naturopathic medicine or “nature cure” was defined by Lust as both a way of life and a concept of healing that used various natural

means of treating human infirmities and disease states. The “natural means” were integrated into naturopathic medicine by Lust and others based on an emerging naturopathic theory of healing and disease etiology. The earliest therapies and healing practices associated with the term involved a combination of American hygienics and Austro-Germanic nature cure and hydrotherapy. Leaders in this field included Lindlahr, Trall, Kellogg, Holbrook, Tilden, Graham, Kuhne, McFadden, Rikli and others who wrote foundational naturopathic medicine treatises, or developed naturopathic clinical theory, philosophy and texts, enhancing, agreeing with and diverging from Lust’s original work (Zeff, Snider, Myers in Pizzorno, 2004). Henry Lindlahr’s seminal text, *Nature Cure*, is a foundation of modern naturopathic practice and theory (Lindlahr, 1913).

Naturopathic Principles and Clinical Theory

Naturopathic clinical practice is guided by six principles, which were articulated by the American Association of Naturopathic Physicians in 1989 (Snider and Zeff, 1988, 1989). In 1989 the American Association of Naturopathic Physicians House of Delegates unanimously approved the Definition of Naturopathic Medicine, updating and reconfirming in modern terms these core principles in a professional consensus, and asserting that “the definition and principles of practice provide a steady point of reference for this debate, for our evolving understanding of health and disease, and for all of our decision making processes as a profession” (Snider and Zeff, 1989). This definition has subsequently been adopted in Canada and Australia. The six principles that define naturopathic medicine are as follows:

First, do no harm (*primum non nocere*). Utilize methods and substances that minimize harm. Apply the least force for diagnosis and treatment. Avoid suppression of the healing process. Iatrogenic disease is a significant source of morbidity and mortality. More than 225,000 deaths per year in hospitals are caused by surgical errors, appropriately prescribed medications, and nosocomial infections (Starfield 2000). The cost of medical mistakes rises with the risk of the intervention.

The healing power of nature (*vis medicatrix naturae*). Organisms are inherently self-organizing and self-healing. The process of healing is ordered and intelligent. It is the physician’s role to support this process by removing obstacles to health and contributing to the creation of a healthy internal and external environment.

Identify and treat the cause (*tolle causam*). The physician’s optimal approach is to seek and treat the causes of disease rather than suppress the symptoms. Symptoms may represent the body’s attempt to defend itself and to adapt and recover. Lack of exercise, poor diet, and other lifestyle elements are major factors in the eventual expression of disease. Some estimates are as high as 70-80% that chronic disease is caused by lifestyle – and yet lifestyle is rarely directly treated. Stress is also a major contributor to disease, yet most health professionals do not treat it unless they are psychologists or social workers.

The doctor is a teacher (*docere*). The physician’s role is to educate the patient and emphasize self-responsibility and self-care. The physician patient relationship is an integral aspect of the healing process. Patient education is important but rarely is fully delivered in the conventional health care setting.

Treat the whole person (*holism*). The multifactorial nature of health and disease requires attention to the physical, mental, emotional, spiritual, social, and ecological aspects of our nature. Diagnosis and treatment that are constitutional and holistic are among the foundations of naturopathic medicine.

Prevention. The prevention of disease and establishment of wellness by the attainment of optimal health is a primary objective.

Naturopathic medicine encompasses treatment and diagnostic modalities whose use is guided by principles and theory of naturopathic medicine that are critical to the practice's identity and, some assert, its effectiveness. Clinical application of naturopathic theory influences case management; selection, sequencing and integration of therapies; patient diagnoses; healing practices, and lifestyle and wellness approaches. Both effectiveness and safety can be influenced by theory. Edmund Pellegrino, PhD, a medical ethicist at Georgetown University, describes its effect on clinical care (Pellegrino 1979): "What physicians think medicine *is* profoundly shapes what they *do*, how they behave in doing it, and the reasons they use to justify that behavior.... [W]hether conscious of it or not, every physician has an answer to what he thinks medicine *is*, with real consequences for all whom he attends.... [T]he outcome is hardly trivial.... It dictates, after all, how we approach patients, [and] how we make clinical judgments" (p. 43).

International perspectives on naturopathic practice principles demonstrate increasing coherence and consistency between North America, Australia and the United Kingdom, as evidenced in a recent publication on naturopathic medicine that included naturopathic physician authors from several countries (Myers et al. 2003). Naturopathic medicine is the eclectic practice of health care, united by the core underlying principles described above. Central to these principles is the healing power of nature (*vis medicatrix naturae*), a concept that is ascribed to Hippocrates and is as old as the healing arts. The healing power of nature refers to the inherent self-organizing and healing process of living systems that establishes, maintains and restores health (Myers, Hunter, Snider, Zeff 2003). In the words of Newman Turner (1984), "naturopathy is based on the recognition that the body possesses not only a natural ability to resist disease but inherent mechanisms of recovery and self-regulation." Lewith (in Newman Turner, 1984) suggests that the healing power of nature underpins nearly all the techniques in complementary medicine. The application of this concept gives rise to the use of natural methods to assist the healing process, the use of food, sunlight, water, rest and relaxation. Modern naturopathic medicine has its basis in nature cure, which focuses on the application of these simple natural modalities (Myers, Hunter, Snider and Zeff, 2003).

Naturopathic clinical theory. Clinical methods used by naturopathic physicians are applied in an ordered manner, consistent with stimulating the healing power of nature, which directs maintenance of health and healing in the organism. The order of this application defines a hierarchy of healing, or a therapeutic order (see Table 1). This order proceeds from least to most force, assumes an order of efficiency in integration of therapies and is determined by both the "natural laws of healing" (Zeff, Snider, Myers et al., 2004) and the patient's individual priorities.

Table 1. The therapeutic order

1. Establish the conditions for health (see "Determinants of health"):
 - Identify and remove disturbing factors
 - Institute a more healthful regimen
2. Stimulate the healing power of nature (*vis medicatrix naturae*), the self-healing processes
3. Address weakened or damaged systems or organs:
 - Strengthen and balance the immune system
 - Decrease toxicity
 - Normalize inflammatory response
 - Optimize metabolic function
 - Balance regulatory systems
 - Enhance regeneration
 - Harmonize with the life force
4. Correct structural integrity
5. Address pathology: use specific natural substances, modalities or interventions
6. Address pathology: use specific pharmacological or synthetic substances

During the “naturopathic physician” definition process in the United States, many naturopathic physicians described the need to further examine the concepts of an innate order to the healing process. Today, this healing order has re-emerged and been re-articulated from the core principle, the healing power of nature, as the unifying theory of naturopathic medicine (Zeff, 1997; Zeff and Snider, 1996; Myers et al., 2003; Zeff et al., 2004).

Determinants of health. Health promotion is a key trend in public health awareness today, along with changing societal values regarding consumption, ecology, and our relationship with the natural world. These concerns will play a significant role in the future of health care and are factors in the naturopathic approach to health care (Snider, 1996). Naturopathic medical leaders articulated the determinants of human health as seen in Table 2 (Zeff and Snider, 1996; Myers et al., 2003; Zeff, Snider and Myers, 2004). Naturopathic medicine is not primarily the diagnosis and treatment of disease with natural agents. Its practice is based upon the restoration of health. Although health is the natural state of being, health is seen by NDs as being affected by the interaction of the being with the environment in which that being exists, both internally and externally. Health is perceived as a product of conditions, which create health, and has specific determinants, which are studied and evaluated in patients of naturopathic physicians. Naturopathic physicians address these important determinants as the first clinical step in the therapeutic order.

Note: A more extensive narrative on the history, theory, and practice of naturopathic medicine is included in Appendix B.

Table 2. The determinants of health

Inborn

Genetic make-up (genotype)

Intrauterine/congenital

- Maternal exposures
- Maternal nutrition
- Maternal lifestyle
- Constitution and susceptibility

Hygienic factors/lifestyle factors: How we live

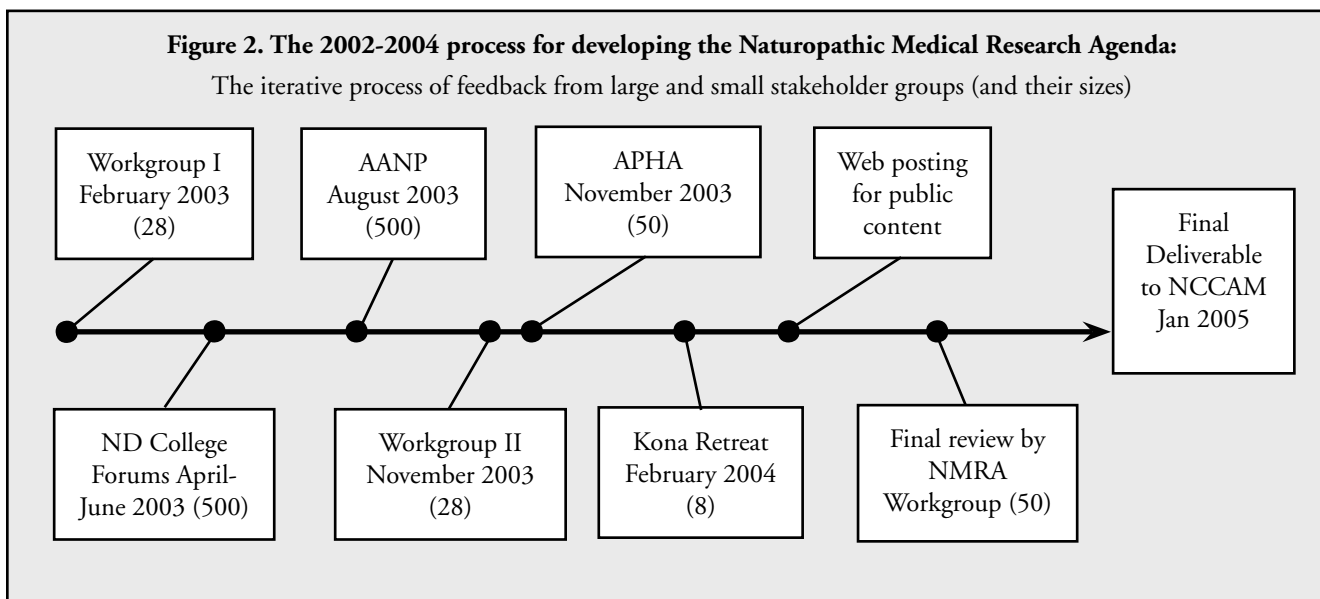
- Spiritual factors (spiritual life/practice, sense of purpose, relationship to the universe)
- Environment (water, air, light, exposure to toxins, access to nature, trauma)
- Lifestyle (diet, quality of food, nutrition, exercise, addictions, stress)
- Psychoemotional and psychosocial factors (emotional trauma, pathobiography: illnesses and medical interventions,

THE PROCESS OF DEVELOPING THE NMRA

Consensus Building for the NMRA

The NMRA Workgroup conducted a structured and sequenced consensus-building process, involving formal presentations and critical feedback from many key stakeholder groups (see Figure 2 below). Although it was not possible to achieve a true consensus position on all the issues, due to the diversity of opinions and perspectives represented in the process, widespread agreement was achieved for the core content of the Agenda. Reviews by potential collaborators have been instrumental in helping to ensure that the final document has its intended impact in stimulating and guiding research activities of participating scientists and clinicians.

The need for a national coordinated research agenda for naturopathic medicine has been recognized since the early 1990s by naturopathic medical researchers at the six naturopathic medical colleges. Discussions with Drs. Straus and Nahin at the NIH's National Center for Complementary and Alternative Medicine in 1999 confirmed NCCAM's interest in developing detailed research agendas from each of the major CAM disciplines. A proposal was submitted to NCCAM in 2000 requesting two years of funding for the development of a research agenda and a strategic plan to implement the naturopathic medical research agenda. This document is the summary of the NMRA Workgroup's two-year process, the goal of which was to develop a prioritized research agenda for collaborative execution by naturopathic and conventional medical academic institutions.



The NMRA Workgroup

The NMRA Workgroup consists of the research directors from each of the six naturopathic medical colleges in North America and Australia working together with more than 20 scientists from major conventional universities who bring to the group expertise in research methodology and biostatistics. Twenty-eight clinical and basic research scientists, experienced naturopathic physicians, and naturopathic researchers together developed this research agenda which brings forward the best that naturopathic medicine has to offer public health under the scrutiny of rigorous science.

Our vision is that the current partnerships between the naturopathic institutions and the conventional academic medical and public health research academic centers within their respective cities will be further strengthened in the directions described by the Agenda. It is envisioned that these partnerships will form active interrelating nodes, coordinated by diverse leadership, in a network of research centers, and partnering with the NIH and other federal agencies toward the mutual goals of responding to the broad questions posed by naturopathic medicine and establishing the value of naturopathic medicine to and role in our health care system.

The Workgroup utilized the Bastyr University campus, a serene and productive environment for its coordination center and as the venue for two Workgroup meetings in February and November 2003.

Developing the Research Agenda — the Broad Outline

Collaboration and partnership are the result of shared visions, shared resources, and consensus on the most important scientific questions to address. This Agenda will provide guidance for the research foci of the naturopathic medical colleges for the next decade, and it must also aid the NIH and other public agencies in developing research objectives and portfolios appropriate to naturopathic medicine. For these reasons, the process by which we developed the Naturopathic Medical Research Agenda was as critical to its success as the final report. In order to produce a research agenda for naturopathic medicine that has the potential for a substantive impact on patient health and the delivery of effective care, the process emphasized building widespread agreement – first within the naturopathic medical colleges, then the profession of naturopathic physicians, and finally through critical input from the public health clinical and medical research communities. The information and opinions generated were then brought back to the Workgroup to identify common themes, select priorities, and come to agreement on a draft Agenda. The draft Agenda was then presented once more for critical feedback to the naturopathic profession, the NMRA Workgroup, and the public health and clinical research communities. Final decisions on the content and language of the Agenda were the responsibility of the investigators.

The Process in Detail

- First, a statement of the problem and goals was drafted by the investigators and summarized for the NMRA Workgroup in the *NMRA White Paper* written by Drs. Standish and Calabrese and distributed in January 2003. A set of prioritization criteria (The Guiding Principles chapter) for potential research issues and questions in the ultimate Agenda were drafted and considered. At the first meeting of the Workgroup, 28 individuals from inside and outside the naturopathic profession posed 133 research questions that they considered important for naturopathic medicine; these were reduced to 25 and then to 12 by consensus (see Appendix C). A video document of the first NMRA workgroup meeting presentations was created for viewing by faculty and students at each of the naturopathic medical colleges.
- Next, a forum of faculty and students at each of the naturopathic academic institutions was held to consider the plan and priorities for the developing agenda, and to solicit feedback on the priority research questions that the NMRA Workgroup had developed. From the transcripts of the Forums, the Workgroup Core derived 10 conclusions (see Appendix C), and identified areas for focused discussion.

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...it must also aid the NIH and other public agencies in developing research objectives and portfolios appropriate to naturopathic medicine.

...unique concepts of naturopathic medicine will contribute to significant discoveries in basic science and health care...

...NCCAM grant has allowed a group of successful and experienced naturopathic and conventional scientists and physicians to engage deeply with each other...

- Then, during the American Association of Naturopathic Physicians' (AANP) annual convention, the draft Agenda was presented to the general assembly of 500 naturopathic physicians attending the convention. NMRA-related AANP Special Topics focus groups were held, with more attention to depth of discussion and detail across a broad array of topics. 11 conclusions emerged (see Appendix C). Critical feedback from this meeting, and also from the American Public Health Association meeting in November 2003 with conventional public health scientists and scholars, were extremely important in helping to refine, clarify, and focus The Naturopathic Medical Research Agenda.
- At a second Workgroup meeting, analysis of these multiple layers of feedback yielded four common themes for the Agenda: 1) a health/healing focus as a critical identifying principle of the practice; 2) studies should evaluate what is specific to naturopathic medicine; 3) whole practice methods should be of primary importance; and 4) observational study is important, especially in early work. On the issue of studying what is specific to naturopathic medicine, the Agenda should preferentially investigate practices that are particularly identified with naturopathic practice and those where research could result in the improvement of the practice. Observational research was recommended for description, effect size estimates, developing accurate and appropriate measures for health services research (for access, cost, program evaluation and effectiveness). Observational studies were seen as efficient to evaluate the practice of naturopathic medicine pragmatically, where growing services provide opportunities for evaluations in new clinical environments and with larger groups of patients.

The final product—the “deliverable”—for this two-year (2002-2004) project is this report: *The Naturopathic Medical Research Agenda*. This document presents the prioritized, sequenced research agenda, as well as the thought process by which the Workgroup arrived at its conclusions. It is our contention that the implementation of the research outlined in this document will improve the health and well being of patients through the delivery of validated health care systems and interventions. It is our contention that the unique concepts of naturopathic medicine will contribute to significant discoveries in basic science and health care, as they are subjected to the rigor of scientific exploration and study. The execution of the research agenda that the Workgroup proposes will depend largely on the collaborative relationships and resource sharing that have developed during the project period. The NCCAM grant has allowed a group of successful and experienced naturopathic and conventional scientists and physicians to engage deeply with each other as colleagues with a mutual interest in doing high quality research that focuses on topics of public health significance.

Naturopathic medical science offers rich opportunity to both scientists and physicians. It presents big questions. Big questions require sophisticated science that in turn calls for distributed sub-systems of specialty. The intellectual exchange and formation of intermural collaborations that emerged from these meetings will help make the NMRA achievable.

Results from Stakeholder Prioritization Filters

NMRA Workgroup questions and conclusions. Producing an achievable NMRA required that the NMRA Workgroup identify a limited set of priority research topics with the greatest potential to serve the public interest and the scientific goals of the project. The iterative process of designing the NMRA also produced hundreds of thoughtful research questions (see Appendix C). These questions and themes suggest significant trends in research interests emerging from the naturopathic profession and collaborating conventional researchers.

An indirect outcome of the NMRA's efforts will be the evolution of research in areas not selected as the top priorities in this process, but which were retained in the conclusions of each of the prioritization processes. This catalog of research interests, priorities and opportunities is a fertile resource and provides useful content for the long-range development of naturopathic research. It provides a snapshot of the range and specificity of potentially unique scientific contributions

that naturopathic medicine can make and that can be used to stimulate individual researchers and colleges to develop greater capacities in these areas. As the NMRA is implemented, a Web-based catalogue of these research issues can be made available to naturopathic professionals and conventional researchers who may wish to focus their research efforts in these areas.

From an initial set of 133 questions submitted by WG members, the Workgroup selected 12 questions as top research priorities. These questions centered on evaluating the whole practice of naturopathic medicine, the comparison of MD to ND practice, effectiveness of whole practice naturopathic care across various populations, and measuring the effect of chronic toxicity. The questions included an emphasis on researching mind-body aspects of health and healing, as well as the scientific basis of the healing process, and evaluation of concepts from the principles of naturopathic medicine. Cost effectiveness of naturopathic care and defining and describing the work of naturopathic physicians were identified as priorities. Finally, research on the non-conventional laboratory and diagnostic testing methods used by NDs was strongly recommended. The final NMRA validated the importance of these issues through the iterative process.

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Naturopathic Medical College Forums, Special Topics Sessions

There was extensive and enthusiastic participation by naturopathic physicians, faculty, students and researchers in the college forums and AANP special topics sessions—the cornerstones of the iterative process.

College forums. Naturopathic medical college research directors hosted forums at each college from April 2003 to September 2003, engaging students and faculty in providing focused, rigorous input to the NMRA. The directors provided written summaries of the input received. Tools were developed by the core research team to provide consistency between the colleges in their approach. These tools included a video synopsis of presentations from the February 2003 Workgroup meeting, a Power Point presentation of the prioritized questions developed by the Workgroup, the proposed prioritization criteria, a draft research agenda, advertising material, instructions, and a qualitative survey. Over 500 naturopathic medical college students and faculty participated.

Areas of clinical strength for naturopathic medicine were perceived to include women's health, mental health, environmental medicine, perinatal health, diabetes, cardiovascular disease, allergies, infectious diseases, immunology, and oncology. Health services research (cost, utilization, access, satisfaction), research on health outcomes and the science of healing, and investigation of environment health and disease were also areas of importance. Permeating all college forums was the widely held view that the research agenda should be aligned with naturopathic medical values, and should focus on what is unique to naturopathic medicine and has the potential to relieve the burden of human suffering. Participants in the college forums noted that a research agenda that can be undertaken by any major medical research center will be less relevant than a research agenda focused on what is unique to naturopathic medicine. The prioritization criteria were widely supported.

AANP special topics sessions. Of particular note were contributions to NMRA by 40 naturopathic physician experts or "thought leaders" recognized by their peers for their expertise in key areas of naturopathic medicine. (See Table 3.) These thought leaders conducted sessions outlining research trends and issues in their respective areas throughout the five day AANP convention held in Portland, Oregon, in August 2003. (Presentation topics, thought leaders, teams, and contact information are available in Appendix D. Detailed reports on selected Special Topics presentations – Women's Health, Environmental Medicine, Diabetes, Asthma, and Health Services and Workforce Issues – are available in Appendix E.) These sessions provided an opportunity for all members of the profession to submit input to the priorities and research questions developed by the NMRA Workgroup in February 2003. The sessions strengthened the quality and specificity of the NMRA process by engaging experts in evaluating implications for naturopathic research in their areas of expertise. These physicians presented scientific updates, priority research questions, and

critical feedback on NMRA prioritization criteria, the draft agenda model, and the Workgroup's proposed questions. Twelve conclusions or themes emerged from the sessions, which were moderated and attended by the core research team. These themes are condensed and summarized below. A series of new topics was also identified, and experts have been invited to develop brief reports and recommendations in these areas for submission to the peer-reviewed *International Journal of Naturopathic Medicine*.

Table 3. Special topics presentations at the 2003 American Association of Naturopathic Physicians

Acute Illness and Infectious Disease	Mental Health
Asthma	Musculoskeletal Disorders
Autoimmune Conditions and Immune Function	Natural HRT and Women's Health
Cancer	ND Specialty Lab Tests
Cardiovascular Disease	Neurodegenerative Disease
Diabetes/Obesity	Perinatal Morbidity and Mortality and Natural Childbirth
Environmental Health	Science and Process of Healing
Health Services Research	Spirituality, Health and Consciousness Science
Human Genome and Prevention	
Immune Function and Autoimmune Conditions	
Medical Education Research	

The sessions revealed the rich base of clinical expertise in the profession. They also revealed several important findings about ND research readiness and infrastructure needs. To be successful, the NMRA must take at least the following three steps: (1) engage junior and senior naturopathic clinicians in scientific research through participation in NMRA Delphi panels in order to develop best practice naturopathic medical protocols for clinical studies; (2) create and implement research mentorship programs; and (3) engage naturopathic clinicians and faculty in writing for peer-reviewed scientific publications.

Summary of themes and trends from special topics sessions. Research questions centered on evaluating the “terrain” of health and healing; the role played by host-related and environmental factors in susceptibility. The importance of researching specifically naturopathic concepts of health and healing was broadly supported. It was acknowledged that the terms and language used to describe these concepts should be updated in light of scientific advances and rigorously defined as a basis for scientific investigation. Operational definitions are required for some key naturopathic concepts, such as the “vital force”. Environmental medicine research emerged as a priority across a number of sessions, suggesting that naturopathic research on any condition should also address environmental toxicity, its causal role in disease, and treatment approaches.

There was vigorous support for whole-practice, whole-person RCTs...

Naturopathic physicians held the view that there are important public health priorities in addition to those identified by the STEPS to a Healthier US initiative (<http://www.healthierus.gov/steps>), such as rising rates of autism in children and neurodegenerative disease in the elderly. However, there was agreement that it is practical to begin the NMRA with a STEPS priority, while also building naturopathic research capacity in health priorities recognized as important by naturopathic medicine—such as toxic burden, mental disease, health promotion, and prenatal prevention. There was vigorous support for whole-practice, whole-person RCTs, for building research infrastructure and establishing more training opportunities for new researchers, and for conducting health services research. Basic sciences research on both principles and mechanisms of naturopathic practice was identified as critical in many sessions. Often heard throughout the AANP meetings was the importance of cultivating research partnerships with a wide range of non-health care scientists—from physicists to mathematicians and environmental researchers—in order to implement the NMRA.

Among naturopathic physicians at the AANP meeting, there was general agreement regarding both overall research priorities and which projects to implement first in a pragmatic framework for strategically developing naturopathic research over time. The prioritization criteria were again widely validated. The core value of a focus on issues of importance in public and community health was widely expressed and often repeated. There was frequent acknowledgment of the importance of research to improve naturopathic education and practice, and of the need to establish initial steps that respect the modest state of the present ND research infrastructure. Participants communicated that the NMRA must resist the temptation to focus only on what is easiest to research, such as single-agent trials, because the result would be a “reductionist” research agenda that does not address crucial elements of the practice.

In summary, the common themes from stakeholders played a major role in shaping the NMRA. The NMRA core team presented findings from the college forums and the special topics sessions to the NMRA Workgroup in November 2003. Using the prioritization criteria as a filter, the research team and the workgroup developed these findings into two overarching themes: the NMRA should have a health and healing focus; and, because naturopathic medicine is a complex medical system, it should utilize whole-practice methods to study its safety and efficacy. These ideas formed the framework for the core research team’s deliberations in the February 2004 retreat of research directors from the six naturopathic medical schools. These commonalities are the foundation for the final prioritized naturopathic medical research agenda.

NMRA Core Team’s Retreat

The NMRA core team (a subset of the NMRA Workgroup) consisted of nine naturopathic physicians, the research directors and deans from each of the naturopathic medical colleges, the Chair of Scientific Affairs for the AANP, along with the PI and co-investigators. They met by conference call quarterly, and finalized the agenda at a two-day retreat in February 2004. This group extracted 10 conclusions from the reports on the forums. These conclusions confirmed that the NMRA should make it a top priority to do randomized controlled trials (RCTs) of whole-person naturopathic treatment protocols, and that multimodality naturopathic whole practice should be compared to conventional, standard care through trials developed in collaboration with conventional medical and public health schools. These whole-practice, whole-person RCTs should focus on populations and conditions with high public health burden. These conclusions were highly consistent with the draft prioritization criteria.

...NMRA must resist the temptation to focus only on what is easiest to research, such as single-agent trials...

...multimodality naturopathic whole practice should be compared to conventional, standard care...

...focus on populations and conditions with high public health burden.

THE GUIDING PRINCIPLES

What is Naturopathic Medical Research?

The NMRA Workgroup recognized early that naturopathic medical research is more than simply research done by NDs. In Figure 1 (page 4), three perspectives on naturopathic medical were summarized as “Research Perspectives”: research on the whole practice; research on components of the practice, and research regarding the context of practice. These categories can be cross-referenced with the research domains of conventional medical research: *in vitro*, *in vivo*, and clinical study (observation and intervention) to form the field of naturopathic research.

We recognize that research on the *content* (components) of naturopathic medicine (modalities, treatments) is important and relatively straightforward; however, the profession’s input repeatedly emphasized that research on the whole practice and its combination of therapies will show the greatest benefit. It also critical at this stage of development that the tools to undertake this kind of research be better developed.

Research on the clinical, laboratory, and quality of life outcomes of naturopathic medical care, and evaluation of whole practice (not just treatments or modalities) have been lacking. Most research to date has been on the content of naturopathic medicine on specific naturopathic medical treatments such as *Echinacea* for respiratory tract infections, homeopathic treatment for HIV/AIDS, and vitamin B₆ for carpal tunnel syndrome. Little research has been done on naturopathic medical practice itself, or its context. Examples of naturopathic context research include study of patient-physician interaction and ND work force studies. Naturopathic medical research has thus far used, and will continue to use, similar methods as conventional science including *in vitro*, *ex vivo*, and *in vivo* clinical observation and RCTs. Nevertheless, it was strongly felt that naturopathic medical research must be characterized by whole-practice research methods that are required to address NMRA hypotheses 1 and 2.

Three Hypotheses

Selection of the hypotheses to be tested was initially derived from the American Association of Naturopathic Medicine’s (AANP) 2001 publication “Naturopathic Medicine: Primary Care for the 21st Century” and workgroup discussions stimulated by this document.

1. Naturopathic medicine is safe and effective for health promotion and for the prevention and management of a broad range of common conditions.
2. Increased availability of the services of naturopathic physicians will improve patient health in a cost-effective manner.
3. The scientific exploration of naturopathic medical practices and principles will yield important insights into the nature of health and the biology of healing.

These hypotheses are based on more than 100 years of clinical practice and observation, naturopathic principles and theory, and on existing scientific data on specific treatments and modalities

(content research as opposed to whole practice research). The first two hypotheses will be addressed through clinical studies, both prospective observational studies and randomized clinical trials.

The third hypothesis is inherent in the origins of the medicine but has gained emphasis within the field in the last twenty years, as core naturopathic medical principles and theory have been articulated and analyzed. When confronted with ideas such as *vis medicatrix naturae* (a core principle for NDs) and the therapeutic order, or practices such as homeopathy, many conventionally trained scientific materialists are skeptical. Some are intrigued. Hypothesis 3 will be addressed by basic and clinical research on naturopathic principles and clinical theory. The NMRA identified three elements that will be necessary for naturopathic “discovery” research: clear operational definitions of concepts such as the *vis medicatrix naturae* (the “vital force,” “healing power of nature”); new tools to detect and measure forces such as the *vis* and modalities such as homeopathy (studying ultrahigh dilutional biology as a way to study homeopathy); and research methods that can test key clinical theories such as the therapeutic order (see THE BACKGROUND chapter, section on Naturopathic Principles and Clinical Theory).

Criteria for Prioritization

By the end of the first NMRA Workgroup meeting on February 6-7, 2003, six prioritization criteria were agreed upon (see Table 4). They were again vetted for approval by the naturopathic medical profession at the national meeting of the American Association of Naturopathic Physicians in August 2003. These six criteria guided our selection of NMRA research topics—who and what we will study in order to test hypotheses 1, 2 and 3. The NMRA Workgroup was influenced by the “Steps To A Healthier US” initiative issued in April 2003 by former Secretary of Health, Tommy Thompson (<http://www.healthierus.gov/steps>). Secretary Thompson argued that the prevention and treatment of five conditions (diabetes/obesity, cancer, cardiovascular disease, and asthma) should be a major focus of the public health system. The NMRA Workgroup agreed.

Our purpose was to develop a naturopathic medical research agenda for cooperative action in the near- to mid-term. In this complex undertaking it was felt that an explicit statement of the criteria for prioritizing possible projects would assist the Workgroup in choosing the most important research directions to pursue. These six criteria for prioritizing the NMRA were adopted by the NMRA Workgroup only after substantial feedback from stakeholders. Participants in the process slowly absorbed the implications of each of the criteria, and reflections on their meaning contributed to the research directions and methods chosen for the agenda.

Table 4. Six criteria developed by the NMRA Workgroup to filter research ideas

1. Study conditions with the highest burden of suffering
2. Study problems of emerging public health significance
3. Study those naturopathic treatments thought to be most effective
4. Study naturopathic approaches with revolutionary potential to make significant advances in basic science and patient care
5. Foster the development of needed methods and infrastructure
6. For initial studies, focus on near-term feasibility

1. Focus on treatment and prevention of diseases and conditions with the highest burden of suffering.

The measure of human suffering (prevalence, deaths, “quality adjusted years of life,” productivity or dysfunctionality, etc.) should be a significant factor in the selection of targeted research. The geographical region in which the measurement is taken (world, US, jurisdictions with naturopathic regulation) could alter the specific targets.

Naturopathic clinical theories and concepts...should...be investigated.

whole practice... rather than only its components...

...naturopathic medicine's orientation is towards health promotion and wellness...

2. Focus on problems with emerging public health significance.

Good health is a public as well as a private goal. Naturopathic physicians should partner with government agencies, private businesses, and communities, in collaborations that take a population approach to important health improvement issues such as environmental quality, the social promotion of healthy lifestyles, and the spread of both new and familiar infectious diseases. The epidemics of obesity, diabetes, depression, and asthma; our aging population; growing antibiotic resistance; and the threat of bioterrorism are all issues of great significance to our nation today. Cost, cost-effectiveness, and access to care, as well as the translation of scientific findings into generalized practice, will play essential roles in reaching the health goals of the research agenda.

3. Focus on those naturopathic treatments thought to be most effective.

The value of this criterion is that it utilizes the profession's experience to determine likely effectiveness in clinical research. There are two sources for targeting decisions in this regard: 1) the evidence present in the scientific literature relevant to naturopathic practices, and 2) the preliminary studies, observations, records and opinions of practicing naturopathic physicians. Since this criterion is meant to guide definitive research, it is understood that evidence of effectiveness will be preliminary and may have substantial uncertainty associated with the choices made, but that, nevertheless, there is value in pursuing areas where naturopathic physicians expect better outcomes.

4. Study naturopathic approaches with the potential to make significant advances in basic medical science and patient care.

Approaches that include the concept of vitalism, the use of homeopathy, holism and individualized care, and maximally recruiting the patient's own resources are among those that the profession identified. Naturopathic clinical theories and concepts about the healing process, including the therapeutic order and sequelae of suppressed symptoms, should also be investigated. This criterion, through the iterative feedback process, has also come to mean that research methods that preserve the identity of naturopathic practice in the investigational methodology (i.e., including principles and modalities of the medicine working together) are strongly preferred in clinical studies. We should study practices and perspectives that are specifically naturopathic, that are not used or held widely outside the naturopathic profession, and that are therefore less likely to be studied by non-NDs despite the promise they may hold. This suggests that the whole practice as an integrated identity, rather than only its components, is an important target of research. Also of critical importance is naturopathic medicine's orientation towards health promotion and wellness in practice. This focus on health, beyond the amelioration or prevention of particular diseases, is expected by naturopathic practitioners to yield benefits currently not effectively delivered by much of the national health care system.

5. Foster the development of needed methods and infrastructure.

Some research questions require methodological innovation because we do not yet know exactly how to answer them: for example, whole systems approaches to disease, long-term safety, ultra high dilution and combinatorial effects, spiritual practices, transpersonal biology and the concept of vitalism. As suggested above, the memes of naturopathic medicine have not always been identified, or consensually defined and definitive description of the practice is just beginning. Thus preparation for the study of what may be critical elements of the practice is incomplete. Important questions may well call for complex designs with a broad array of new measures collected with information technology only now under development. A corollary of this criterion is that development of research infrastructure in naturopathic institutions is an important concomitant to project funding. The core of research expertise within the profession needs to be supplemented both by recruitment of seasoned collaborators and by support for the growing cadre of young researchers who will carry out the studies called for by present and future questions. On a more structural level,

access to sufficient specific patient populations for large studies may need to be assured by enhanced relationships between medical and naturopathic collaborators.

6. For initial studies, focus on near-term feasibility.

The need for external funding for implementation of the NMRA requires attending to the issues four funding sources—NIH, foundations, commercial interests, and naturopathic professional agencies—are prepared to act upon. The NIH NCCAM issued both five-year strategic plans and yearly research priorities to which the NMRA should attend. Other NIH research institutes and centers have their own priorities that are coincident with elements of the NMRA. Commercial interests have not yet been maximally engaged in collaborations with naturopathic researchers. However, questions can be shaped that contribute to corporate goals as well as advancing the naturopathic research agenda. Similarly, the health goals of charitable foundations should be reviewed for cooperative opportunities where the potential of naturopathic medicine may make a significant contribution. An important aspect of infrastructure that has immediate consequences for research is naturopathic experience with a given clinical condition and availability of an accessible patient population. Thus, it will be easier to do early clinical research with conditions that are frequently seen by naturopathic physicians.

Vision and Values

Like the NIH, “healthy people” describes the overarching mission, vision and values of the NMRA. However, we recognize that attainment of this goal depends substantially on healthy communities and a healthy environment, as well as on skilled health professionals. The environmental causes of rising rates of chronic disease and the important role that naturopathic medicine can play in environmental medicine were consistent themes raised by naturopathic physician stakeholders at the naturopathic medical colleges and at the national professional organizational level. Since the resurgence of naturopathic medicine in the 1970s, NDs perceive a significant impact of the profession in two areas of medical care highly related to environmental etiologies: preventive medicine and care of the chronically ill. Naturopathic medicine is inherently systems oriented. Thus, if “healthy people” is our goal, we must at the same time heal our communities and environment.

Goal Statement

Over 1200 scientists and physicians from both conventional and naturopathic medicine academic and professional communities (the NMRA stakeholders), led by an experienced and dedicated Workgroup, participated in a two-year process of discussion, debate, and iterative review and feedback for refinement of concepts and plans for a naturopathic medical research agenda. The results of this process are the following goal statements:

1. The NMRA will focus on populations, not diseases.
2. The NMRA will focus initially on two populations: people with diabetes and the elderly.
3. The NMRA will utilize whole-practice research methods to evaluate NMRA hypotheses 1 and 2.

The NMRA Workgroup’s approach to the methodological and logistical demands of an adequate response to the hypotheses, while attending to the prioritization criteria, was to select two populations as research topic areas, as opposed to selecting two conditions or diseases. This is a subtle but important distinction. While the methods are not radically different, the population and health orientation distinguishes the naturopathic approach to scientific evaluation of its own practices. The populations selected are defined by either a diagnosis (type 2 diabetes mellitus) or by a stage of life (the elderly), but overall it is the people, not just their diseases, on which the research will focus.

...naturopathic medicine may have an important role to play in environmental medicine...

...if “healthy people” is our goal, we must at the same time heal our communities and environment.

The NMRA will focus on populations, not diseases...people with diabetes and the elderly.

NATUROPATHIC MEDICAL RESEARCH – THE AGENDA

The Methodological Environment for the Agenda

The first problem in evaluating the effectiveness and safety of naturopathic medicine as a whole practice is its broad scope. A taxonomic model mapping the types of research studies that may be done with existing methods in regard to naturopathic medicine identifies three major perspectives on the practice:

1. whole-practice research that studies naturopathic medicine as practiced;
2. research on components of naturopathic medicine (e.g., single agents for a particular diagnosis, a particular principle or procedure); and
3. context research, with a focus on observations about aspects of the practice of naturopathic medicine (e.g., the patient-practitioner interaction) or its relationships with the larger health system (integration studies).

Most research to date on naturopathic medicine has been from the perspective of component research. Each of these perspectives, however, may be appropriate for numerous topics of study: the prevention and treatment of diseases, symptoms and risk factors, or the health of different populations (see Table 5). With the awareness that most research relevant to naturopathic practice has been on components of practice and will likely continue to be so, the section below touches on issues that will be encountered in studies of naturopathic medicine.

Clinical Trials

Clinical research properly done is a demanding discipline encompassing study design, ethics, clinical care, definition and sensitive measurement of disease markers and outcomes, data management and statistics, analysis and interpretation. In the specific case of naturopathic clinical research, the following bear additional attention:

1. Standardization
2. Individualization of treatment—nosology and indication
3. Combination therapies—effect size and safety
4. Non-specific healing effects
5. Outcomes and measures
6. Controls and blinding
7. Whole practice models

1. Standardization

Since replicability is a hallmark of the scientific method, specifically *what* is tested—whether a substance, a treatment procedure, or a system of practice—needs to be defined, described, and stabilized so that it can be delivered reliably from patient to patient and study to study. While

standardization is a great strength of modern medicine’s pharmacotherapeutics, modern naturopathic medicine as yet does not have a definitive codex. Rather, it is a practice with developments that evolve year-by-year, highly dependent in some areas on current scientific discoveries and in others relying empirically on procedures and concepts that are hundreds or thousands of years old. Its concepts are often implicit in the practice rather than theoretically explicit. It was only in 1989 that the American Association of Naturopathic Physicians codified the modern principles of professional practice and only in 2002 were the first naturopathic medicine flow charts for disease management published by an authority in the field. Even those patterns described are not universal among naturopathic physicians (Pizzorno, 2002). Only with the very recent advent of health insurance coverage for the licensed practice have practitioner review panels (empanelled by third party payers) regularly adjudicated the appropriateness of specific naturopathic treatments on a case-by-case basis. Even the standard of qualification for naturopathic physicians to practice is still developing, because only 14 US and four Canadian jurisdictions regulate the practice. Thus, development of practice guidelines trails by about a half century a similar evolution in conventional medicine. Rigorous research in naturopathic practice can help to speed up this process.

Using standard clinical practice concepts and biomedical research metaphors, communication about CAM research issues can be problematic. One way to understand the problem is to say that naturopathic medicine lacks modern articulation and operationalization of accepted and

Table 5. Types of naturopathic medical research: A proposed taxonomy

Research Design Priorities	Study Types	Study Topics	Potential Outcomes Measures
Whole-system research	Whole-practice, non-protocol clinical trials	Primary vs. specialty care Principles of practice Clinical theory	Biomedical Patient health Population health Costs Utilization
	Whole-practice, systematic protocol clinical trials		
Component research	Single agent clinical trials	Botanicals Nutrients Homeopathics	Biomedical Patient health Population health Mechanisms
	Clinical trials of combination agents within a rigorous protocol	Multiple agents Agents and procedures	
Context research	Observational Survey Self-report Economic Workforce	Sole practitioner	Biomedical Costs
		Multi-disciplinary clinic setting	Biomedical Cost comparisons Utilization Integration Access
		Patients	Perceived benefit quality of life issues Costs Sociocultural factors
		Patient-doctor interactions	Psychological

widely understood “memes.” Memes are collective concepts: ideas, behaviors, or skills that are transferred from one person to another by imitation and that are replicable on a population basis (see Blackmore 1999). The term was coined by Richard Dawkins in his best selling 1976 book, *The Selfish Gene*. When a meme is expressed in a phrase, it invokes meaning beyond that of the words themselves, such as in the naturopathic principle, *vis medicatrix naturae* (the healing power of nature).

The lack of this explicit articulation accounts in part for the wide variations in naturopathic practice. This is not to say that the memes of naturopathic practice are not generally transmitted from one generation to the next; only that they are not yet specifically articulated with consistent modern language and interpretations, which can present a challenge for the standardization of clinical protocols for research purposes. The working definitions glossary in Appendix I, provides an initial starting place for the development of standardized definitions.

Some problems in standardization are increasingly well understood—for example, those in botanical medicine. With herbs, it is quite possible to perform a single-agent, controlled trial in a specific disease. Standardization in botanical studies begins with verification of plant species used, conditions under which the plant is grown and harvested, and the storage and stability of active compounds. There are choices of whether to use the whole plant, or particular parts, or various crude extracts, or a specific chemical constituent that may be concentrated in various ways and to varying degrees of purity. Crude fresh extracts, to which many naturopathic physicians are partial, are susceptible to deterioration. In more sophisticated systems of botanical medicine preparation, a product is standardized for a number of ingredients—for some, guaranteeing a minimum concentration and, for others, a maximum concentration. This, for example, is true of the *Ginkgo biloba* extract (Egb761: Schwabe GmbH), which has been heavily researched.

Homeopathics rely solely on standardization of the manufacturing process, as in vitro or chemical standards have not been developed.

Standardizing on single constituents may present complications. For instance, active ingredients in plants are often classes of molecules (like polysaccharides, saponins, or terpenes) that are difficult to differentiate in biological activity. Different compounds in a single species may have similar and possibly complementary effects, such as the polysaccharides and isobutyramides in *Echinacea* spp. During *in vitro* assays, which guide fractionation of the crude extract toward a single active molecule, it is not unknown for activity to increase but then diminish as greater purity of an identified active molecule is reached, as was the case with the terpenes of *Andrographis paniculata* (Androvir: Paracelsian, Inc.), which have influences in cell signaling. Some manufacturers are adding cellular activity assays in the effort to standardize for an effect rather than a chemical constituent. When such problems are successfully addressed, many levels of standardization may lead to testing effects in industrialized botanical medicine, but may not answer the question of whether the commonly-used crude extracts or powdered herbs produce the hoped for clinical benefits.

Nutritional therapy comprises both diet and nutritional supplements. Nutritional supplements, whose chemistry is usually well understood, present no special problems in standardization. Studies in dietary interventions, however, are demanding. The gold standard for feeding studies is a residential facility to assure adherence to a therapeutic regimen, an intervention that is difficult to recruit for and expensive to execute. Often in naturopathic dietary studies, lengthy observation is needed as treatment goals may be preventive and restorative, requiring time for clinical outcomes to become measurable. Special medical foods and nutritional supplements like probiotics (live bacteria, taken to normalize commensal bacterial populations) or algae have some of the same complications as botanical medicine studies. Homeopathics rely solely on standardization of the manufacturing process, as *in vitro* or chemical standards have not been developed.

Patients may turn to naturopathic medicine because it affords greater attention to a spiritual dimension.

A naturopathic leitmotif is “body, mind, spirit”. Intentional spiritual intervention (such as personal prayer, meditation, and religious practice or belief) is an arena of significant interest to most naturopathic physicians. Patients may turn to naturopathic medicine because it affords greater attention to a spiritual dimension. Questions regarding spirituality remain of persistent investigative interest, though they are a small proportion of all health studies. In the study of spiritual medical

practices, however, there are few authoritative and widely used research methods. Operationalization of spiritual experience is likely to be idiosyncratic or culture specific. It is only in the 4th edition of DSM-IV (1995) that the possibility of a religious or spiritual problem, was even recognized. Definitions of spirituality in the medical literature may refer to hope and meaning, a personal relationship with God (Swanson, 1995), serenity (Roberts and Whall, 1996), connectedness. A number of thinkers bemoan the lack of definition in the area (Goddard 1995). Though efforts to present a cogent, broadly acceptable definition have been made (Dyson et al., 1997; Pehler, 1997), they have not been widely adopted. Thus, a better approach to specifying spiritual interventions may be needed before they will be accessible to replicable research. There were only seven randomized trials of “spiritual” interventions among the twenty-nine citations called up in January 2003 when the denominator of “spiritual” is crossed with “clinical trial” in *PubMed*. The majority of the studies showed positive results; unfortunately, none have been replicated.

2. Individualization of treatment

A skilled naturopathic physician expects success through individualization of treatment regimes, meaning that treatments are not prescribed solely on the basis of a disease entity. Relevant patient characteristics may be transient or constitutional or they may be representative of the entire constellation of the patient’s health problems and strengths and their capacity for self-care. The lack of fit of a person’s symptoms with conventional diagnoses may be one reason a patient turns to naturopathic medicine. If a medical system does not recognize, or have a label (diagnosis) for a condition, it is less likely to have an effective therapy for it. The complaint will be managed as something else, resulting in ineffective treatment while still exposing the patient to the side effects of the “remedy.” Conversely, a medical system that provides an adequate explanatory model for a particular patient’s experience of his/her symptoms and their origins, aggravators and ameliorators, has, on face validity, a better chance of having effective treatment or management for the condition. As with other CAM whole systems of care, naturopathic disease nosology (its classification of human distress) is not always congruent with that of Western molecular biomedicine. Thus, inclusion and exclusion criteria based only on Western diseases may mischaracterize patients for a given naturopathic treatment.

For example, “strengthening the immune system” or “decreasing toxicity” are common goals in naturopathic therapeutics but are rare in conventional medicine. Since many diseases are treated under these rubrics, treatment responses would be expected to have different profiles. Thus, the time to healing, as well as the disease being treated, may be confounded in evaluating one system by the other’s definitions and rules. Some naturopathic concepts may not have a conventional biomedical equivalent and, while they are not diseases, they are diagnostic labels that help guide treatment. These include, for example, the “constitution” (a patient’s given biological potential, tendencies and patterns of longstanding psychophysical strengths and weakness that are genetically and embryologically determined), the “biological terrain” (background physical health and the individual context for the medical problem of immediate concern), and the “vital force” (the motive, plan or spirit animating mind and body, expressed as physiological and psychological functionality and adaptability). Sometimes biomedical equivalents exist for naturopathic concepts but naturopathic physicians will exploit them therapeutically with more thoroughness. Such concepts include “balance” (as in the immune system, among microbial symbionts, hormones, neurotransmitters, etc.), deficiency (not just nutritional but organ deficiencies – e.g., hypochlorhydria, hypothyroidism), functional reserves, endogenous and exogenous toxicities, and dysmetabolisms (e.g., Syndrome X, hypoglycemia). Licensed naturopathic physicians have no more difficulty assigning an International Classification of Disease (ICD-9) code to their patients than conventional practitioners do. However, it was hypothesized by the NMRA that their view of pathogenesis might cause concentrations in code numbers that would be unexpected by conventionally trained doctors.

An important naturopathic concept is that a disease syndrome may be an attempt by the body to adapt to ecological stress and should not be unnecessarily suppressed. This will not only be of interest as an independent variable but will have an influence on the measurement of the depen-

An important naturopathic concept is that a disease syndrome may be an attempt by the body to adapt to ecological stress and should not be unnecessarily suppressed.

dent variable as well. Compromises may be made in practice to make a trial of specified therapy possible, but such compromises may diminish therapeutic effects. If the need for individualization is neglected in research design, the study will fail to apply the medicine as practiced and thus fail to evaluate fully its potential benefit.

If the need for individualization is neglected in research design, the study will fail to apply the medicine as practiced and thus fail to evaluate fully its potential benefit.

3. Combination therapeutics—effect size and safety

Combination treatment is almost a rule among naturopathic physicians, who use multiple treatments, individualized for the case. This complicates the design of clinical trials, yet the evaluation of combination interventions is critical to assessing naturopathic medicine. Single natural agents may have a true effect that is small enough by itself that a very large patient sample size would be required to detect a treatment difference. Several agents acting together, however, especially if by different mechanisms, may have a larger effect size determined by cumulative or synergistic interactions. Larger effects are more readily detectable in a clinical trial. Combination treatment also affords the practitioner latitude in choosing the correct approach for each patient's condition, thereby increasing the treatment responder rate. Another strategy in choosing elements of combinations is tailoring them to efficiently address multiple conditions simultaneously, achieving better global outcomes. Yet another is to use some agents as "governors" to ameliorate potential side effects of primary remedies.

The possibility of adverse events theoretically rises with combinations (drug research definitely connects a higher incidence of adverse events to higher numbers of prescriptions). While the problems of additive and synergistic actions, inhibition, and toxicity associated with multiple synthetic and novel pharmaceuticals in combination are formidable, the history of use of natural remedies and the experience of clinicians in using combinations of natural products mitigates these problems in everyday practice. For example, when using whole botanicals at a traditional dose, early toxicity is likeliest to result in nausea and vomiting or diuretic action. More serious adverse events, such as anaphylaxis reactions, are rarer with nutrients and botanicals of traditional medicinal use than with novel drugs of a single molecular species. Naturopathic physicians often combine modalities, e.g., homeopathy and counseling, or manipulation and herbs. These combinations are unlikely to lead to a deleterious interaction, but they could each stimulate patient improvement by a different route. Because of the breadth of options in treating a condition, a skilled practitioner can avoid treatments that pose a risk in a particular case while still attaining the targeted therapeutic action. While there is no systematic study of the safety of combinations, data from licensing authorities and professional liability companies show very modest levels of adverse events.

4. Non-specific healing effects

A confounder in a clinical trial is an apparent therapeutic effect that can be attributed not to the test treatment but to a factor associated with the treatment. This is a risk inherent in all research. These are reasons why randomization, blinding, and "hard" measures are valuable in distinguishing true differences in effect among medications. The most honest scientists may have conscious or unconscious behaviors that could bias study results. Yet, similar behaviors are at work in everyday clinical practice to induce affiliation, confidence, commitment and satisfaction in patients and are, in fact, the responsibility of skilled clinicians. Naturopathic medicine has little language around placebo and other non-specific healing responses, despite knowing that many conventional scientific authorities expect that this is an area where naturopathic physicians have much to offer. Distinguishing whether the consultation effect is different from the placebo effect may assist in understanding these non-specific phenomena. Methodology for how this may be undertaken has recently been proposed for homeopathy (Baker et al., 2003).

An important confounder that may be integral to treatment is intentionality. The potential therapeutic action of pure intention, which is not mediated by language or any well-known material force, might be espoused by only a small minority of naturopathic physicians though it may actually be widely practiced among them. This may be called "psychic" healing or simply "healing." Trials of intercessory prayer may provide a model (Harris et al., 1999 Targ, 1997, Astin et al.

Several agents acting together...may have a larger effect size determined by... synergistic interactions.

2000). Design differences may be called for if the therapists are special (gifted) in comparison to other practitioners, or if the healing energy is hypothesized to be directed/willed by the individual versus being invoked from God or spirits. There is little written on the capacity of intention to influence physical outcomes; in fact, there is implicit rejection of the idea based on Cartesian mind-body duality. Nevertheless, there are a number of studies that indicate its existence (Benor, 1993; Schlitz and Braud, 1997).

A similarly numinous practitioner-associated quality that may have an influence on outcome is intuition. This might be thought to bear on diagnosis as a source of data or on therapeutics as a guide among possible alternative strategies. While intentionality and intuition are not listed in the educational catalogs of naturopathic academic institutions as requisite health care skills to be acquired, they are common concepts in the culture of naturopathic institutions. They are not generally considered as anti-scientific concepts that should be expunged from the awareness of students. Indeed, they might be acknowledged and even honored as long as their “discoveries” are not contradicted by harder evidence. The informality of the inclusion of intention and intuition in naturopathic practice compounds the difficulty of including these concepts in some reproducible way in research protocols.

Conventional medical care is also practiced within a cultural context, wherein practitioners and patients have roles and expectations that reinforce belief in expected outcomes. Some studies have indicated that good physician-patient communication results in better medical outcomes. Some of the magnitude of effect may depend on the setting in which naturopathic care is offered. Differences in outcome between medical practices may hinge on the difference between research versus non-research settings. For example, it is possible that those who refuse to be randomized have a psychological orientation that may work synergistically with the physical effects of the practices of a medical culture that they prefer or are native to. If this is true, the evaluation of systems of practice relative to each other would preclude simple randomization. Trials that should be of real interest to policy makers are not simply those that determine whether a practice “works” for anyone to whom it is applied but whether it works (and is cost effective) among those who choose it. A study design that could determine the added value of the availability of naturopathic care in those who choose it is to randomize to either (a) a group randomized to strict assignment of alternative or conventional care, or (b) to a free choice of alternative or conventional care (Eisenberg, 1993). Such a four-group trial would compare the effect of the different practices among those patients who discriminatively select among them versus those who are simply assigned to them.

Both unintentional non-specific healing effects and intentional psycho-spiritual medicine are areas where the evolution and definition of important memes, especially those that may serve research, are poorly evolved not only for naturopathic medicine but also for Western biomedicine.

5. Outcomes and measures

Because naturopathic medicine is oriented toward health as well as disease, and is expected by practitioners to have broad benefit, i.e., correcting deficiencies, strengthening and balancing metabolic processes, and “removing the obstacles to cure”. Benefit for more than one disease condition is often a treatment goal. To “treat the whole person” is a precept of naturopathic medicine. The RCT, as usually but not necessarily performed, tends to neglect effects on diseases other than the target disease. Naturopathic physicians and their patients expect to see positive results not only in specific disease parameters, but also in general health functions (e.g., fatigue, performance, mood), as well as the reduction of risk factors for future disease. Thus, efforts to assess the efficacy of naturopathic medicine should use holistic measures accounting for effects in all body systems and over the life cycle, if possible. Ideally, measures of a whole practice should address environmental, social and economic outcomes, as well as patient and population health.

In recent years, substantial strides have been made in the development of measures that assess individual health globally. Among such health measures are a sense of well-being, functionality,

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Among such health measures are a sense of well-being, functionality...risk of future disease... C-reactive protein... survival, cost-benefit,... even satisfaction with care.

performance, productivity, role fulfillment, response to treatment, risk of future disease (measured by diet, body-mass index, cholesterol, C-reactive protein, etc.), survival, cost-benefit, and even satisfaction with care. There has been progress with the development and wide adoption of instruments such as the SF-36 and of measures such as “quality-adjusted life years.” However, there continues to be a lack of sensitivity to changes in disease at the upper levels of function where the burden of human suffering is great (given the number of the “walking wounded”); that lack of awareness has enormous societal costs in life quality, functional impairment, and missed opportunity. This relates to the general neglect of health measures (when compared to disease measures) in most clinical trials. Gentle natural treatments may show smaller, more gradual, but more widespread improvements than may be expected from narrowly targeted pharmaceutical and surgical interventions, and instruments sensitive to change will be needed if trials are to be efficient in size and length.

The concept of the “healing crisis,” a temporary exacerbation of symptoms on the way to more definitive improvement, also calls for longer increments of time over which to make measurements in order to evaluate the response to treatment. The reluctance of naturopathic physicians to suppress symptoms while seeking and treating the cause may also require a lengthening of the assessment period in order to fully evaluate therapeutic impact. Ultimately, evaluation of naturopathic care in a few areas, such as effects on longevity or the incidence of chronic disease, or of occurrence of disease in progeny, ideally may require multi-decade evaluations. Measures have not so far been attempted for such naturopathic concepts as the “vital force,” due to a lack of a modern naturopathic definition or demonstration of their correlation with other health outcomes. However, they may be fundamental to vitalist traditions such as naturopathic medicine.

6. Controls and blinding

The choice of appropriate comparison controls is an important issue, as different controls answer different questions. The different questions involve comparisons of naturopathic interventions to placebo, specific standard care, usual care (the patients’ baseline care) or time-attention-behavior controls. Sometimes ethical reviewers may prevent a naturopathic therapy from being evaluated without a concomitant conventional therapy. Some questions of special interest are whether naturopathic care leads to lower overall morbidity and mortality (1) for those who are randomized to it versus not randomized, (2) for those to whom it is equally available on the basis of cost and access versus those to whom it is not equally available, and (3) for those who choose to use it when it is available versus those who do not. The answers to these questions involve belief, motivation, cost and the restraints due to cost, and compliance. The answers may be fundamental to determining both the efficacy and efficiency of naturopathic medicine in a rationally structured health care delivery system.

Naturopathic treatments can be categorized fairly simply into substances, procedures, and interactions (verbal and behavioral medicine). The double blind RCT test system is most easily applied with the evaluation of substances. Non-material procedures such as manipulation, exercise, acupuncture, and psychological or spiritual treatment are more methodologically problematic for the RCT desideratum of blinding. Blinding is likely to prove difficult for most dietary, manipulation, psycho-spiritual, or whole-practice interventions. In these cases, blinding may often be at least partially maintained by separating evaluation from treatment and by blinding the evaluator. In considering the value of blinding, it should be remembered that studies which blind the practitioner and patient may decrease or eliminate the possibility that intentionality will contribute to a positive outcome. Yet, CAM theories explicitly accommodate bonding and expectation as contributions to outcome (Wirth, 1995).

7. Whole-practice models

Given that individualized combinations of modalities and remedies are generally the rule in naturopathic medicine and that their selection is guided by the medical system’s own principles, evaluation of naturopathic medicine in whole-practice models is most likely to reveal its potential

...evaluation of naturopathic medicine in whole-practice models is most likely to reveal its potential health benefit.

health benefit. Attaining replicability of the intervention is the challenge. Although innovative and difficult to execute, a number of useful intervention models are available. The simplest is a fixed combination of remedies, though this approach would abandon individualization. If applied in trials with very specific inclusion and exclusion criteria, the loss of individualization may be tolerable, though recruiting may be strenuous.

A slightly more ambitious approach to whole practice would be a menu of choices applied, for example, to several possible etiologies in a symptom manifestation (disease) under study. One model increasingly used as alternative medicines have been explored in recent years is “pragmatic” trials, which essentially treat the practitioner of some specified level of qualifications as the unit of intervention. This may be understood as treating the practitioner as a “black box.” In a further step in sophistication, an algorithm may drive the intervention. Such algorithms may be derived through expert practitioner panels. The design and the replicability of “best practice” protocols are just beginning to be studied in naturopathic medicine. The complexity of the models that have resulted may well require a manual for practitioners, who must be well trained to assess patients and deliver the intervention according to the protocol. A manualized practice would also provide the documentation required for ethical and regulatory reviews. A new question that would arise in such studies of whole practice is the degree of adherence by the provider to the protocol. “Best practice” models of naturopathic medicine are theoretically most likely to show replicable benefit and thus are a good choice for clinical study.

Observational Studies

Observation and experiment are two faces of clinical research. Observation is needed to describe existing practices and outcomes, and is how we form ideas of association and generate hypotheses preliminary to experiment. Experiment tests hypotheses in study designs that model a current or potential reality. In medicine, the experimental question is often, “Can we cause a desired outcome by manipulating the independent input variables?” The input variables are generally discovered through observation. Observation is the only way to study a practice in its natural setting with natural incentives for patients and practitioners. Observational studies, where well designed, can be more generalizable than clinical trials. Thus, both systematic observation and experiment are needed to fully evaluate medical practices. For many CAM practices, which lack a history of research in the modern sense, observation is a prerequisite to appropriate experiment.

Some challenges in collecting observational data include addressing the question of whether the observation itself has a measurable impact on outcomes, and whether observed associations reflect causative relationships. Quantitative observational studies have been considered low on the hierarchy of validity in evaluation of medical practices. Effect sizes found in observational studies have been considered inflated. Yet recent work has shown effect sizes from clinical trials and observational studies to be similar (Benson and Hartz, 2000; Concato et al., 2000). Further challenges to observational studies are that staffing, data collection, and management needs are higher per data point than with other methods. Program evaluation is frequently under funded in demonstration projects. Longitudinal outcomes research is especially valuable but requires substantial infrastructure for success. Despite these drawbacks, observational studies have some unique advantages in the study of naturopathic medicine and other whole systems of practice. There are no ethical conflicts about withholding conventional treatment, as the patients choose their practitioners. The effect of intention on the part of patient and practitioner is not abrogated. The medicine is implemented fully individualized with no constraint on the combinations necessary. Cost of research per case, if fees are charged, is a lesser constraint than in randomized trials (where fees cannot be charged), and cost-effectiveness can be incorporated as an outcome. More early observational studies will help to guide future trials. Even the “best case series,” a very simple approach to observational study, is having an effect on directions in CAM research (Nahin, 2002).

The increasing coverage by third party payers of naturopathic care in the past 10 years has generated a great deal of proprietary data on utilization and costs that could (if they were made available) be

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used for comparison to other professions; some of these data are just beginning to be explored. William Lafferty's study of mandated coverage of CAM in Washington State is a rare example. Observational studies in naturopathic medicine have been undertaken, although most have been preliminary and unpublished. Daniel Cherkin's descriptive NAMCS survey (Cherkin et al., 2002), and Canadian College of Naturopathic Medicine's collection of data led by Tom Jaeger, on nearly 2000 longitudinal patient visits, are of particular interest. Others include Tim Callahan's work at Bastyr, Krista Heron's at NCNM, and Carlo Calabrese's at Bastyr and NCNM. The records of patients currently utilizing naturopathic physicians may become a valuable source of data.

Observational work may generate large amounts of data in the course of well-designed studies. The complexities of naturopathic medicine with its multiple inputs (patient characteristics and combination individualized treatments) and broad measures, standardization data, complex control conditions (e.g., "usual" care), and early descriptive work all encompass data for specification and exploration. To plan studies, including single-agent trials, and understand their results, naturopathic research urgently requires more infrastructure for data management and quantitative analysis.

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Basic Science Studies

Basic sciences are relevant primarily, but not exclusively, in research on components of the practice. Data from the basic sciences clarify the causal chain linking naturopathic intervention and clinical observation. Naturopathic medicine would benefit from greater exposure to the entire array of laboratory work now possible. In the exploration of naturopathic theory and in refining remedies, it would be useful to have access to a range of techniques from analytic chemistry to classical microbiology to advanced molecular biology and advanced neurophysiology. Thousands of natural products have been screened for numerous laboratory outcomes. However, new understandings of human biology and advances in technology have made many more types of studies possible in the areas of combinatory chemistry, gene expression, proteomics, glycobiology, and immunology.

A continuing need is in standardization of *materia medica*, not only on chemical constituents but also on biological activity (NCCAM Web site on natural products). Other *in vitro* work particularly associated with naturopathic medicine includes combination effects and safety and high/ultrahigh dilutional effects. Mechanistic studies of naturopathic treatment with substantial clinical evidence may provide knowledge useful across medical cultures. NCCAM has recently explicitly turned towards the basic sciences in its strategic research priorities. Laboratory science capacity is an area where a rationally distributed development of different functions among naturopathic academic institutions may be of value. Each such institution doing research would gain the in-depth experience needed to produce significant work in a focused area and to collaborate with colleagues at other institutions.

Mechanistic studies of naturopathic treatment ...may provide knowledge useful across medical cultures.

Animal studies present complexities beyond those of species' physiological differences. Some naturopathic institutions have policies prohibiting animal research, arguing that informed consent is a uniform ethical code across sentient beings. Vitalists feel that neither animal studies nor *in vitro* work appropriately reflects the human being. Such arguments bear legitimate scrutiny. Where animal work is the only way to pursue an important clinical goal, at least some of the institutions are willing to collaborate in animal studies at biomedical facilities.

The NMRA and Public Health

Medicine and Public Health

The practice of medicine plays only a small role among all the variables that produce public health. No medical “system,” conventional or alternative, effective or not, influences the public’s health in a vacuum. Today, citizens in developed nations tend to take water quality, food safety, nutritional status, decent housing, solid waste management, and dozens of other critical determinants of the public’s health for granted, focusing instead on access to quality medical care as our chief health concern. High-quality care is certainly important, and providing universal access to such care stands as one of the last great health challenges for developed nations—nations that have otherwise addressed many of the environmental and infectious threats that have heretofore plagued humankind. But given the myriad determinants of health, we must recognize that even important improvements in medical care are unlikely to result in a dramatic impact on the overall health of a community, or a nation, as measured by traditional public health statistics (e.g., mortality and morbidity rates). Thus, while we believe the naturopathic medical research agenda proposed here will be instrumental in improving health outcomes for patients, we do not expect to measure evidence of that improvement in terms of its impact on overall public health.

Prevention and Public Health

The research methods proposed in the first five years of this agenda do not incorporate traditional measures of public health, such as national and regional morbidity and mortality rates, health disparities, federal costs of the public health care system, or immunization rates, to mention a few examples. Typically, medical care affects health primarily at the single-patient level, after symptomatic conditions have arisen and access to care has been achieved. (We have yet to assess the long-term effects on health of those who seek and can afford to pay for preventive care—currently a relatively small minority of the populace.) Public health researchers tell us that nothing will lower health care costs except cost containment, and that prevention is key to improving health and lowering costs. Effective population-level preventive interventions are more likely to stem the rising tide of diabetes, heart disease, and cancer,¹ than any medical intervention—conventional or naturopathic. This is where naturopathic and public health scientists agree. Within a “disease care” system, naturopathic medicine is likely to have only a small impact. However, in a “health care” system, naturopathic methods of comprehensive and behavioral preventive medicine are hypothesized to have significant impact on the health, and therefore morbidity, of those individuals who utilize it. Important questions to be answered include whether adjunctive naturopathic care in ill patients is an additive or substitutive cost of disease care; whether naturopathic care, because of its integration of treatment and prevention, has long-term implications for improved individual health and well being; and whether naturopathic care over many years, integrating disease treatment with primary and secondary prevention, would result in lower costs of care. These are all vital issues to explore.

Naturopathic Medicine and Public Health

Naturopathic medicine has its clinical niche, and perhaps even its scientific niche, in the integration of primary care with preventive medicine. However, primary prevention intervention studies are beyond the scope of the first NMRA. Studying people with early diabetes and the elderly is a reasonable way to initiate the long-term naturopathic research agenda. Diabetes in its early stages is often reversible, and secondary prevention can be highly effective (e.g., lifestyle modification is key to success in controlling blood sugar). Studying naturopathic care for the elderly effectively places the NMRA in a model of evaluating health outcomes in a population where treatment and prevention are both of great importance. Clinical research on diabetes and geriatrics using small but adequate samples of patient populations may show that the naturopathic medical protocols developed through research and expert panels are effective and inexpensive for the treatment of early diabetes and early Alzheimer’s and Parkinson’s disease. These studies will help to test the

Public health researchers tell us that nothing will lower health care costs except cost containment, and that prevention is key to improving health and lowering costs.

¹ These are the STEPS to a HEALTHIER US conditions identified by former Secretary of Health, T. Thompson

second NMRA hypothesis (widespread access to NDs will improve health in a cost-effective manner). The whole-practice interventions will mostly consist of diet and exercise prescriptions, along with key science-based nutritional, botanical medicines, and other medicines within the scope of ND licensure. Positive results will provide treatment options to other physicians across medical disciplines. Negative results will help naturopathic physicians improve their clinical protocols and may also help conventional physicians guide their patients who self-prescribe complementary and alternative therapies.

...it was hypothesized that expanding the presence of naturopathic medicine in primary care might lower morbidity, mortality, and costs...

Naturopathic medicine and public health share a focus on disease prevention. The American Public Health Association has similar perspectives on what medicine can do to improve the public's health. Naturopathic and public health research both pose important questions regarding environmental causes of acute and chronic disease. Both communities are likely to agree that one good measure of the success of democracy is the reduction of health disparities across racial, economic, and gender divides (APHA, 2003). During early NMRA Workgroup meetings, it was hypothesized that expanding the presence of naturopathic medicine in primary care might lower morbidity, mortality, and costs in populations that utilize this care both for primary prevention and at the onset of early chronic disease. Discussions at many levels within the nation's healthcare community—from the Institute of Medicine ("Crossing the Quality Chasm," 2001), to the UCSF Center for the Health Professions (O'Neil, 1998), to the *Annals of Family Medicine* (Grumbach, 2003)—propose "a fundamental shift...in the model of and approach to primary care...[emphasizing] the competencies of health promotion, lifestyle intervention and prevention to move from the disease care to the health care system" (Grumbach, 2003). The NMRA reflects these major trends in healthcare policy debate.

Future Directions for Naturopathic Medicine and Public Health

While not a specific hypothesis of the NMRA at this stage, a very interesting question to ask at some point is, "Would the widespread availability of naturopathic medicine, primarily through its education and patient behavior modification aspects, prevent or delay chronic disease in the populations to whom it was made accessible?" This was considered to be too large a question at the current time, but once the foundation for studying naturopathic medicine is established through the implementation of the NMRA, it seems an entirely appropriate subject for future study.

Successful early results of the NMRA will lead to the study of naturopathic medical care in a variety of settings, including public health clinics. Naturopathic medical colleges already provide care in community and public clinics in Portland, Seattle, Phoenix, and Bridgeport, CT. Similar partnerships exist in Canada (Toronto) and Australia. Several members of the NMRA Workgroup are now collaborating on a plan for the establishment of a diabetes demonstration pilot study in low income public health care systems that serve diverse ethnic and economic groups with a high prevalence of type 2 diabetes and neurodegenerative diseases. And, while it is also beyond the initial scope of the research agenda, another important interface between naturopathic medicine and public health is that identified in community-oriented primary care. The personalized care of individuals coupled with the focus on population goals, partnerships, and outcomes, has a significant literature suggesting value using a conventional practice in partnership with a community (Rhyne et al., 1998). It would be valuable to study a community-oriented naturopathic medicine practice and see what kind of population impact it has.

Demonstration of slowed disease progression in diabetes and neurodegenerative conditions...will have translatable impact...

The NMRA has modest and attainable goals that are very much in tune with the values of the public health community. The results of the clinical studies generated under its recommendations could help shape medical treatment for people with diabetes and for people as they age. Positive results at the individual patient and study group level will be translatable into other diverse clinical settings. Demonstration of slowed disease progression in diabetes and neurodegenerative conditions using best practice naturopathic medicine protocols will have translatable impact on greater numbers of people among larger groups. Important topics for future study, that may have impact on the intersection of public health and preventive medicine, will be identified by the first stage of the NMRA.

NMRA Clinical Research in Diabetic Patients and the Elderly

Studying naturopathic care in the two selected populations will provide ample opportunity to test the first two NMRA hypotheses. Clinical studies of people with diabetes and the elderly will provide a broad assessment of the outcomes of naturopathic medicine on multiple parameters including health, safety and disease markers, and costs, in a way that sustains the integrity of the practice along with, presumably, the best and most replicable outcomes.

The two study targets in these populations also meet the six prioritization criteria described in The Guiding Principles chapter. The burden of suffering and costs of care are high in diabetes (O'Brien et al., 2003) and on the increase (Criterion 1); the Centers for Disease Control have estimated that one of every three children born in 2000 will eventually become diabetic. That prospect should drive health professionals to seek all possible solutions for prevention and treatment (Criterion 2). The increased health care needs of the elderly (Caro et al., 2002; Brown et al., 2001) are also significant and, with our aging population and the progress of the baby boomers into late middle age and older, make investigating all possible solutions to healthy aging very important. The effort to study the most effective naturopathic treatments (Criterion 3) leads us to the whole-practice and combined-treatments models most often mentioned as more valid by naturopathic physicians in the NMRA feedback process. The Agenda also directs efforts toward evaluating effectiveness of an expert-driven, standardized, replicable, yet rationally flexible “best practice” intervention for treatment in diabetes. If a clinically significant advance in the treatment of diabetes in the elderly emerges, the research will have returned a significant benefit to society. That is the vision. If safety is assured and costs are assessed, the work will still have been valuable. In any case, the preliminary work on the assessment of naturopathic care presented here would create substantial infrastructure to permit the improvement of the practice and to increase the potential of generalizable discoveries (Criterion 5).

Success in these areas of clinical research (diabetes and geriatrics) depends on distributed, collaborative, and systematic work among multiple conventional and naturopathic institutions. Many of the intellectual and clinical research resources needed are present within the NMRA Workgroup. The NMRA process has strengthened existing collaborations and brought new scientists into the work through the Workgroup meetings. As described more fully in the Research Readiness and Implementation chapters, the naturopathic colleges are already engaged in preliminary work in each of these directions (Criterion 6).

Preliminary activities will provide data to help determine the exact questions and methods of the large studies to be performed. Such activities include:

- systematic reviews and the assembly of clinical, methodological, and ethical expert advice teams;
- component studies on products, procedures, or specific sub-populations to identify productive directions for randomized controlled whole practice clinical trial(s) of diabetes best practices, and on products, procedures, diseases, or sub-populations in geriatrics;
- pilot studies may test subject recruitment, research methods, or approaches to care (the specific clinical research protocols).

NMRA Diabetes Research

The NMRA recommends a large randomized controlled trial assessing the effect of naturopathic medical care in comparison to conventional care in a population of individuals with type 2 diabetes, to begin within the next four to five years. In preparation, systematic reviews of aspects of naturopathic care for diabetes and the collection of observational data are already underway, and the collection of pilot intervention trial data is underway at Southwest College of Naturopathic Medicine. Outcomes of whole-practice research on diabetes will include biomedical markers, health services, and public health end-points. While it is fundamental to assess the impact on the

The NMRA recommends a large randomized controlled trial assessing the effect of naturopathic medical care in...type 2 diabetes...

specific condition, as well as its associated co-morbidities, this research should also adhere to the basic naturopathic premise that overall health outcomes are as important as disease outcomes. Also being planned is the collection of preliminary clinical data from multiple naturopathic and integrative clinics in preparation for applications under NIH's U19 mechanism for establishing an exploratory cooperative center for naturopathic research. The NMRA Workgroup is well aware of the need to begin collecting the data for three R01 level NIH research grants as well as developing adequate administrative, data, and laboratory cores capable of sustaining such a multisite cooperative center grant.

NMRA Gerontology Research

The U.S.'s aging demographic calls for geriatric health care as the second area of focus for the NMRA. The most serious health problems occur with increased frequency in the aged. Controlled studies of naturopathic medical care for geriatric populations for the preservation of health are specified in the Agenda. In particular a Workgroup target is a large, long-term controlled cohort study (or a variant of such a design) that can assess health-oriented naturopathic care for this population, including cost and effectiveness outcomes. This might be done in a demonstration project; in such a setting, the cost-benefit ratio may be assessed along with measures of effectiveness and safety. Though such a study would need to be fairly long (five years or more), health care regulatory and market conditions suggest that opportunities may be available within three to four years to take advantage of expanded licensing, third-party payer coverage, and integration into health maintenance organizations (HMOs). During the interim important work will go forward to assemble adequate methods and infrastructure to address the research questions. Preliminary work in understanding the methods and accumulating the resources for taking advantage of these opportunities has begun.

Justification, interest, and infrastructure exist for focusing some NMRA efforts in the area of neurogerontology. Naturopathic physicians in the field are utilizing innovative methods for preventing and treating some of the most devastating geriatric diseases, such as Alzheimer's and Parkinson's disease. Alzheimer's disease, in particular, has a high burden of suffering and cost. For example, naturopathic physicians prescribe antioxidant and anti-inflammatory natural medicines to their elderly cognitively or motor impaired patients. These techniques are used by NDs in preventing other geriatric disorders as well.

The NMRA Workgroup has strengths in neuroscience, and there are already active naturopathic research programs in some common diseases associated with aging:

- Lynne Shinto, ND, MPH, "Fish oil and alpha lipoic acid in mild Alzheimer's disease" (National Institutes of Aging R21AG023805-01);
- Laurie Mischley, ND, is studying the effectiveness of nebulized glutathione for Parkinson's disease;
- Wendy Weber, ND, MPH, received an NCCAM K award to study St. John's Wort in depression;
- William Lafferty, MD, and Leanna Standish, ND, PhD, are currently accruing patients in a randomized controlled clinical trial (N=300) to evaluate "Mind-body palliative care at end of life" (R01 CA10620).

For this reason, initial NMRA work in gerontology will be in the neuroscience area. We propose to measure neurological and neuropsychological outcomes in the NMRA's longitudinal outcomes study of the elderly receiving naturopathic medical care. Recent findings on the relationship between insulin resistance and Alzheimer's disease may provide an opportunity to advantageously link these two NMRA themes: diabetes and neurogerontology.

The NMRA and Scientific Discovery

The third NMRA hypothesis to be tested is whether the study of naturopathic medical principles and theory will yield new scientific insights into health, disease, and the biology of healing. Naturopathic principles-driven research is distinct from research focused on assessing effectiveness of naturopathic medical care for specific populations or conditions. Many naturopathic medical

Controlled studies of naturopathic medical care for geriatric populations for the preservation of health are specified in the Agenda.

The NMRA Workgroup has strengths in neuroscience...

scientists do not assume that the biology of healing is identical to or subsumed with the biology of disease. Hypothesis 3 is a very broad hypothesis that cannot be tested in a single study; reflections on it will emerge over time. Scientific investigation of these naturopathic principle-driven hypotheses will require diverse basic and clinical methods. Table 6 summarizes some topics and methods for the kinds of study that each naturopathic principle calls forth.

Research work that addresses hypothesis 3 has already begun at the naturopathic medical colleges. ND researchers have published studies on ultrahigh dilutional biology (Brewitt, et al. 2001; Standish, 2001). Mind-body and neuroscience consciousness research is also underway by members of the NMRA Workgroup (Lafferty's group; Standish, Johnson et al., 2003, 2004;). At the February 2004 NMRA Workgroup meeting, it became clear that those scientists who wish to follow the path of discovery as stated in the vision and values statement at the top of Figure 1 are those who will be investigating the basic science implications and translatability of interesting naturopathic concepts such as the vital force, homeopathic ultrahigh dilutional dosing, symptom suppression, the healing crisis, the therapeutic order, *and* healing intention effects, as well as ethnopharmacological exploration of shamanic botanical medicines, to mention a few topics. It is likely that NMRA-inspired research on hypothesis 3 will be performed by individual naturopathic researchers and their students through NIH's investigator-initiated mechanisms such as R21s. This has already occurred at one naturopathic medical school (Bastyr University) in at least one area of NCCAM's frontier science program. The Foundations of Naturopathic Medicine Project led by NMRA Workgroup member Pamela Snider, ND, and partnering with Elsevier Press, has begun engaging naturopathic scholars and scientists from all six naturopathic medical colleges and conventional academic research communities in rigorously defining and updating the terms associated with these naturopathic concepts.

Scientific investigation of these naturopathic principle-driven hypotheses will require diverse basic and clinical methods.

NMRA Research Methods and Strategies

A discussion of the infrastructure needed to adequately address the study of naturopathic medicine in type 2 diabetes and in the elderly can be found in the Research Readiness chapter. The Workgroup identified the following research methods and strategies for executing the NMRA:

1. high validity randomized controlled trials (RCTs) of whole-practice naturopathic medicine for the evaluation of efficacy of “best” protocols derived from expert ND panels;
2. observational study and health services research to assess safety, cost, and effectiveness of current practice and integration;
3. laboratory sciences to establish standards for therapeutic substances/processes and to investigate mechanisms of action, and
4. the building of adequate basic and clinical capacities for the exploration of naturopathic medical principles.

The NMRA Workgroup understands that most of the research that has been done, is underway, and that is likely in the future, will be on components of practice. It is expected that naturopathic research agencies alone and in their partnerships with biomedical colleagues will continue to do studies on the “component” and “context” domains of research. Studies that grow out of this research direction may be specific to naturopathic medicine. More often they will be understood as important to other health professions as well. While some of the principles are necessarily evaluated in the clinical studies in diabetes and geriatrics described above, others will call for innovative approaches.

At the core of the Agenda are two specific research directions. First, the NMRA proposes a high validity RCT of naturopathic medical treatment of patients with type 2 diabetes as a “best practice” trial. Preliminary work on developing a proposal for such a trial is under way. NMRA Core Team member Konrad Kail, PA, ND, at Southwest College of Naturopathic Medicine has appointed members to the “NMRA Delphi Panel” whose task is to develop the best naturopathic medical practice clinical protocol for the comprehensive treatment of people with type 2 diabetes. Work began in 2004. Several of the naturopathic colleges have performed clinical trials (with up to 600 subjects); the more novel streams of future development will need to identify the whole-practice

interventions and assessments. Some of the schools also have statistics and data management abilities, but more expertise in quantitative methods and greater capacity for conducting large studies will be essential. The second central goal of the NMRA is funding of a large observational study of geriatric health. The NMRA requires execution of pre-clinical and mechanistic studies attendant on pursuit of the two topic areas and support of the controlled studies being planned. Research on the third hypothesis requires naturopathic medical scientists to develop a range methods with which to investigate and validate the principles and theories of naturopathic medicine.

To carry out the Naturopathic Medical Research Agenda, a network of naturopathic institutions working in collaborations with neighboring medical and health care institutions has been developed; that network is described in the Implementation chapter.

Table 6. Scientific research directions called for by naturopathic medicine principles and theory

Principle	Topics
First do no harm	Drug-herb, drug-nutrient, herb-nutrient interactions Evaluation of symptom suppression Safety and efficacy of vaccinations Theory of least force
<i>Vis medicatrix naturae</i>	Biology of healing Healing crisis Theory of the therapeutic order Consciousness science Hering's Rules of Cure Spirituality and health Investigate natural medicine modalities: Botanicals Homeopathy Hydrotherapy Nutrition and nutrients Physical medicine Psychology/counseling Nature and healing ("nature cure")
Whole person care	Optimal healing environments Multiple determinants of health and co-morbidity Individualization of care
Treat the cause	Environmental medicine Psychoneuroimmunology Genomics Toxemia and inflammation
Doctor as teacher	Effectiveness and cost of teaching self-care Doctor-patient relationships Role of intention
Prevention	Genomics Wellness, health promotion Lifestyle

Research Readiness

The five North American ND colleges are in varying states of research readiness. The University of Queensland's and Southern Cross University's joint program in naturopathic medical research in Australia is more developed than that of any of the North American naturopathic medical colleges. All accredited naturopathic medical colleges have strong clinical programs and patient populations with over 110,000 patient visits per year, which will prove an invaluable resource for subjects to participate in clinical trials. The goal of the NMRA is to create a focused and executable research agenda for naturopathic medicine that offers the possibility of a scientific program that fulfills some of the highest hopes of the public for a science-based, integrated, comprehensive complementary and alternative medicine. Naturopathic physicians often describe themselves as the physicians of the 21st century because they are trained to provide comprehensive, whole-person care that utilizes the best of science-based natural medicine. The rigorous evaluation of the effectiveness of specific naturopathic therapies, and of the practice as a whole, on health outcomes will provide needed data on a licensed CAM discipline whose practitioners are also licensed as primary care physicians.

The research readiness of the six naturopathic medical institutions at the core of the Naturopathic Medical Research Agenda (NMRA) can be assessed by each institution's faculty publications, the number and capacity of their clinics, the numbers and types of research laboratories, data management and analysis hardware and software, salaried research staff including data management and biostatistical support, and the presence of human subjects ethics oversight by institutional review boards. The data on the research capacities and track record of each of the six naturopathic medical colleges are summarized in Table 7.

Even at the oldest of naturopathic medical schools in North America, research infrastructure is weak compared to most conventional medical institutions. The Australian Centre for Complementary Medicine and Research has the most developed research infrastructure and faculty publication track record. This is because it is part of a major conventional medical institution. Each of the North American naturopathic medical colleges has strengthened research capacity by collaborating with neighboring conventional medical universities. These collaborations have led to NIH-funded grants. Bastyr, NCCNM, and SCNM have utilized this strategy with good results. Canadian College and the School of Naturopathic Medicine at the University of Bridgeport are utilizing similar strategies with their respective neighboring universities, University of Toronto and McMaster University, and Yale University, respectively.

The proposed NMRA will be implemented through further development and use of the infrastructure and collaborations that each naturopathic college currently enjoys. We will build upon and expand these capacities and collaborations in order to perform the multi-site, multidisciplinary clinical studies called for in the Naturopathic Medical Research Agenda.

Table 7. Scientific research infrastructure and track record for the six accredited naturopathic medical schools in North America and Australia

	SCU (ACCMER) ¹	BU ²	CCNM ³	NCNM ⁴	SCNM ⁵	UBNM ⁶
Year Founded	1995 (2001)	1978	1978	1956	1992	1997
No. of cumulative faculty peer-reviewed publications (papers, books, and book chapters) of work performed while a member of the faculty at each respective school	73 (42)	76	56	118	63	9
2002-2003 Data						
No. of graduating NDs	75	108	120	96	62	110
No. of patient visits per year	3600	36,000	18,000	36,415	11,717	5,200
No. of clinics	1 base; 1 clinical trials facility in a major public hospital	1 base; 12 satellite	1 base; 6 satellite	2 base; 11 satellite	1 base; 11 satellite	1
No. of research labs	10	1	1	1	1	1
Research staffing FTE	9 FTEs	2.75 FTEs	4 FTEs	3.8 FTEs	1.5 FTE	1 FTE
No. of biostatisticians on staff	2	1	1	1	1	0
Data management staff FTE	0	1 FTE	0	0	0	0
Data management and analysis software	SPSS	SPSS	none	none	SPSS GB STAT	SPSS
No. of active funded federal grants in 2002–2003	0	13	2 (CIHR)	2	2	0
IRB	yes (3)	yes	yes	yes	yes	yes

1 The naturopathic medicine program in the School of Natural and Complementary Medicine at Southern Cross University (SCU) [the Australian Centre for Complementary Medicine Education and Research (ACCMER), a joint venture between the University of Queensland and SCU]

2 Bastyr University

3 Canadian College of Naturopathic Medicine

4 National College of Naturopathic Medicine

5 Southwest College of Naturopathic Medicine

6 University of Bridgeport College of Naturopathic Medicine

Implementation of the NMRA

Overview

The iterative NMRA process of debate and discussion articulated the breadth and depth of the needs and priorities of naturopathic medical research. This document, which arose from that process, may serve as a guide for the collaborating agencies in shaping the future of naturopathic research.

In order to strengthen naturopathic medical research, the team and institutions that developed the NMRA will form the basis of an ongoing collaborative network. Each of the naturopathic institutions represented on the Workgroup Core has already committed to and is engaged in lines of work related to at least one of the populations of interest, with the initial emphasis in diabetes. An inter-institutional naturopathic Expert Clinical Panel on diabetes has been formed and is active. A survey of the profession about diabetes care is also in development. This report will be internationally circulated to other naturopathic scholars and colleges who will be invited to participate in the collaborative network.

The NMRA Implementation Core Team

Participants

The NMRA Core Research Team has agreed to form the coordinating body for implementation of the NMRA (Table 8). Diabetes and Health of the Elderly population tracks chairs and their support staff will together be responsible for overall coordination. The remaining scientists from NMRA's Workgroup will collaborate on all research tracks, and will form the Scientific Advisory Committee for the NMRA. The Scientific Advisory Committee will meet with the NMRA chairs and associates annually to provide ongoing guidance to and collaboration in implementation of the NMRA.

In addition to the individuals listed who have responsibilities for implementing their tracks, NMRA Core Team member Michael Traub, ND will continue to participate as chair of AANP's Scientific Affairs Committee. Linda Kim, ND, Southwest College of Naturopathic Medicine's research director, will participate in supporting the diabetes track. Ryan Bradley, ND and Erica Oberg, ND (Bastyr University) are seeking NCCAM post-doctoral fellowships in diabetes research, as a step toward a diabetes RCT (clinical and health services pilot in public health settings) for the NMRA. Pamela Snider, ND will work with Drs. Oberg, Standish and Kail on the clinical and health services pilot study and coordinate updated and rigorous definitions for concepts in naturopathic clinical theory in an academic textbook through the Foundations of Naturopathic Medicine Project (Elsevier Science).

Purpose of the NMRA Core Team

A research agenda is successful only if it is implemented; it must mobilize research activity, produce credible results, and publish those results. The NMRA team was charged with drafting a specific plan and mechanisms for implementation that would also foster collaboration among naturopathic medical colleges and conventional institutions.

The purpose of the NMRA Core Team is to provide structure for the six naturopathic medical colleges to coordinate and execute the Naturopathic Medical Research Agenda (NMRA). The Naturopathic Medical Research Associates will provide decentralized and efficient leadership across the naturopathic colleges to accomplish the implementation of the agenda described in this report. Implementation will foster continued collaboration within the NMRA network of conventional and naturopathic institutions and researchers, while supporting and fostering new collaborations. The NMRA Core Team will meet yearly at the annual national meeting of the American Association of Naturopathic Medicine.

The purpose of the NMRA Core Team is... to coordinate and execute the Naturopathic Medical Research Agenda (NMRA).

Table 8. NMRA Implementation Core Team members and their institutional affiliations**Bastyr University**

Leanna Standish, ND, PhD, LAc; Chair; Gerontology Track
 Pamela Snider, ND; Co-Chair, Publications, Information, and Dissemination Track
 Erica Oberg, ND
 Ryan Bradley, ND

Southwest College of Naturopathic Medicine

Konrad Kail, ND, PA; Chair, Diabetes Track
 Linda Kim, ND; SCNM Research Director

National College of Naturopathic Medicine

Carlo Calabrese, ND, MPH; Co-Chair, Whole Practice and Methods Track
 Heather Zwickey, PhD; Co-Chair, Whole Practice and Method Track

Canadian College of Naturopathic Medicine

Ed Mills, DPh; Chair, Publications, Information, and Dissemination Track

Australian Center for Complementary Medicine, Education and Research

Stephen Myers, PhD, BMed, ND; Co-Chair Publications, Information, and Dissemination Track

University of Bridgeport, Naturopathic Medicine Program

Mark Mattie, PhD; Research Director

American Association of Naturopathic Physicians

Michael Traub, ND, DHANP; Chair, AANP Scientific Affairs Committee

Web-based Network

It is important to note that due to constraints in funding, some NDs involved in research were not able to participate as frequently or deeply in the NMRA as would have been desirable. The success of the NMRA will depend on its ability to obtain funding for and connect this network of ND and conventional researchers involved in, or considering, research in naturopathic medicine to the NMRA Web-based resources. Multi-institutional and multidisciplinary collaborations needed for the execution of the NMRA will require efficient Web-based means of communication and document production.

The website will be available on a password-protected basis, and it will include grant announcements, the NMRA map and agenda, databases of research activities, information and contact data, a list-serve for an ND research newsletter, and newflashes. Such a website will provide cost-effective, efficient facilitation of the NMRA's broader implementation plans and will foster new collaborations by providing easy access to data, procedures, and contact with colleagues. Conventional and naturopathic medical researchers and physicians throughout the world will be invited to join the NMRN team through this website. Progress on NMRA's implementation will be posted regularly.

The network will draw from elements in the design of the Web-based Canadian Interdisciplinary Network for Complementary and Alternative Medicine Research (IN-CAM). NMRA investigators communicated with IN-CAM investigators, who have shared information and offered to share expertise and resources and to collaborate with NMRA. IN-CAM is funded by a three-year Interdisciplinary Capacity Enhancement Grant from Health Canada, via the Natural Health Products Directorate and Canadian Institutes of Health Research—through the Institute of Health Services and Policy Research, the Institute of Musculoskeletal Health and the Institute of Arthritis and Infection. The network is based bi-regionally at the University of Toronto, and the University of Calgary (<http://www.incamresearch.ca/about/mission.html>).

Funding will be needed to support this kind of infrastructure for the NMRA. A Web-based network offers a streamlined and economical solution to enhanced coordination and the fostering of new research collaborations. It has been suggested that a combination of support from the naturopathic colleges, NCCAM, and foundations would be appropriate and feasible to establish such a Web-based research network for NMRA.

NMRA Mentorship Program

Outreach to naturopathic clinical thought leaders through the NMRA project period had an unexpected effect: the discovery of many experienced physicians who expressed interest in doing clinical research. This network of senior naturopathic clinicians will be an important resource for the NMRA in the future. Over 100 individual clinicians, faculty and leaders were contacted and interviewed to obtain the forty who presented at the Special Topics sessions.

There are fellowship programs available through NCCAM to train current ND graduates to do research. However, it is challenging for senior NDs, whose primary activity has been clinical practice, to enter the research process. Yet these clinicians have valuable protocols and approaches that they would like to see investigated. Many of them wish to remain directly engaged in the research process as co-investigators throughout the research process from pilot to larger studies. A simple mentorship program involving supervision by an experienced principal investigator should be developed to cultivate participation in research by this untapped resource of experienced clinicians who were trained during a time when there was little support and few avenues available for NDs to engage in research. Ultimately, this would help to strengthen, and deepen the resources for the implementation of the NMRA projects.

Structure of the NMRA Implementation: The Tracks

The structure of the NMRA implementation plan is built on the premise of fostering diverse leadership at all naturopathic medical colleges, and collaborative relationships with conventional medical and public health research partners. All six ND colleges will participate in research designated in the NMRA. Four research foci and infrastructure tracks have been established:

- **Publications and Information Dissemination Track**
- **Diabetes Track**
- **Populations Track: Health of the Elderly**
- **Whole Practice and Methods Track**

These tracks, their leaders, and their purposes are summarized below. While each track will be based primarily at a single college, all ND colleges will participate in each track. Naturopathic college researchers will lead the tracks. The diabetes and elderly populations tracks each will require technical and administrative support in order to coordinate the overall logistics and information management necessary to implement the agenda, maintain the Web-based network, and organize meetings among the NMRA Core Team.

1. Publications and Information Dissemination Track

Chair: Edward Mills, DPh, MSc. Co-Chairs: Pamela Snider, ND, and Stephen Myers, PhD, Bmed, ND (Canadian College of Naturopathic Medicine, Bastyr University, and Australian Centre for Complementary Medicine, Education, and Research/Southern Cross University School of Natural Medicine, respectively)

The two-year NCCAM grant-funded process to develop the Naturopathic Medical Research Agenda (NMRA) resulted in a consensual decision to focus on whole practice research (WPR) in naturopathic medicine and to disseminate this information in a timely and scholarly manner. As such, the NMRA has developed a research training priority addressing the issue of publication and knowledge dissemination. Edward Mills, DPh, Director of Research at Canadian College of Naturopathic Medicine and a fellow at McMaster University is chair of the NMRA publication track. He is responsible for the development and coordination of training programs in scientific writing and knowledge transfer involving all six of the naturopathic medical colleges in North America and Australia.

The AANP Special Topics sessions provided highly informed perspectives that the NMRA Core team viewed as useful to the profession's research endeavors. While there is rich clinical and academic expertise in these areas, there are few published peer-reviewed articles, systematic reviews, clinical protocols, or practice guidelines in these areas of naturopathic practice. A first step in increasing high quality naturopathic medical publication is to provide pathways for peer-reviewed publication of the special topics sessions in the *International Journal of Naturopathic Medicine* (IJNM). The senior editor of this journal is NMRA Workgroup member and Publications Track Chair, Edward Mills, DPh, Director of Research at Canadian College of Naturopathic Medicine. The IJNM has announced a special section of the journal dedicated to publication of NMRA special topics reports through a peer-review process. The NMRA core team is working directly with thought leaders to encourage and provide early editorial commentary on these submissions to IJNM. As of the date of publication of this report, five papers (diabetes, women's health, environment and health, asthma, and health services research) have been submitted for publication to the IJNM and have been assigned to peer review. In August 2004 the first paper (on asthma) was published in IJNM (Saunders and Barrett, 2004). Detailed Special Topics Reports are included in Appendix E.

Published naturopathic clinical guidelines currently tend to reflect the author's assessment of best practices, in textbooks such as Pizzorno and Murray (1999). There are two expert panel-generated protocols: rheumatoid arthritis and multiple sclerosis. A diabetes protocol is underway through the NMRA's diabetes track. Examples of these clinical protocols and guidelines are in Appendix F. There are also several published naturopathic clinical protocols for conditions such as breast cancer (Standish et al., 2002), hepatitis C (Milliman et al. 2000), and HIV AIDS (Standish, et al., 2001).

One goal for this track is to create an avenue for experienced naturopathic physicians to begin participating in the peer-review process involved in submitting a paper for publication in a scientific journal. By establishing a two-year series in the IJNM on NMRA special topics reports, the IJNM will foster interest, encourage activities, and provide opportunities for collaboration in implementing the NMRA. It is anticipated that several articles will be published. This track will also facilitate training at all six ND colleges in scientific writing, from systematic reviews to publication of research studies.

In 2004 the Canadian College of Naturopathic Medicine...established a new peer-reviewed journal...the International Journal of Naturopathic Medicine (IJNM).

The goals of this inter-institutional track are:

1. Develop an expert based published series on writing style for scientific publications, grants and abstract presentations.
2. Conduct workshops for interested investigators at the six naturopathic medical colleges
3. Publish a special series of peer-reviewed scientific papers on the NMRA Special Topics Sessions over a period of two years in the *International Journal of Naturopathic Medicine*.
4. Coordinate updated, rigorous, operational definitions for key concepts in naturopathic clinical theory in an Elsevier Science academic textbook entitled *Foundations of Naturopathic Medicine* (Snider, Zeff, Myers, et al in preparation).
5. Develop mentorship programs between young investigators and well-published established researchers.
6. Establish a Web-based resource of all research publications on naturopathic medicine.

Progress to date:

- In 2004 the Canadian College of Naturopathic Medicine, with the support of the NMRA, established a new on-line peer-reviewed journal entitled the *International Journal of Naturopathic Medicine* (IJNM) (www.intjnm.org). This journal is currently the only peer-reviewed journal specific to naturopathic medicine. The aims of this journal are to publish rigorous and relevant scientific manuscripts. This journal will serve as an ideal format with which to provide NDs with continuing education on the issues of publication, writing style and knowledge transfer. Specifically, we intend on developing a skills training series addressing the following topics:

- Introduction to publishing and the peer-review process
 - Introduction to scientific writing styles
 - Grant writing
 - Dealing with the peer-review process
 - Writing up case reports and case series
- Five papers from the NMRA's Special Topics Sessions have been submitted to the IJNM and accepted for peer review. One was published in August 2004.
 - Workshops on writing and publishing: The group will conduct workshops for students and NDs at the annual American Association of Naturopathic Physicians conference. In addition, we will conduct a series of workshops at the individual naturopathic medical colleges. This curriculum will be developed and set by the NMRA and conducted by the respective research directors.

2. Diabetes Track

Chair, Konrad Kail, PA, ND, Southwest College of Naturopathic Medicine.

The two-year NCCAM grant-funded process to develop the Naturopathic Medical Research Agenda (NMRA) resulted in a consensus decision to focus on whole practice research (WPR) in naturopathic medicine and to focus on two patient populations: people with diabetes and the elderly. Each of these top priority research areas has been assigned a Chair for implementation. Dr. Kail is Chair of the NMRA Diabetes Research Track. He is responsible for the generation and coordination of diabetes medical research at all six of the naturopathic medical colleges in North America and Australia.

This research track will implement sequenced research on the efficacy and mechanisms of naturopathic care in populations with diabetes. Activities in diabetes research are underway at most of the ND colleges, including submission of postdoctoral fellowship applications, activation of a Delphi process to develop an expert-generated and peer-reviewed type 2 diabetes naturopathic practice guideline incorporating naturopathic principles, and establishment of data collection through the Diabetes Collaborative of Arizona.

The goals of this inter-institutional track are as follows:

1. Using a Delphi Panel approach, generate an expert-driven WPR treatment algorithm with a manual and training to guide clinicians.
2. Collect prospective clinical, laboratory, and quality of life data on the naturopathic WSR protocol in multiple clinic sites including public health clinics, naturopathic medical clinics and HMOs.
3. Design, obtain funding, and implement R21 and R01 level RCTs of specific naturopathic therapies
4. Within three years submit a center grant application to NIH that coordinates the diabetes research programs at accredited naturopathic medical colleges.

Progress to date:

Southwest College of Naturopathic Medicine, Tempe, AZ:

- ND practitioner survey of diabetes treatment protocols (lead is Dr. Kail)
- Diabetes Delphi Panel established with 14 members (lead is Dr. Kail)
- Phoenix Veteran's Administration Hospital pilot program (lead is Dr. Kail)
- N=30 consecutive case study at SCNM's clinic (lead is Dr. Morstein)
- Diabetes Collaborative data entry from SCNM's clinic (lead is Dr. Morstein)
- WPR RCT using expert-driven protocol developed by Delphi Panel (leads are Dr. Kail and Dr. Kim)

*Diabetes Delphi Panel
established with 14
members...*

National College of Naturopathic Medicine, Portland, OR:

- R21 effect of DHEA-mediated cortisol control on insulin resistance (lead is Dr. Calabrese)
- WPR RCT using expert-driven protocol developed by Delphi Panel (lead is Dr. Calabrese with Drs. Kail & Kim)
- Observational cohort study in the elderly in an HMO setting (i.e., Kaiser-Permanente) (lead is Dr. Calabrese)

Bastyr University, Kenmore, WA:

- R21 (submitted 6-1-04) RCT of chromium + Metformin (n=76) (lead is Dr. Bradley)
- F32 postdoctoral training grant to conduct outcomes study of Delphi Panel protocol in two clinical settings: public and community health clinic in Kent WA and an integrated clinic in Seattle (Oberg)

Southern Cross University and ACCMER, Australia:

- Effect of carbohydrate modifying diets on cardiovascular outcomes in type 2 diabetes (lead Steven Eddy, PhD candidate, under supervision of Dr. Cheras and Dr. Myers)
- Laboratory exploration of the effects of herbal medicines on glucose metabolism (lead Dr. Myers)

3. Gerontology Track: Health of the Elderly

Chair: Leanna Standish, ND, PhD, LAc, Bastyr University

This research track will implement sequenced research and RCTs on health outcomes in the elderly, and will develop methods for investigating the range of determinants of health in reducing multiple co-morbidities in the elderly. More specifically, it will investigate the effect of naturopathic whole practice on neurodegenerative disease in the elderly, and will implement research on health promotion in geriatric populations.

It was hypothesized... that the introduction of whole person naturopathic care into an integrated care system for people as we age will reduce incidence of chronic disease and improve quality of life in those groups who have access to the care and select it.

The NMRA Workgroup identified the elderly as an important patient population in which to develop, evaluate, and improve naturopathic preventive and therapeutic care. It was hypothesized by members of the Workgroup that the introduction of whole person naturopathic care into an integrated care system for people as we age will reduce incidence of chronic disease and improve quality of life in those groups who have access to the care and select it. Therefore, the NMRA network will proceed with the planning and implementation of clinical studies of the impact of naturopathic care in people 55 and older enrolled in health maintenance organizations such as Group Health Cooperative or Kaiser Permanente. The NMRA Workgroup hypothesized that the rates of clinical depression, cardiovascular disease, cancer, and neurodegenerative diseases will be lower in those groups of elderly patients who receive whole person, individualized naturopathic care as their primary health care. There is activity among Workgroup members to work on identifying a collaborating HMO and planning, funding, and implementing a controlled study of health and disease outcomes in elderly patients who are given the choice to receive naturopathic care within their HMO. The elderly population is also a potential group in whom to evaluate preventive intervention studies on patients at high risk for cardiovascular disease, adult onset diabetes, and specific adenocarcinomas. The infrastructure, personnel, and clinical site for such a large study have not yet been firmly identified. The NMRA Gerontology Track committee, chaired in the first year by Leanna Standish, ND, PhD, L. Acup, has identified as high priority an observational HMO cohort study of outcomes associated with naturopathic medical care. An early step is an R21 application on naturopathic intervention for Parkinson's disease. The NMRA Gerontology Track team will oversee design decisions, proposal planning, and grant submission for this multidisciplinary, intermural collaborative study of the impact of naturopathic medical care on the elderly. This team consists of naturopathic physicians already engaged in naturopathic research (Drs. Shinto and Zwickey at NCM and OHSU in Portland OR; Drs. Weber, Mischley, and Standish at Bastyr in Seattle).

It has also been hypothesized that naturopathic medicine has an important role to play in palliative and end-of-life care. For example, many NDs provide adjunctive care to end stage cancer and AIDS patients. Research is already ongoing that evaluates the effectiveness of meditation and massage (two naturopathic modalities) in improving quality of life and death in stage IV cancer patients and stage C3 AIDS patients.

The NMRA Workgroup identified neurodegenerative disorders as a special health care need and challenge in the elderly. The development and evaluation of naturopathic medical protocols for the prevention and treatment of neurodegenerative functional decline meets the NMRA criteria for prioritizing research areas. The burden of suffering is high for dementia (including both Alzheimer's and ischemic dementias) and Parkinson's disease. Both conditions are in high prevalence and case numbers are rising as the populations in industrialized nations increase. Naturopathic physicians utilize nutritional and botanical medicines to help treat and prevent neural degeneration (Jones et al., 2004). Some neuroscience expertise and infrastructure already exists at the naturopathic medical colleges and in naturopathic research clinics for the evaluation of naturopathic therapies for treating dementia (Lynne Shinto, ND; R21AG023805-01) and Parkinson's disease (Laurie Mischley, ND, is evaluating nebulized glutathione and coenzyme Q10 in the treatment of patients with Parkinson's disease). Two of the NMRA Workgroup have academic credentials and research experience in the neurosciences (Standish and Weber).

The goals of this inter-institutional track are:

1. Submit an R21 grant application to study naturopathic medical treatment for Parkinson's disease.
2. Submit R21 grant to collect preliminary data on feasibility of and outcomes associated with introduction of whole person naturopathic care for people 55 and older.
3. Using a Delphi Panel approach generate an expert-driven WPR diagnostic and treatment algorithm, including a manual and training to guide clinicians to provide individualized early intervention in order to prevent cardiovascular disease, cancer, and neurodegeneration.
4. Submit a developmental center grant application to the NIH that coordinates CAM neuroscience and neurogerontology research at the participating naturopathic and collaborating conventional researchers and their institutions.

Progress to date:

National College of Naturopathic Medicine, Portland OR

- Observational cohort study in the elderly in an HMO setting (in planning) (lead is Dr. Calabrese)
- "Fish oil and alpha lipoic acid in mild Alzheimer's disease" Lynne Shinto, ND, (National Institutes of Aging R21AG023805-01)

Bastyr University, Kenmore WA

- R01 CA10620: CAM Comfort Care in the end of life: an RCT of meditation, massage and standard of care (University of Washington/Bastyr University) collaboration currently in first year.
- Laurie K. Mischley ND at the University Health Clinic and Research Center in Seattle submitted a research grant to study antioxidants in Parkinson's disease.
- The first NMRA Neurogerontology Track team met by conference phone on October 27, 2004.

Southern Cross University and ACCMER, Australia:

- Effects of essential oils on dementia (lead Dr. Myers)
- Laboratory exploration of the effects of herbal medicine in inflammation and immune function (lead Dr. Myers)

4. Whole Practice and Methods Track

Co-Chairs: Carlo Calabrese, ND, MPH and Heather Zwickey, PhD National College of Naturopathic Medicine

This track will provide guidance and support to the NMRA on methodological issues and approaches needed to implement the NMRA, including whole-practice research methods. Opportunities for training and skills development will be pursued in order to improve infrastructure. One activity within this track will be sponsorship of an NMRA whole-practice research conference. NMRA's conventional scientists will be invited to join NMRA's ND researchers at this conference. Meetings to strengthen and coordinate inter-institutional collaboration to implement the NMRA will be held at this conference.

Naturopathic medicine is characterized by a "systems" approach to patient diagnosis and subsequent treatment regimens. Since this form of medicine does not lend itself easily to the simple double-blind, placebo-controlled clinical trial, new methods are in development and must be validated for the study of whole practice naturopathic medicine. Evaluation of naturopathic medicine in whole practice models is most likely to reveal its potential health benefit. The problems inherent in evaluations of whole practices and the need for their solution have been acknowledged by NCCAM staff (Nahin and Straus, 2001) and other researchers (Mason et al., 2002, Shinto et al., 2002). Several approaches to operationalizing naturopathic interventions for research are in use or development. The simplest would be a fixed combination of remedies, though this approach would abandon individualization. A second model increasingly used as alternative medicines have been explored in recent years is "pragmatic" trials, which essentially use the practitioner of some specified level of qualifications as the unit of intervention. A somewhat more ambitious approach to whole practice would be a menu of choices applied to different presentations in syndrome or disease under study. In a further step in sophistication, a well-articulated algorithm may drive the intervention. Such algorithms should be derived through expert practitioner panels. "Best practice" models of naturopathic medicine are theoretically most likely to show replicable benefit and thus are an ideal for clinical study. The algorithmic approach best captures naturopathic practice. Naturopathic medicine is a process, an algorithmic process.

Carlo Calabrese and Heather Zwickey, Senior Investigators at the Helfgott Research Institute at the National College of Naturopathic Medicine will co-chair the NMRA Whole Practice Methods track. They will form a work center linking the naturopathic medical colleges in North America and Australia for the development and communication of research methods appropriate for the clinical study of the whole practice and integrated practice of naturopathic medicine.

The near-term goals of this inter-institutional track are:

1. Establish a Whole Practice Research Conference in collaboration with the Whole Systems Research Conference.
2. Conduct workshops and maintain communications for interested investigators at the naturopathic medical colleges participating in developing the NMRA.
3. Initiate and collaborate in the design of pilot whole practice research studies in the two foci of the NMRA: type 2 diabetes and the health of the elderly. Funding will be sought through the NIH U19 or other grant mechanism.

Progress to date:

The current discussions on the Naturopathic Medical Research Agenda (NMRA) have revealed the importance naturopathic physicians place on studying the interactive procedures and agents in naturopathic medicine yielding an emphasis on whole practice research methods. Several descriptive observational studies of modern naturopathic whole practice have been done (Boon et al., 2003, Calabrese et al., 1992, Cherkin et al., 2002, Cramer et al., 2003, Jaeger et al., 2002, and Louise, 2000) though all are limited. The dataset of one of these (Jaeger) has not been analyzed. None, with the exception of the Cramer menopause records review, was in either of the two focus areas of the NMRA. Two intervention studies are now coming to a close wherein naturopathic practice has been modeled in different ways and applied to multiple sclerosis (L. Shinto, PI) and temporomandibular joint disorder (C. Ritenbaugh, PI). Both of these are being done in Portland, OR and both were funded as part of NIH P50 grants in CAM, one at Oregon Health & Sciences

University and the other at Kaiser Permanente Center for Health Research. The design and replicability of 'best practice' protocols are just beginning to be studied in naturopathic medicine.

The Whole Practice Methods Research Track emerging from the NMRA will take the lead on fostering collaborative development of two pilot studies: 1) the evaluation of expert-guided 'best practice' of naturopathic medicine in type 2 diabetes in a randomized controlled trial, and 2) a prospective controlled cohort study of naturopathic care for the elderly. Work on the trial in diabetes has begun with initiation of literature reviews, the formation of a Delphi panel by K. Kail, and therapeutic component studies currently ongoing at Southwest College and National College and being planned at Bastyr University. Recruiting networks for early type 2 diabetics are established in Portland. Discussions about a setting and the conditions for the interventional cohort study in geriatrics in a large HMO are also underway with candidate agencies. Applications for funding of these two pilots will be made to NIH within one year, a step towards larger studies (initiated within five years) with sufficient power to provide the evaluations outlined in the NMRA.

Goals and Activities of the NMRA Core Team

The NMRA Core Team's overarching goal is the execution of the Naturopathic Medical Research Agenda on four tracks through specific research, publications, and methods and infrastructure development. This goal will be accomplished through by implementing the following activities:

- **Perform Research**
 - **Submit** grant proposals to implement NMRA
 - **Implement** sequenced five-year NMRA research tracks on populations and diabetes
 - **Engage** ND senior clinicians in research implementing NMRA
 - **Sponsor** an NMRA whole-practice research conference
 - **Strengthen** existing research collaborations between conventional medical, nursing, and public health schools and their local ND colleges.
 - **Operationalize** key concepts of naturopathic medicine in preparation for the development of research designs
 - **Collect** preliminary data
- **Organizing and Strengthening the NMRA (research network)**
 - **Coordinate** NMRA working meetings
 - **Identify** members of NMRA Network, including the NMRA Workgroup, ND faculty, clinician researchers, and conventional public health and medical researchers.
 - **Establish** the NMRA Workgroup as an on going Scientific Advisory Group for the NMRA.
 - **Create** Web-based research network (NMRA Network) to foster research on NMRA priorities
 - **Provide updates** on NMRA map, progress and research opportunities
- **Mobilize** implementation of NMRA in ND colleges and profession
 - NMRA ND College meetings
 - AANP research track
 - *International Journal of Naturopathic Medicine*: Special Topics Series in Publications Track
- **Provide** core infrastructure necessary to implement NMRA priorities

NMRA Deliverables 2005-2010

The implementation and execution of the NMRA will produce the following deliverables over the next five years. Research papers will be published on the results of funded studies. Additional results and deliverables will be shared through the NMRA Web-based network.

- R21 diabetes clinical trial
- U19 ND college diabetes collaboration
- R21 and U19 in gerontology

- Research agenda developed by NMRA Task Force for NMRA pediatrics research
- NCCAM postdoctoral fellowship training
- STEPS pilot study (observational data): establish health services research demonstration project
- Naturopathic medicine concepts operationally defined and published
- Whole Practice Research and Methods conference
- Twelve papers on special topics published in *IJNM*
- Functional widespread research network

Collaborative partnerships with conventional medical researchers, public health researchers and researchers in other disciplines will be actively pursued and strengthened where they currently exist. The presidents of the naturopathic medical colleges have committed to supporting this Agenda. Supporting letters are included in Appendix H. More formalized consortia are expected to arise around the specified research directions.

Both recently graduated naturopathic physicians and senior ND clinicians are in need of research mentoring. An area where support is crucial is in the development of another wave of naturopathic scientists beyond the current junior ND investigators receiving research training through NCCAM-funded postdoctoral training (T32 and F32) and career development programs (e.g., Drs. Greenlee, Herman, McCarty, Shaw, Shinto, and Weber). An NCCAM-funded mentorship program to develop research capacity among senior naturopathic physicians would help to achieve this goal.

*We anticipate
that NCCAM...will
continue to support...
naturopathic medical
research...*

Conclusion

The NMRA Workgroup acknowledges the crucial role that NCCAM has played in supporting research in naturopathic institutions to date. We anticipate that NCCAM, in line with its legislative mandate, will continue to support the development of research in complementary and alternative medicine and especially naturopathic medical research and infrastructure through funding the research activities and collaborations among institutions toward fulfillment of the Agenda. The NMRA Workgroup recommends particularly that NCCAM issue requests for applications (RFAs) over the next few years for research in naturopathic medicine in the areas identified as NMRA priorities, whole-practice research in diabetic populations and in the elderly.

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APPENDICES

THE NATUROPATHIC MEDICAL RESEARCH AGENDA: THE FUTURE AND FOUNDATION OF NATUROPATHIC MEDICAL SCIENCE

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APPENDIX A: Affiliations of Key NMRA Participants

NMRA Research Associate Workgroup Members

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Annette Fitzpatrick, PhD	Research Assistant Professor	University of Washington
Clark Johnson, PhD	Research Assistant Professor	University of Washington
Wayne Jonas, MD	Director	Samueli Institute of Information Biology
Konrad Kail, PA, ND	Director of Research	Southwest College of Naturopathic Medicine
Linda Kim, ND	Associate Medical Director	Southwest College of Naturopathic Medicine
David Kroll, PhD	Senior Research Pharmacologist	Research Triangle Institute Duke University
William Lafferty, MD	Associate Professor	University of Washington
Richard Lyons, MD, MPH	Clinical Associate Professor (Retired)	University of Washington
Peter Martin, ND, DC	Former Dean	University of Bridgeport, College of Naturopathic Medicine
Mark Mattie, MD, PhD	Director of Research	University of Bridgeport, College of Naturopathic Medicine
Diana Miglioretti, PhD	Assistant Scientific Investigator	Group Health Center for Health Studies
Edward Mills, DPh	Director of Research	Canadian College of Naturopathic Medicine
Stephen Myers, PhD, BMed, ND	Professor & Director	Southern Cross University/ACCMER
Patrick O'Carroll, MD, MPH, FACPM	Regional Health Administrator	US, DHHS, USPHS-Region X
June Reidlinger, R.Ph, PharmD	Former Associate Professor/Current ND Student	Massachusetts College of Pharmacy and Health Sciences/Southwest College of Naturopathic Medicine
Cheryl Ritenbaugh, PhD, MPH	Senior Investigator	Kaiser Center for Health Research
Pamela Snider, ND	Co-Investigator	Bastyr University
Leanna Standish, ND, PhD, LAc	Professor/Principal Investigator	Bastyr University
Janet Stecher	Clinic Manager Emeritus	University Health Clinic

Alan Trachtenberg MD, MPH	Director of Research	Indian Health Services, Department of Health and Human Services
Michael Traub, ND, DHANP, CCH	Chair, Scientific Affairs	American Association of Naturopathic Physicians
Henry Ziegler, MD, MPH	Staff Physician	Madigan Army Hospital
Heather Zwickey, PhD	Director of Research	National College of Naturopathic Medicine

NMRA Research Associate Workgroup Members

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Wendy Weber, ND, MPH	Assistant Research Professor	Bastyr University

APPENDIX B: History, Theory, and Practice of Naturopathic Medicine*

Natural medicine finds itself in the midst of an unprecedented explosion into mainstream health care today, in part because conventional standard treatments cannot, by themselves, solve the problems of chronic disease. Consumers are spending more annually out of pocket for alternative medicine than for conventional care. Naturopathic medicine is a valuable model for integrative primary care, and natural medicine is undergoing a powerful resurgence. With its unique integration of vitalistic, scientific, academic and clinical training in medicine, the naturopathic medical model is a potent contributing factor to this health care revolution.

Naturopathic medicine is a distinct system of health-oriented medicine which, in contrast to the currently dominant disease-treatment system, stresses promotion of health, prevention of disease, patient education, and self-responsibility. But naturopathic medicine symbolizes more than simply a health care system; it is a way of life. Unlike most other health care systems, naturopathic medicine is not identified with any particular therapy, but rather is a way of thinking about life, health and disease. It is defined not by the therapies it uses, but by the philosophical principles that guide the practitioner.

History of Naturopathic Medicine[†]

Although naturopathic medicine traces its philosophical roots to many traditional world medicines, its body of knowledge derives from a rich heritage of writings and practices of Western and non-Western nature doctors since Hippocrates (circa 400 BC). Modern naturopathic medicine grew out of healing systems of the 18th and 19th centuries. The term, “naturopathy,” was coined in 1895, by Dr. John Scheel of New York City, to describe his method of health care. But earlier forerunners of these concepts already existed in the history of natural healing, both in America and in Austro-Germanic Europe. Naturopathy became a formal profession after its creation by Benedict Lust in 1896. Over the centuries, natural medicine and biochemistry-based medicine have alternately diverged and converged, shaping each other, often in reaction. During the past century, the profession progressed through several fairly distinct phases:

Latter part of the 19th century: The Founding By Benedict Lust

Originating in the Germanic hydrotherapy and nature cure traditions, naturopathy, or “nature cure,” was defined by Lust as both a way of life and a concept of healing employing various natural means of treating human infirmities and disease states. The earliest therapies associated with the term involved a combination of American hygienics and Austro-Germanic nature cure and hydrotherapy.

1900-1917: The Formative Years

The American dietetic, hygienic, physical culture, spinal manipulation, mental and emotional healing, Thompsonian/eclectic, and homeopathic systems converged into a single naturopathic medical discipline.

1918-1937: The Halcyon Days

During a period of great public interest and support, the philosophical basis and scope of therapies diversified to encompass botanical, homeopathic and environmental medicine.

1938-1970: Suppression and Decline

Growing political and social dominance of the American Medical Association, lack of internal political unity, and lack of unifying standards combined with the American love affair with tech-

* This Appendix is adapted, in part, from Pizzorno JE, Snider P. *The Fundamentals of Complementary and Alternative Medicine*, Churchill Livingstone 2001 (Chapter 11). Used by permission.

nology, and the emergence of “miracle” drugs and effective modern surgical techniques perfected in two world wars, resulted in legal and economic suppression.

1971-present: Naturopathic medicine reemerges

The American public regains interest in health promotion, prevention of disease, and concern for the environment. The emergence of modern, accredited, physician-level training reestablished public interest in naturopathic medicine, resulting in rapid resurgence. Projections from a study in the mid-1990s predicted a continuing increase in naturopathic physicians: “The per capita supply of alternative medicine clinicians (chiropractors, naturopaths and practitioners of Oriental medicine) will grow by 88% between 1994 and 2010, while allopathic physician supply will grow by 16%... The total number of naturopathic medicine graduates will double over the next five years. The total number of naturopathic physicians will triple” (Cooper and Stoffet, 1996).

Schools of Thought that Formed the Philosophical Basis of Naturo-pathic Medicine

Due to its eclectic nature, the history of naturopathic medicine is complex. A wide range of diverse schools of thought contributed to the foundation and philosophical basis of naturopathic medicine. These distinct schools of thought are listed below. The distinctions are somewhat artificial as those that founded and practiced these arts (especially the Americans) were often trained in, influenced by, and practiced, several therapeutic disciplines or modalities. However, it was Benedict Lust who first began to weave the many threads together into a unified professional practice, making naturopathic medicine the first Western system of full scope integrative natural medicine based on the *Vis Medicatrix Naturae* (the healing power of nature). Nutrition and botanical medicine were addressed within a number of these approaches. The formative schools of Western thought in natural healing and some of their leading adherents were:

- Hydrotherapy (Germanic hydrotherapy movement, Floyer, Priessnitz, Kneipp, Kellogg)
- Nature Cure (Rickli, Kuhne, Lahman, Bilz, Lindlahr)
- The Hygienic System (Graham, Alcott, Trall, Hollbrook, Shelton)
- Auto-toxicity (Tilden, Metchnikoff)
- Thomsonianism (Thomson)
- The Eclectic School of Medicine (Beach, King, Felter, Lloyd)
- Homeopathic Medicine (Hahnemann, Lippe, Hering, Kent)
- The manipulative disciplines and therapies: Osteopathy and Chiropractic (Still, Palmer,)
- Christian Science (Baker-Eddy) and the role of belief and spirituality in healing (Lust, Lindlahr, Weltmer)
- Physical Culture (McFadden)

While the therapies differ, the philosophical thread of promoting health and supporting the body’s own healing processes runs through them all. These threads are derived from centuries of medical scholarship, both Western and non-Western, concerning the self-healing process. Hippocrates’ contribution to this central tenet of naturopathic philosophy and natural medicine, is seminal. Hippocrates and centuries of nature doctors’ writings remain rich repositories of empirical clinical observations (Neuberger, 1932).

Prehistoric people believed that disease was caused by magic or supernatural forces such as devils or angry gods. Hippocrates, breaking with this superstitious belief, became the first naturalistic doctor in recorded history. Hippocrates regarded the body as a whole and instructed his students to only prescribe beneficial treatments and to refrain from causing harm or hurt. Hippocratic practitioners assumed that everything in nature had a rational basis; therefore, the physician’s role was to understand and follow the laws of the intelligible universe. They viewed disease as an effect and looked for its cause in natural phenomena: air, water, food, etc. They first used the term *vis medicatrix naturae*, the healing power of nature, to denote the body’s ability and drive to heal itself. One of the central tenets of naturopathic medicine is that “there is an order to the process of healing which requires certain things to be done before other things to maximize the effectiveness of the therapeutics” (Zeff, 1998). The “therapeutic order” is a cornerstone of natu-

ropathic medicine. The step order employed by Tibetan medicine is also an example of this tenet represented in Asian traditional world medicines.

Influence on the 19th and 20th Century Public Health Movement

Most of our current and accepted public hygiene practices were brought into societal use by the early hygienic reformers. Prior to their efforts, neglect of these basic physiological safety measures was rampant. The Hygienists had a great influence on decreasing morbidity and mortality and increasing lifespan, as well as influencing the adoption of public sanitation. Orthodox medicine is commonly credited with these advances (Shelton, 1968). Today, professional natural hygienists are participating in scientific research concerning supervised clinical fasting, hygiene practices and their effects on chronic disease. Naturopathic physicians continue to include natural hygiene, including fasting, in clinical procedure. Naturopathic medicine employs the precepts of natural hygiene in reestablishing the basis for health, the first step in the “therapeutic order.”

Recent Influences

“It is now well established that nutritional factors are of major importance in the pathogenesis of both atherosclerosis and cancer, the two leading causes of death in Western countries, and studies validating their importance in the pathogenesis of many other diseases continue to be published. . . . A tremendous amount of scientific support for the principles of naturopathic medicine has been conducted at mainstream research centers. In fact, allopathy is increasingly turning to the use of naturopathic methods in the search for effective prescriptions for today’s intractable and expensive diseases” (Werbach, 1996).

The combined effects of several factors resulted in the rejuvenation of naturopathic medicine. These influences include counter-culture ideologies of the late 1960s, the public’s growing awareness of the importance of nutrition, lifestyle issues, and the environment, and America’s disenchantment with organized institutional medicine. At this time, a new wave of students was attracted to the philosophical precepts of the profession. They brought with them an appreciation for the appropriate use of science and expectations of quality education.

John Bastyr, DC, ND, (1912-1995), through his firm, efficient, and professional leadership, inspired the development of science-based training in natural medicine. Dr. Bastyr, whose vision was one of “naturopathy’s empirical successes documented and proven by scientific methods,” was the prototype of the modern naturopathic doctor, who culls the latest findings from the scientific literature, applies them in ways consistent with naturopathic principles, and verifies the results with appropriate studies. Bastyr also saw “a tremendous expansion in both allopathic and naturopathic medical knowledge, and he played a major role in making sure the best of both were integrated into naturopathic medical education” (Kirchfield and Boyle, 1994).

While naturopaths were astute clinical observers, the scientific tools of the time were inadequate to assess the validity of their concepts. As a group they seemed to have little inclination to the application of laboratory research, especially as “science” was the bludgeon utilized to suppress the profession in the middle years of the 20th century. This has now changed. In the past few decades, many studies have provided scientific documentation of many precepts of naturopathic medicine, and the new breed of scientifically trained naturopaths is utilizing this research to continue development of the profession, and is seeking careers in naturopathic medical research.

The most important areas of research that have influenced the development of the modern profession are therapeutic nutrition, botanical medicine, environmental medicine and clinical ecology, public health and lifestyle research, and spirituality in health and medicine. The continuing development of laboratory methodologies for the objective assessment of nutritional status, metabolic dysfunction, digestive function, bowel flora, endogenous and exogenous toxic load, and liver detoxification function have also been significant influences. Useful clinical tools for accurate assessment of patient health status and effective application of naturopathic principles have emerged from research in these fields.

Naturopathic Medical Practice Today

Today's naturopathic physicians are licensed primary care providers of integrative natural medicine and are recognized for their clinical expertise and effectiveness in preventive medicine. Naturopathic doctors are trained as general practice family physicians, regardless of elective postdoctoral training or clinical emphasis. This is intentional and consistent with naturopathic principles of practice. Naturopathic doctors are trained to assess causes and develop treatment plans from a systems perspective and with systems skills, based on naturopathic principles and, specifically, on the principle: Treat the whole person.

“Naturopathy, in fact, is typically *meta-systematic*... the organism [is] always seen in the context of its physical and social environment.... Beyond this, naturopathic medicine, ultimately might even be considered *cross-paradigmatic* (Commons et al., 1984), touching inevitably on the economics, politics, history, and sociology of the various healing alternatives (Walters, 1993), ultimately penetrating to the contrasting philosophies underlying naturopathy and allopathy. Naturopathic medicine results from a guiding philosophy at odds with the dominant mechanistic philosophy undergirding Western industrialized society. Allopathy, in contrast, is more derived from the premises of industrialization. In Eisler's terms (1987), naturopathic medicine embraces a *partnership* model of relationship, while allopathy falls within the *dominator* model. As indicated below, this partnership/dominator contrast extends not only to the treatment process, but to the healer/patient relationship itself” (Funk, 1995).

Naturopathic doctors may also practice as specialists, after postdoctoral training in botanical medicine, homeopathy, nutritional medicine, physical medicine, acupuncture, Ayurvedic medicine, Oriental and Chinese herbal medicine, counseling and health psychology, spirituality and healing, applied behavioral sciences, and midwifery. Some naturopathic physicians choose to focus their practice on population groups such as children, the elderly, women, or in clinical areas such as cardiology, gastroenterology, immunology, oncology, infectious diseases, or environmental medicine. In addition to these specialties, at one end of a spectrum are practitioners who adhere most strictly to the nature cure traditions which since the days of Hippocrates have involved the use of water, plants, light, air, touch, and nutrition for healing. Thus, NDs focus clinically only on diet, detoxification, lifestyle modification, hydrotherapy and other self-healing modalities. At the other end are found those whose practices appear to be similar to the average conventional medical practice with the primary apparent difference being the use of pharmaceutical grade botanical medicines and clinical nutrition instead of synthetic drugs. However, fundamental to all styles of naturopathic practice is a common philosophy: the unifying theories in the *Vis Medicatrix Naturae* (the healing power of nature) and the Hierarchy of Therapeutics or the Therapeutic Order described below. The Therapeutic Order is derived from all of the principles and guides the naturopathic physician's choice of therapeutic interventions.

Philosophy and Definition of Health

“What physicians think medicine is profoundly shapes what they do, how they behave in doing it, and the reasons they use to justify that behavior... Whether conscious of it or not, every physician has an answer to what he thinks medicine is, with real consequences for all whom he attends... The outcome is hardly trivial... It dictates, after all, how we approach patients, [and] how we make clinical judgments” (Pellegrino, 1979).

Medical philosophy comprises the underlying premises on which a health care system is based. Once a system is acknowledged, it is subject to debate. In naturopathic medicine, the philosophical debate is a valuable, ongoing process which helps the understanding that disease evolves in an orderly and truth-revealing fashion” (Bradley 1985).

While the context and life force of naturopathic medicine is its vitalistic core, both vitalistic and mechanistic approaches are applicable to modern naturopathic medicine. Matter, mind, energy and spirit are all part of nature, and therefore are part of a medicine that observes, respects and

works with nature. The vitalism of naturopathic medicine is essentially a non-dualist, idealist philosophical position that is gaining new respect in physics. For the ND, everything is interconnected; mind, body, and are all manifestations of the same thing. Everything is alive and conscious. As one naturopathic physician put it, “For NDs, nothing is inert.” Applied in a vitalistic context, mechanistic and reductionistic interventions provide useful techniques and tools to naturopathic physicians. The unifying theory of naturopathic medicine provides clinical guidance for integrating both approaches. Vitalism has re-emerged in today’s terms in the body/mind/spirit dialogue, and in the discussion of complexity theory and science.

For the naturopathic physician, health is much more than the absence of disease or symptoms. For Samuel Hahnemann, the 19th century German homeopath, health occurred when the “animating force rules with unbounded sway” (*Organon*, paragraph 9, page 95). A guiding definition of health was provided by Hahnemann that continues to be taught to contemporary naturopathic medical students.

“In the healthy condition of man the spiritual vital force, the dynamism that animates the material body, rules with unbounded sway and retains all parts of the organism in admirable, harmonious, vital operation as regards both sensations and functions so that our indwelling reason-gifted mind can freely employ this living healthy instrument for the higher purposes of our existence.”
—Samuel Hahnemann, *The Organon of Medicine*, 1810

For naturopathic physicians this is the mission of medicine. This is what we mean by health. Naturopathic medicine has aligned itself with some of the loftiest goals of the human potential movement that began in the 20th century.

Complexity Science

Naturopathic medicine uses combination therapies for the treatment of most disorders and naturopathic physicians utilize complex strategies to develop comprehensive, whole person and individualized therapies. For this reason any naturopathic medical research agenda will require complexity science thinking. A series of articles in the *British Medical Journal* from September 15, 2001 to October 6, 2001 addresses complexity science and health care. In the first article of the series, “Complexity Science: The challenge of complexity in health care,” the authors state that “the new science of complex adaptive systems may provide new metaphors that can help us to deal with these issues better” (Plesk and Greenhalgh, 2001). They conclude that their introductory article has “acknowledged the complex nature of health care in the 21st century, and emphasized the limitations of reductionist thinking and the ‘clockwork universe’ metaphor for solving clinical and organizational problems. To cope with escalating complexity in health care we must abandon linear models, accept unpredictability, respect (and utilize) autonomy and creativity, and respond flexibly to emerging patterns and opportunities” (Plesk and Greenhalgh, 2001). (See also Wilson and Holt, 2001; Plesk and Wilson, 2001; Fraser and Greenhalgh, 2001; Wilson, Holt, and Greenhalgh, 2001.)

Wilson and Holt, in their final article of the series offer the following: “Biological and social systems are inherently complex, so it is hardly surprising that few if any human illnesses can be said to have a single ‘cause’ or ‘cure’.” Examples of clinical conditions for which this is so include the control of blood glucose levels in diabetes, the management of diagnostic uncertainty, and health promotions. “A complex adaptive system is a collection of individual agents with freedom to act in ways that are not always totally predictable, and whose actions are interconnected so that the action of one part changes the context for other agents, in relation to human health and illness there are several levels of such systems” (Wilson and Holt 2001).

“For all these reasons neither illness nor human behavior ... can safely be ‘modeled’ in a simple cause and effect system. The human body is not a machine and its malfunctioning cannot be adequately analyzed by breaking the system down into its component parts and considering each in isolation. Despite this

fact, cause and effect modeling underpins much of the problem solving we attempt in clinical encounters; this perhaps explains why we so often fail” (Wilson and Holt 2001).

Wilson and Holt also suggest “human beings can be viewed as composed of and operating within multiple interacting and self adjusting systems (including biochemical, cellular, physiological, psychological, and social systems.” They conclude the following: “Complexity science suggests an alternative model that illness (and health) result from complex, dynamic, and unique interactions between different components of the overall system. Effective clinical decision-making requires a holistic approach that accepts unpredictability and builds on subtle emergent forces within the overall system.... Complexity theory saves both clinician and patient from a futile quest for certainty and upholds the use of intuition and personal experience when general scientific rules are to be applied to the individual in context.” (Wilson and Holt 2001) This emerging discussion shares components of naturopathic theory, and suggests important directions for research on the nature of healing; and health and disease.

Much of modern biomedicine and related research has been based on the implicit application of the doctrine of mechanism (defined in Webster’s dictionary as the “theory that everything in the universe is produced by matter in motion; materialism”), which results in a reductionistic, pathology-based, disease-care model focused on the search for single agent, “magic bullet” correctives. Family medicine, nursing and public health principles and practice are notable biomedical departures from this approach and are consistent with a whole systems approach to health and patient care.

Twenty-first century naturopathic medicine, because of its whole systems, multi-level approach, must utilize complexity science in executing its scientific agenda.

Naturopathic Principles of Practice

Six powerful concepts provide the foundation for defining naturopathic medicine and guide a unique group of professionals practicing a form of medicine that fundamentally changes the way we think of health care. In 1989 the American Association of Naturopathic Physicians unanimously approved the definition of Naturopathic Medicine, updating and reconfirming in modern terms its core principles in a professional consensus. “The definition and principles of practice provide a steady point of reference for this debate, for our evolving understanding of health and disease, and for all of our decision making processes as a profession” (Snider and Zeff, 1988).

1. The healing power of nature (*Vis medicatrix naturae*)

Belief in the ability of the body to heal itself if given the proper opportunity – the *Vis medicatrix naturae* (the healing power of nature), and the importance of living within the laws of nature are the foundations of naturopathic medicine. Although the term, “naturopathy” was coined in the late 19th century, its philosophical roots can be traced back to Hippocrates, and derive from a common wellspring with traditional world medicines: belief in the healing power of nature. Medicine has long grappled with the question of the existence of the *Vis medicatrix naturae* (VMN). As Neuberger stated, “the problem of the healing power of nature is a great, perhaps the greatest of all problems which has occupied the physician for thousands of years. Indeed, the aims and limits of therapeutics are determined by its solution” (Kirchfield and Boyle, 1994). The fundamental reality of the VMN was a basic tenet of the Hippocratic School of medicine, and “every important medical author since has had to take a position for or against it” (Kirchfield and Boyle, 1994).

Naturopathic medicine is “vitalistic” in its approach, i.e., life is viewed as more than just the sum of biochemical processes, and the body is believed to have an innate intelligence or process (the VMN), which is always striving towards health. This approach does not exclude mechanism; mechanistic strategies are employed in a vitalistic context. Vitalism maintains that the symptoms accompanying disease are not typically caused by the morbidic agent (e.g., bacteria); rather, they

are the result of the organism's intrinsic response or reaction to the agent, and the organism's attempt to defend and heal itself. Symptoms are part of a constructive phenomenon that is the best "choice" the organism can make, given the circumstances. In this construct, the role of the physician is to understand and aid the body's efforts, not to take over or manipulate the functions of the body, unless the self-healing process has become weak or insufficient.

Modern interpretations of the concept of the "*vis medicatrix naturae*" have helped maintain its influence in the theory, practice and language of 21st century naturopathic physicians. In 1987, the American Association of Naturopathic Physicians operationalized and reformulated core principles, including the *vis* (AANP Position Paper on Definition of Naturopathic Medicine, 1989). In keeping with modern biological convention the *vis medicatrix naturae* was defined as the "self organizing principle of living organisms." The biology of healing emerges as a new field within the medical sciences, not to replace the biology of pathology, but to complement our complete understanding of the health:disease continuum. In the early 21st century the goal of naturopathic medicine with regard to the *vis* was aptly described as working toward the provision of the "optimal healing environment." Both external and internal environments shape the moment-to-moment state of all living organisms. Naturopathic physicians and biologists alike are currently discussing how to define the internal and external environment. Does the organism end at the skin? From a biological perspective the question arises as to what is self vs. non-self, what is internal and what is external? Is the cell membrane the dividing line between the internal and external world?

2. First do no harm (*Primum non nocere*)

Naturopathic physicians prefer non-invasive treatments that minimize the risks of harmful side effects. They are trained to use the least force and lowest risk preventive, diagnostic, therapeutic and co-management strategies. They are trained to know which patients they can safely treat and which ones they need to refer to other health care practitioners. Naturopathic physicians follow three precepts to avoid harming the patient:

- Naturopathic physicians utilize methods and medicinal substances that minimize the risk of harmful effects, and apply the least possible force or intervention necessary to diagnose illness and restore health.
- Whenever possible the suppression of symptoms is avoided, as suppression generally interferes with the healing process.
- Naturopathic physicians respect and work with the *vis medicatrix naturae* in diagnosis, treatment, and counseling, for if this self-healing process is not respected the patient may be harmed.

3. Find the cause (*Tolle causam*)

Every illness has an underlying cause or causes, often in aspects of the lifestyle, diet or habits of the individual. A naturopathic physician is trained to find and remove the underlying cause(s) of disease. The Therapeutic Order (see below) helps the physician remove them in the correct "healing order" for the body. As the new science of psychoneuroimmunology is explicitly demonstrating, the body is a seamless web with a multiplicity of brain-immune-gut-liver connections. Not surprisingly, chronic disease typically involves a number of systems, with the most prominent or acute symptoms being those chronologically last in appearance. As the healing process progresses and these symptoms are alleviated, further symptoms then resurface that must be addressed to restore health.

4. Treat the whole person (*Holism*)

As noted in the preceding principle, health or disease comes from a complex interaction of mental, emotional, spiritual, physical, dietary, genetic, environmental, lifestyle and other factors. Naturopathic physicians treat the whole person, taking all these factors into account. From the naturopathic approach, the body is viewed as a whole. Naturopathic medicine is often called holistic medicine, referencing the term "holism" as coined by philosopher Jan Christian Smuts in 1926, to describe the gestalt of a system as greater than the sum of its parts. A change in one part causes a change in every part; therefore, the study of one part must be integrated into the whole, including the

community and biosphere. Naturopathic medicine asserts that one cannot be completely healthy in an unhealthy environment and is committed to the creation of a world in which humanity may thrive. Emphasis is placed on the physical, emotional, social, and spiritual integration of the whole person, including awareness of the impact of the environment on health.

5. Preventive medicine

The naturopathic approach to health care helps patients avoid disease and prevent minor illness from developing into more serious or chronic degenerative diseases. Patients are taught the principles with which to live a healthful life and, by following these principles, they can prevent major illness. Health is viewed as more than just the absence of disease; it is considered a dynamic state, which enables a person to thrive in, or adapt to, a wide range of environments and stresses. Health and disease are points on a continuum, with death at one end and optimal function at the other. The naturopathic physician believes that a person who goes through life living an unhealthy lifestyle will drift away from optimal function and move relentlessly towards progressively greater dysfunction. Genotype, constitution, maternal influences and environmental factors all influence individual susceptibility to deterioration, and the organs, and physiological systems affected. These and other determinants of health are addressed by the naturopathic physician in both treatment and prevention. (See Table 1.)

Table 1. The Determinants of Health

Determinants	Disturbances	Hygienic & Lifestyle Factors
Genetic make-up (genotype)	Illnesses: pathobiography	Nutrition
Constitution (determines susceptibility)	Medical intervention (or lack of)	Rest
Intrauterine/congenital	Physical & emotional exposures, stresses, and trauma	Exercise
Maternal exposures	Toxic & harmful substances	Psycho-emotional health
Drugs		Spiritual health
Toxins		Community
Viruses		Culture
Psycho-emotional		Socio-economic factors
Maternal & paternal genetic influences		Fresh air
Maternal nutrition		Light
Maternal lifestyle		Exposure to nature
Loving and being loved		Clean water
Meaningful work		Unadulterated food

In our society, although our lifespan at birth has increased, our health span has not. We are living longer but only as disabled individuals (Pizzorno, 1996). Although such deterioration is accepted by our society as the normal expectation of aging, it is not common in animals in the wild, nor among those fortunate peoples who live in an optimal environment, i.e., no pollution, low stress, regular exercise, and abundant natural, nutritious food. In the naturopathic model, death is inevitable; progressive disability is not. This belief underscores a fundamental difference in philosophy and expectation between the conventional and naturopathic models of health and disease. In contrast to the disease-treatment focus of allopathic medicine, the health-promotion focus of naturopathic medicine focuses on the means of maximizing health span.

6. Doctor as teacher (*Docere*)

The original meaning of the word “docere” is teacher. A principal objective of naturopathic medicine is to educate the patient and emphasize self-responsibility for health. Naturopathic physicians also recognize the therapeutic potential of the doctor-patient relationship. The patient is engaged

and respected as an ally and a member of her/his own health care team. Adequate time is spent with patients in order to thoroughly diagnose, treat, and educate them.

Naturopathic Clinical Theory: The Healing Power of Nature and the Therapeutic Order

In facilitating the process of healing, the naturopathic physician seeks to use those therapies that are most efficient and that have the least potential to harm the patient. The concept of harm includes suppression or exhaustion of natural healing processes including inflammation and fever. These precepts, coupled to an understanding of the process of healing, result in a therapeutic hierarchy. This hierarchy (or therapeutic order) is a natural consequence of how the organism heals. Therapeutic modalities are applied in a rational order, determined by the nature of the healing process. The natural order of appropriate therapeutic intervention is:

- Re-establish the basis for health achieved by addressing the determinants of health
- Stimulate the VMN (*Vis medicatrix naturae*): achieved through hydrotherapy, homeopathy, certain botanical approaches, counseling, spiritual, meditative or mind-body practices, physical medicine.
- Tonify and nourish weakened systems: achieved through establishing strong physiological function in digestive, circulatory, endocrine, regulatory, eliminative, and other systems.
- Correct structural integrity: achieved through manipulation, massage, surgery, hormone replacement, exercise.
- Prescribe specific substances and/or modalities for specific conditions and biochemical pathways, e.g., botanicals, nutrients, acupuncture, homeopathy, hydrotherapy, counseling.
- Prescribe pharmaceutical substances to stimulate or inhibit disordered biochemical processes.
- Use radiation, cytotoxic chemotherapy, and surgery to ablate abnormal tissue

The concepts expressed in the Therapeutic Order are derived from Hippocrates' writings and those of medical scholars and nature doctors since Hippocrates concerning the function and activation of the self-healing process. Jared Zeff, ND (National College of Naturopathic Medicine, Portland, OR), has summarized and expressed these concepts as the Hierarchy of Therapeutics in his article, "The Process of Healing: a Unifying Theory of Naturopathic Medicine" (Zeff, 1997). The Therapeutic Order proceeds from least to most force, although all modalities can be found at various steps, depending on their application. The spiritual aspect of the patient's health is considered to begin with Step 1 (Zeff, 1997, Pizzorno and Snider, 2001).

The philosophy represented in the naturopathic therapeutic order does not determine what modalities are good or bad. Rather, it provides a clinical framework for all modalities, used in the order consistent with that of the natural self-healing process. It respects the origins of disease, as well as the applications of care and interventions necessary for health and healing with the least force. The Therapeutic Order schematically directs the naturopathic physician's therapeutic choices in an efficient order based on individual patient needs and priorities for safe and effective care, rather than using a "shotgun" approach. It is this common philosophy and theory that both distinguishes the field of naturopathic medicine and enables it to consider and incorporate new therapies.

Naturopathic medicine's philosophical approach to health promotion and restoration necessitates a broad range of diagnostic and therapeutic skills and accounts for the eclectic interests of the naturopathic profession. Obviously, at times the body needs more than just supportive help. The goal of the naturopathic physician in such situations is to first utilize the least force and lowest risk clinical strategies, i.e., the least invasive intervention which will have the most effective therapeutic outcome or, when necessary, to co-manage or refer to specialists and other health care professionals.

Since the goal of the naturopathic physician is restoration of normal body function rather than the application of a particular therapy, virtually every natural medicine therapy may be utilized. In addition, to fulfill their role as primary care family physicians, naturopathic doctors may, when less invasive options have been exhausted or found inappropriate, also administer therapies such as minor office surgical procedures and prescription drugs and vaccines. In the restoration of health, prescription drugs and surgery are a last resort but are used when necessary.

Diagnosis

Naturopathic case analysis and management can be charted using the conventional SOAP format (Subjective, Objective, Assessment, Plan), documenting the clinical application of philosophy and principles to patient care. For example, while a conventional pathology-based diagnosis is made through the use of physical, laboratory and imaging procedures, it is done in the context of understanding the underlying causes of the pathology and the obstacles to recovery. Naturopathic medical disease nosology is similar to that of western conventional medicine; however, diagnosis of functional, metabolic and structural disorders are more emphasized in naturopathic medicine.

Therapeutic Modalities

Naturopathic medicine is a vitalistic system of health care that uses natural medicines and stronger interventions when needed. Natural medicines and therapies, when properly used, generally have low invasiveness and rarely cause suppression or side effects. This is because, when used properly, they generally support the body's healing mechanisms rather than taking over the body's processes. The naturopathic physician knows when, why, and with which patients more invasive therapies are needed based on the Therapeutic Order and appropriate diagnostic measures. Naturopathic physicians are thoroughly trained in drug, nutrient and herb interactions. They recognize that the use of natural, low force therapies, lifestyle changes, and early functional diagnosis and treatment of nonspecific conditions are forms of primary prevention on a different scale.

Traditional health care disciplines such as traditional Chinese medicine (TCM), Yunani medicine and homeopathic medicine also have philosophies, principles of practice, and clinical theories that shape their approaches to diagnosis, treatment, and case management. A philosophy of medicine is, in essence, the rational investigation of the truth and principles of that medicine. The principles of practice provide general guidelines to the main precepts or fundamental tenets of a system of medicine. Clinical theory provides a system of rules or principles for applying that system to the patient via diagnosis, treatment and management. The specific substances and techniques, as well as when, why, to whom they are applied, and for how long, are different for each system. Modalities (e.g., botanical medicine, physical medicine) are not systems; they are therapeutic approaches used within these systems. One modality may be used by many systems, but often in different ways. Efficacy, safety, and efficiency of diagnostic and treatment approaches vary with the system in use, much as different therapeutic substances have different detectable effects on physiology or bio-chemical pathways.

This is exemplified by data in the TCM Work Force Survey conducted by the Department of Human Services in Victoria, New South Wales, and Queensland, Australia and published in *Towards A Safer Choice*, November 1996. This study assessed adverse events and length of TCM training for practitioners. "The number of adverse events reported was compared to the length of TCM training undertaken by the practitioner. It appears from these findings that shorter periods of training in TCM (less than one year) carry an adverse event rate double that of practitioners who have studied for four years or more..." In answer to the question, "Do you rely more predominantly on a TCM philosophy and theoretical framework for making your diagnosis and guiding your acupuncture or Chinese herbal medicine treatments," ninety percent of primary TCM practitioners answered yes, in contrast to twenty-four percent of non-primary practitioners. Non-primary acupuncture practitioners were typically educated for less than one year and were medical doctors (Bensoussan and Myers, 1996). It is the system used by each of these disciplines, which makes it

a uniquely effective field of medicine, rather than a vague compendium of CAM modalities and therapies. Techniques from many systems are used within naturopathic medicine because of its primary care integrative approach and strong philosophical orientation.

Therapeutic modalities used by naturopathic physicians continue to develop with the progress of knowledge. The following modalities are used today: clinical nutrition, botanical medicine, hydrotherapy, physical medicine (including manipulative therapy and electrotherapy), homeopathic medicine, detoxification and natural hygiene, minor office surgical procedures, spirituality, counseling and health psychology, lifestyle and behavioral modification.

The Therapeutic Approach of Naturopathic Physicians

The therapeutic approach of naturopathic physicians begins with deep respect for nature. We are natural organisms, our genome developed and expressed in the natural world. The patterns and processes inherent in nature are inherent in us. We exist as a part of complex patterns of matter, energy and spirit. Nature doctors have observed the natural processes of these patterns in health and disease and determined that there is an inherent drive toward health, which lives within the patterns and processes of nature. The drive is not perfect. There are times when unguided, unassisted or unstopped the drive goes astray, causing preventable harm or even death: the healing intention becomes pathology. The naturopathic physician is trained to know, respect and work with this drive, know when to wait/do nothing, act preventively, assist, amplify, palliate, intervene, manipulate, control or even suppress using the principle of the least force. In addition to physical and laboratory findings, important consideration is given to the patient's mental, emotional and spiritual attitude, lifestyle, diet, heredity, environment, family and community life. Careful attention to each person's unique individuality and susceptibility to disease is critical to the proper evaluation and treatment of any health problem.

Naturopathic physicians believe that most disease is a result of ignorance and violation of "Natural Living Laws," which can be summarized as:

- consuming natural, unrefined, organically-grown foods;
- ensuring adequate amounts of exercise and rest; living a moderately paced lifestyle;
- having constructive and creative thoughts and emotions;
- avoiding environmental toxins; and
- maintaining proper elimination.

During illness, it is also important to control these areas in order to remove as many unnecessary stresses as possible and to optimize the chance that the organism's healing attempt will be successful. Therefore, fundamental to naturopathic practice is patient education and responsibility, lifestyle modification, preventive medicine and wellness promotion.

The therapeutic approach of the naturopathic doctor is therefore basically two-fold: to help patients heal themselves, and to use the opportunity to guide and educate the patient in developing a healthier lifestyle. Many challenging conditions respond well to naturopathic approaches.

A typical first office visit with a naturopathic physician takes one hour. The goal is to learn as much as possible about the patient using thorough history and review of systems, physical examination, laboratory tests, diagnostic imaging, and other standard diagnostic procedures. The patient's diet, environment, toxic load, exercise, stress, and other aspects of lifestyle are evaluated, and laboratory tests to determine physiological function are utilized. Once a good understanding of the patient's health and disease status is established (making a diagnosis of a disease is only one part of this process), the doctor and patient work together to establish a treatment and health promotion program. Naturopathic physicians work with both acute and chronic conditions in all populations.

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APPENDIX C: Input from the NMRA Workgroup and the Naturopathic Profession on Research Priorities

List of 11 Conclusions from the AANP NMRA Special Topics Sessions held in August 2003

Naturopathic physicians and thought leaders provided input on naturopathic research priorities identified by NMRA Workgroup and College Forums in 19 focus groups held by the NMRA core team on specific topics at the 2003 AANP Convention in Portland Oregon. Naturopathic physician thought leaders presented key trends and their views on research priorities to stimulate discussion. The 11 conclusions below summarize the feedback and were presented to the NMRA Workgroup November 2003.

1. The importance of the “terrain” and host factors in disease was emphasized. Also emphasized were naturopathic concepts of health and healing. Principles and mechanisms must take a priority position in the model. Areas for research include determinants of health, cleansing and detoxification, nature cure, nutrition, systems and complexity, consciousness science, healing biology, principles, vital force, healing order, healing crisis, toxemia. Terms and language should continue to be addressed and investigated in terms of modern scientific advances.
2. Environmental medicine research must take a priority position in the NMRA plan.
3. There was consensus that it is wise to start with STEPS to a Healthier US priorities.
4. Conditions and diseases where naturopathic medicine plays a useful role include mental health, attention deficit disorder, autism, brain aging, acute illness and infectious disease, environmental health and reduction of toxic burden, prenatal and perinatal nutrition, and menopause. A critical area of research is the safety and efficacy of bioidentical therapy for menopausal women.
5. As the NMRA grows, continue to prioritize nationally recognized public health conditions AND naturopathically recognized health priorities such as toxic burden, prenatal prevention, functional and genomic medicine, mental disease. Create intersections in research design.
6. The NMRA should begin its work in four areas simultaneously:
 - Whole person, whole practice RCTs
 - Principles and mechanisms
 - Health services research and demonstration projects
 - Infrastructure building through ND college research consortium and public health partnerships
7. Principles and mechanisms research should include whole person, whole practice RCTs. Research to be conducted within this category also includes:
 - Environmental health and medicine research
 - Research on principles, theory of NM
 - Drug-nutrient-herb interactions
 - Functional systems research
 - Research on the terrain of health and healing
 - Physics of healing research
 - Unique whole person ND care
8. Genomic research and ND care
9. Health services research is critical, should be done early, be multi-site, and STEPS-condition focused. Research to be conducted within this category includes:
 - Cost effectiveness
 - Outcomes
 - Practice guidelines

- Test ND primary care model
 - Refine and expand King County Natural Medicine Clinic model
 - Invest in educational research and curriculum research
 - Diabetes and asthma are high priorities
10. Consortium building and infrastructure development are critically required for the profession to accomplish and implement its research responsibilities. Areas of development identified by the profession for focus are:
 - Establish NMRA network infrastructure through AANMC and federal grants.
 - Train naturopathic medical students and graduates in research.
 - Create programs to cultivate, train, and mentor senior NDs and thought leaders to participate in research studies, share protocols, and perform data collection/evaluation.
 - Establish NMRA Scientific Review Committee.
 11. Pursue partnership with wide range of non-health care scientists. Physicists, mathematicians, environmental researchers should be solicited actively as research partners for the NMRA.

List of 10 Priorities from NMRA College Forums

Faculty, students and research directors gave input on the NMRA priority research areas, and the Core Team NMRA developed the following 10 priorities based reports on the Forum results submitted by the research directors in August 2003.

1. All naturopathic medical colleges should prioritize whole person, whole practice combination multimodality protocols.
2. The NMRA must include RCTs comparing naturopathic treatment protocols with conventional standard of care.
3. The research agenda should focus on both what is unique to naturopathic medicine and will relieve the burden of human suffering.
4. The work of naturopathic doctors in mainstream health care should be studied to measure cost offsets, access, satisfaction, workforce, and utilization.
5. Naturopathic research needs to better inform naturopathic practice (lab tests, guidelines, mechanisms).
6. Understanding how the environment affects health and disease, and what naturopathic physicians can do about it, should be a top priority.
7. Research health and the science of healing, rather than disease and science of pathology.
8. Use the prioritization criteria: align our research priorities with our values.
9. Public and community health should be the leading edge for the NMRA. There needs to be public health pay off.
10. Research should start on populations *already* seeking naturopathic care.

List of Top 12 Prioritized Research Questions from the NMRA Workgroup

The Workgroup Members narrowed 25 questions to 12, through a voting process in the first meeting of the NMRA Workgroup in February 2003.

1. Are unconventional diagnostic testing and methods used by NDs valid and reliable for measuring defined conditions and outcomes?
2. What is the health impact of treating chronic toxicity?
3. How does naturopathic primary pediatric care compare with MD primary care (i.e., from prenatal care to eight years)?
4. How effective is naturopathic medicine at creating, promoting, and maintaining health?

5. Using an RCT method, is a whole-person naturopathic approach for prevention and/or treatment of metabolic syndrome safe and effective?
6. Is whole-practice naturopathic care as effective as allopathic treatment for rheumatoid arthritis, syndrome X, and breast cancer?
7. Are naturopathic treatments more cost-effective than conventional treatment? Across all populations, compared to conventional standards of care, does naturopathic medicine have an impact on mortality, morbidity, quality of life, wellness, and health care costs?
8. What is the effect of ND care in high health care utilizers?
9. How does healing work and what is the nature of the healing process? For example, can Hering's Law of Cure be demonstrated?
10. Is there a measurable mind-body connection that can be verified with physiological and biochemical markers?
11. How does naturopathic practice impact immune function?
12. What is the "work" of naturopathic physicians, i.e., what conditions are treated (percentages), modalities utilized, patient profiles, practitioner profiles, workload, and income.

List of 35 Prioritized Research Questions from the NMRA Workgroup

The Workgroup Members narrowed the original 133 questions to 25 questions through a voting process in the first meeting of the NMRA Workgroup in February 2003.

- Are unconventional diagnostic testing and methods valid and reliable for measuring defined conditions and outcomes?
- What is the impact of treating chronic toxicity?
- How does naturopathic primary care compare with MD primary care (i.e., from prenatal care to eight years)?
- How effective is naturopathic medicine at creating, promoting and maintaining health?
- Design an RCT investigating a whole person naturopathic approach for prevention and/or treatment of metabolic syndrome.
- Is whole practice naturopathic care as effective as allopathic treatment for rheumatoid arthritis, syndrome X, and breast cancer?
- Are naturopathic treatments more cost-effective than conventional treatment?
- Across all populations, compared to conventional standard of care, does naturopathic medicine have an impact on mortality, morbidity, quality of life, wellness and health care costs? Is a naturopathic intervention for disorder X as cost-effective as, or superior to, the corresponding standard of care approach in allopathic medicine? For which conditions do naturopathic treatments offer the greatest advantages over conventional medical treatments and in what ways are the naturopathic treatments superior? How cost effective are the treatments? How do you study this?
- What is the effect of ND care in high health care utilizers?
- How does healing work and what is the nature of the healing process? Do we need to know if healing occurs before you can say how it occurs? Research the process of healing: identify and describe the metabolic, physiological indicators, clinical signs and symptoms, and clinical outcomes, which differentiate between a healing response, a healing reaction, a healing crisis, and suppression of healing.
- Research the eczema/asthma continuum and clinical suppression vs. clinical healing.
- Research the validity, or lack thereof, of naturopathic principles, including assessment of the healing order, and long-range cost-effectiveness of applying in population health.
- Research the healing order's applicability to public and community health.
- Can Hering's Law of Cure be demonstrated? Research Hering's Law: reverse order, top down, inside out, most important to least important systems and organs.
- Is there a measurable mind-body connection that can be verified with physiological and biochemical markers?
- What are the important outcomes in naturopathic medicine and how are they measured?
- How does naturopathic practice impact immune function?

- Determine through surveys the “work” of naturopathic physicians, i.e., what conditions are treated (percentages), modalities utilized, patient profiles, practitioner profiles, work load, income, etc.
- What is the effect of naturopathic medicine on women’s health. What environmental factors are adversely affecting women’s health? What are the benefits vs. risks of bio-identical natural estradiol vs. synthetic estrogens and conjugated equine estrogens? What are the benefits vs. risks of bio-identical progesterone vs. synthetic progestins? What are the benefits vs. risks of alternate delivery of estrogens and progestins? What non-hormonal nutritional and/or botanical therapies address quality of life issues in menopausal women?
- Characterization of botanical medicines and formulas — exploration of the “active ingredient” vs. whole-plant extracts.
- What is/are the mechanism(s) of action and efficacy of bio-energetic treatments?
- How can we develop methodology to study energy medicine and the technology to observe the phenomena (consciousness, etc.)?
- Are there long-term adverse effects of routine childhood vaccinations?
- How can we use the human genome project to aid decisions regarding treatments (gene/nutrient interaction, gene/toxin interaction)?
- Can we develop instruments for evaluation of naturopathic care?
- Is intention effective?
- How does the practitioner affect patient outcome? (Does the naturopathic physician change health behavior?) Study patient-provider relationship, time spent in visit, practitioner intention, patient intention, and so forth.
- What role does naturopathic medicine have in the diagnosis and treatment of health threats from bioterrorism?
- What is the role of naturopathic medicine in the integrative approach to the health care system?
- Determine the reliability and validity of “functional medicine” diagnostic protocols.
- Does increased reimbursement for behavioral change in primary care practice contribute to significant reduction in the rate of complex chronic disease in North America (e.g., diabetes, heart disease, obesity)?
- What are the criteria by which patients measure health?
- What is the impact of homeopathic medicine on the whole person in a select population?
- How can we use naturopathic clinical evaluation to assess risk?
- Develop an RCT of whole practice naturopathic care for osteoarthritis.

List of 133 Original Research Questions from NMRA Workgroup: The “raw data”

At the February 2003 Workgroup Session I, NMRA Workgroup members were each asked to write down five research questions and ideas that each thought were important for the evaluation of naturopathic medicine.

- Evaluation and documentation of clinical outcomes of specific natural therapies that are “known” to work based on naturopathic clinical practice. There should be an emphasis on therapies for conditions for which there are no successful conventional treatments.
- Prospective study comparing a population of newborns (from prenatal care of the mothers) to eight years of age. One group treated naturopathically and the other group treated allopathically (using predefined protocols). Compare incidence of morbidity and level of health and vitality at the end of the study period (including mental/ emotional parameters and learning disabilities, etc.)
- What specific naturopathic medicine practices can be used to keep older adults independent and functional longer?
- In our society, seniors are on way too many medicines. What can naturopathic medicine do to evaluate an older person and reduce the number and cost of medicines he/she is on? Medicare is in crisis!

- Obesity and type 2 diabetes are epidemic in children. What models of naturopathic medicine can be implemented to reduce this epidemic (i.e., educational models, nutritional and exercise interventions)?
- Study the impact of spirituality and meditation interventions for quality of life in the elderly.
- What can naturopathic medicine do to help us think better, longer?
- Can bioenergy-based therapies reduce pharmacotherapy requirements that control chronic disease states?
- Is addictive disease caused by soul sickness? Can addictive disease be overcome or cured by healing a person's soul?
- Is naturopathic medical evaluation and management less costly than conventional medicine assessments? If more costly, are they more cost effective, especially considering the actual time spent with patients?
- How can allied care health care practitioners (RPh, MD, RN, PA, ARNP, etc.) be best educated to appropriately refer patients to ND practitioners?
- Support research that promotes optimal cross-fertilization between health service disciplines.
- Identify basic research with implications that support or extend the naturopathic medical model. Support research to 1) move these results into the mainstream of scientific thought and 2) systematically explore the implications for health promotion.
- Promote development of research designs, methods, measures, and analyses that generate good science with minimal impact on the process being investigated.
- Develop a community-based health intervention based on the naturopathic medical model and test its efficacy.
- Provide a national center of research specialists to mobilize naturopathic physicians' interest in the systematic study of their practice.
- Demonstrate/ examine Hering's Laws of Cure. Research pathophysiological basis, biochemical markers matched to clinical signs and symptoms.
- Formulate a mechanism for characterizing multi-botanical phytomedicines.
- Bioenergetic medicine:
 - a. Demonstrate electromagnetic signature of homeopathic remedies.
 - b. Demonstrate mechanism of effects of acupuncture.
- Health services research: Research utilization, cost effectiveness, cost offsets of naturopathic care/ services.
- Whole-ractice research: Outcomes of whole protocols, not single agents.
- Develop a template for doctors to organize data to report outcomes from their practices.
- Is naturopathic medicine safe and effective as an adjunctive treatment for cancer?
- Do homeopathically prepared substances alter biological organisms including humans?
- Does consciousness intervention affect medical outcomes?
- Do consciousness-altering botanicals have medical application?
- Would the integration of naturopathic medicine into primary medical care reduce the reliance on costly and toxic pharmaceuticals? Could this be demonstrated for specific conditions that are not particularly well managed by allopathic care such as chronic pain syndromes and depression?
- Can clinical practice guidelines be created that integrate naturopathic medicine into the medical management and prevention of specific conditions? Heart disease, diabetes, obesity, menopause, hypertension, end-of-life care, HIV infection, and cancer would be important conditions to consider.
- Interdisciplinary care teams, informed patients, and improved data systems are three tools used in combination that have been shown to improve the quality of patient care if the outcome is adherence to practice guidelines and reduction of medical error. Do naturopathic physicians have a role to play in interdisciplinary care teams to improve the quality of care?

- Can advanced degree tracks (PhD, MPH) with a focus on research methodology be created that will appeal to naturopathic physicians? The intention of this would be to augment current efforts to integrate efficacy trials and other research into the profession.
- How would the integration of naturopathic medicines into primary medical care affect the health status of minority populations? What would the acceptance of naturopathic medicine be among these groups?
- Evaluate the reliability and validity of diagnostic tests for specific issues in naturopathic medicine.
- Develop methods to test individualization of treatment.
- How do naturopathic practitioners achieve patient adherence to lifestyle change?
- Development of design strategies for whole-systems research.
- Evaluate menopausal symptom management from a naturopathic medical perspective.
- Conduct ND-driven epidemiological studies.
- Across all populations, compared to conventional standards of care, does naturopathic medicine have an impact on mortality, morbidity, quality of life, wellness and health care costs? Is a naturopathic intervention for syndrome X as cost-effective as, or superior to, the corresponding standard of care approach in allopathic medicine?
- For which conditions do naturopathic treatments offer the greatest advantages over conventional medical treatments and in what ways are the naturopathic treatments superior? How cost effective are the treatments?
- How does the process of healing work? What is the nature of the healing process? Research the process of healing.
- Identify and describe the metabolic, physiological indicators, clinical signs and symptoms, and clinical outcomes that differentiate between a healing response, a healing reaction, a healing crisis, and suppression of healing.
- Research the eczema/asthma continuum and clinical suppression vs. clinical healing.
- Is Hering's Law of Cure valid?
- Research the validity/efficacy of the naturopathic principles, including assessment of the therapeutic healing order, and long-range cost-effectiveness of applying the principles in population health.
- Is intention effective in changing medical conditions?
- How effective is naturopathic medicine at creating, promoting and maintaining health?
- How can we develop methodologies to study energy medicine and the technology to observe the phenomena?
- What is the effect of naturopathic medicine on women's health?
- What environmental factors are adversely affecting women's health?
- What are the benefits vs. risks of bio-identical natural estradiol vs. synthetic estrogens and conjugated equine estrogens?
- What are the benefits vs. risks of bio-identical progesterone vs. synthetic progestins? What are the benefits vs. risks of alternate delivery of estrogens and progestins?
- What non-hormonal nutritional and/or botanical therapies address quality of life issues in menopausal women?
- How can we use the human genome project to aid decisions regarding treatments (gene/nutrient interaction, gene/toxin interaction, constitutional type)?
- Does increased reimbursement for provider's focus on patient's behavioral change in primary care practice contribute to significant reduction in the rate of complex chronic disease in North America (e.g., diabetes, heart disease, obesity)?
- Evaluate the existing roles and effectiveness of naturopathic medicine in underserved communities.
- How can advances in pharmacogenomics be used to demonstrate the basis of individualized naturopathic care?
- What biochemical end-points can be measured in blood, urine, perspiration, saliva, etc. to demonstrate exactly what "detoxification/cleansing" therapies do?

- Research the potential cost-effectiveness of implementing a gradual, sequential, increased funding for addressing and improving the broad range of determinants of health in North America, including under-served communities.
- Assess whether health improvement strategies decrease the incidence and morbidity of chronic and complex chronic diseases.
- Does conscious intention from the naturopathic physician engage the patient's healing process and how?
- If one assumes that homeopathic cures are real and not statistical anomalies, how can we reconcile the counter-intuitive principles of homeopathy and dose-response pharmacology such that both can intellectually co-exist?
- Given the numerous, well-documented large variations in active principles for herbal/botanical medicines and non-herbal/metabolic intermediate supplements (e.g., CoQ10, glucosamine, etc.), how do we decide which preparations to use for pre-clinical and clinical studies without a) appearing to endorse a specific manufacturer, or b) having to test every one of the dozens of supplements on the market?
- What multivariable, fractal, and chaotic mathematical systems can be used to analyze studies in naturopathic, Chinese, and energy medicine?
- How can we design a system that emphasizes the individual in the clinical research setting?
- Explain what it means to treat the cause, with concrete examples of common pathology.
- Can we be at the forefront of psychoneuroimmunology (PNI)?
- What are the most appropriate roles for naturopathic physicians and naturopathic treatments in the American health care?
- What factors most distinguish naturopathic medical care from allopathic medical care and how are these factors related to patient outcomes?
- Do people seek naturopathic care because of a belief in the underlying philosophy of naturopathic medicine, or because their stomach hurts (for example) and the treatment they received from their conventional medical practitioner did not help?
- Is individualized naturopathic treatment, in fact, more effective than standard conventional treatment for conditions most frequently seen by NDs?
- Identify and validate strengths for wellness maintenance.
- Research naturopathic medicine's effectiveness in maintaining wellness.
- What works in supporting holistic self-health maintenance and prevention?
- Research naturopathic medicine's roles and effectiveness in working with communities.
- Evaluate the effectiveness of naturopathic medicine's approach to AIDS prevention and treatment.
- Can we identify and apply a research methodology that will enable identification or exclusion of effect-modifiers, i.e., factors leading to qualitatively or quantitatively different causal effects among members of a target population under study? This issue seems especially important for naturopathic medicine, given the tendency to treat individuals holistically based on medical histories which uniquely characterize individuals, a tradition which seems to presume strong effect-modification based on high-dimensional variables (e.g., medical history and personal idiosyncrasy). It may thus be necessary to consider effect-modification differently and certainly more carefully in the design of RCTs/observational studies of naturopathic medicine compared to conventional medical studies, so that important effects are detectable.
- Study how to structure research and disseminate findings to convince a skeptical public.
- Research how to cost-effectively use NCCAM and other research funding, by way of partnering among CAM institutions, practicing NDs, and conventional research institutions?
- Address how to train CAM research personnel in statistical methodology so that they can completely evaluate, report, and plan their own research in response to others' expert research findings.
- How will results of this research be translated into practice, both of NDs and MDs?

- Research the clinical efficacy and specific physiological activity involved in naturopathic constitutional hydrotherapy. Compare whole-practice outcomes of this modality to whole-practice outcomes in other modalities and disciplines
- Develop practice guidelines for naturopathic medicine.
- Genome research: is it possible to map constitutions metabolically to the human genome?
- Is constitutional hydrotherapy effective?
- Does homeopathy have any efficacy over placebo?
- Does chronic “strengthening” of the immune system increase the incidence of autoimmune disease, leukemia, and lymphoma?
- Does “strengthening” the immune system with prophylactic agents significantly decrease sickness in otherwise healthy patients?
- What measurable index of immune system activity is the most predictive of immune system strength?
- Does naturopathic breast cancer prophylactic treatment work better than prophylactic mastectomy in decreasing morbidity and mortality in women?
- Does the randomly assigned availability of naturopathic care in addition to standard conventional care vs. the availability of standard conventional care alone over 10 years (or other extended period) lead to lower morbidity, mortality, global health outcomes, and cost? Measure in three age groups: conception-9 yrs, 30-40 yrs, and 60-70 years.
- How many patients choose to use naturopathic care in addition to standard care vs. just standard care if given the choice?
- What are the characteristics of those who elect to access naturopathic medicine?
- Do those who use naturopathic medicine benefit more than those to whom it is available, but don't use it?
- What are health outcomes for high utilizers of third party payer HMOs, insurance companies, Medicare, VA or Medicaid, of those randomized to the availability of ND care compared to those offered only standard care? A variant would be to randomize to a certain amount of care: say 20 visits over one year for high utilizers who consent to randomization.
- RCT of whole practice naturopathic care for osteoarthritis.
- RCT of whole practice naturopathic care for dysglycemia.
- RCT of whole practice naturopathic care for asthma.
- RCT of whole practice naturopathic care for depression. The above diseases were chosen on the basis of 1) reputation among NDs for being successfully treatable by NDs and 2) high burden of unaddressed suffering.
- Whole practice implies some important precedent questions: What is good whole practice care for any condition?
- What is the variation of practice of NDs? Does this variation matter to outcomes?
- What are the long-term adverse effects of routine childhood vaccinations?
- What are the effects of chronic mercury toxicity?
- What tool can be used to collect data from all naturopathic teaching clinics and willing NDs for outcome studies?
- How can a whole person naturopathic approach be used to prevent and treat the leading types of cancer in North America?
- How can a whole person naturopathic approach be used to prevent and treat diabetes?
- How can a whole-person naturopathic approach be used to prevent and treat coronary artery disease?
- What is the impact of naturopathic protocols for a specific chronic disease currently demanding other treatment approaches in the health care system?
- What is the impact of treating chronic toxicity using naturopathic practice principles?
- What research methods can reliably test the significance of naturopathic patient evaluation?
- What is the impact of detoxification and removing obstacles to cure prior to addressing any chronic diseases or symptoms?
- What is the role of patient individuality and naturopathic treatment response?

- What is the role of naturopathic medicine in the integrative approach to health care system?
- What is the impact of naturopathic medicine in improving overall health care and improving cost-effectiveness in delivery of treatment for chronic diseases?
- What research methods can appropriately address, if a specific treatment is found to be effective, the relevance of naturopathic treatment with respect to availability to the target population (practicality, cost, patient compliance, practitioner delivery)?
- How can we adapt a holistic, multiple-therapy protocol to a reductionist research model without abandoning our unique approach to health care?
- How can we quantify outcomes that are largely qualitative in nature?
- Determine through surveys the “work” of naturopathic physicians, i.e., what conditions are treated (percentages), modalities utilized, patient profiles; practitioner profiles, work load, income, etc.
- Determine reliability and validity of “functional medicine” diagnostic protocols.
- Determine inter-examiner reliability in diagnostic methods of energy/vibrational medicine (i.e., homeopathy, etc).
- How can we develop parameters to measure “quality of life”, leading to developing “quality of life” care guidelines?
- How can we create a population that is open to and empowered to choose health care that is affordable, accessible, effective and includes themselves in the process?
- How can we teach a population to not confuse the symptom with the disease, the response with the cause?
- What are the criteria by which patients measure health?
- How does the predominant paradigm of power relationships affect the efficacy of the doctor-patient relationship?
- What are the findings regarding how co-management benefits the patient? What doesn’t work well?
- How can we overcome the prevalence of using medical visits as a debt payback device? “If I put out resources, I can continue my destructive lifestyle.”
- How do people stay healthy?
- Hypothesis: the body reacts by creating symptoms for a good reason. What is the intelligence behind hot flashes?
- Are the natural medicine principles valid? Do the diagnostic procedures measure what we think they do?
- Do the interventions make the impact we think they do?
- If the interventions do what we expect, does this result in health improvement?
- Does health improvement eliminate disease?
- What is the heart of medicine? How do we increase the vital force, catalyze our patients to access vital force, teach people how to access their own vital force, and empower our patients?

APPENDIX D: AANP Special Topics NMRA Presentations, Thought Leaders, Teams, and Contact Information

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APPENDIX E: AANP Special Topics Reports by Thought Leaders

Report on Women's Health and Hormone Replacement for the Naturopathic Medical Research Agenda

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Highlights and Key Trends

Menopause management has drastically changed in the last two years since the first Women's Health Initiative paper was published in the summer of 2002. This dramatic change in how and when and for whom hormone replacement is indicated presents the naturopathic community with a unique and strategic opportunity to participate in basic and clinical research. These opportunities include research in natural bio-identical hormone replacement for menopausal women, nonhormonal (herbal and nutritional) alternatives to hormone replacement therapy (HRT), and research for menopausal women at risk for, or survivors of, breast cancer.

Safety and efficacy concerns about conventional hormone therapy have resulted in the premature discontinuation of two arms of the Women's Health Initiative (WHI), a large multi-center clinical research trial. This has led to changes in conventional treatment guidelines for menopausal vasomotor symptoms that include recommendations such as dietary and exercise recommendations, soy isoflavones, vitamin E, and botanical medicines (1). These are therapies that naturopathic physicians have been using for many years. While this is certainly an encouraging trend, there is still a significant lack of data on safety and efficacy for many of these alternative interventions. Additionally, there is almost no research on typical naturopathic practices that utilize multi-interventional, whole person strategies on menopausal symptoms, quality of life measures, and effects on risk or prevention of breast cancer.

The evidence that does exist is limited to small, short-term randomized, controlled trials of single agents such as soy, black cohosh, red clover, dong quai, flax seeds, vitamin E, and a few others (2). The conclusion of these researchers is that black cohosh, phytoestrogenic herbs, and foods that contain phytoestrogens show promise for the treatment of menopausal symptoms, but inconsistent results and a lack of randomized controlled trials and insufficient evidence leave us with inadequate research as to both safety and efficacy for the others. These researchers urge federal agencies to provide more support for additional research in these areas to evaluate both efficacy and safety concerns.

Use of alternative therapies for menopause, menopausal women with breast cancer risk, adjunctive treatments for breast cancer and other women's health conditions is currently very popular. Women account for two thirds of health care appointments for complementary and alternative therapies (3). A national magazine received over 15,000 responses to a survey of alternative treatments for menopausal women in 1994; a tremendous response rate that confirms interest and use of CAM by the general population is in large part driven by women and women's health concerns (4).

Equally significant is the discontinuation rate of conventional hormone replacement therapy (HRT) by women. Even before the WHI findings, recent studies have shown that about 50% of women discontinued HRT after one year due to unacceptable side effects or other health concerns (5, 6, 7). Dr. Koon Teo, at McMaster University, presented data in 2003 demonstrating that women in his research trial drastically reduced their use of HRT after the first WHI arm was stopped early. In his group of 6,623 women participating in a trial on a cardiology drug, 6% of the women were

taking HRT prior to the publication of the WHI findings, but only 3.9% of them were taking HRT afterward. (8). The number of women who have stopped taking HRT has continued to decline since this time, and according to prescriptions filled at retail pharmacies is thought to be about 66% for Prempro and 33% for Premarin (9).

Finally, there is a growing awareness that research on CAM should not only be focused on clinical medicine with outcomes about safety, efficacy, and mechanism of action. Since about 50% of the population of industrialized countries and up to 80% of the population in developing countries uses CAM, public health research should also be a priority. This research must consider social, cultural, political, and economic contexts to maximize the potential contributions CAM can potentially contribute to health care systems globally (10).

Key Naturopathic Ideas that Differ from Standard/Conventional Medicine

Naturopathic physicians who care for women use comparable patient assessment and diagnostic approaches to those typical in conventional medicine, while the treatment strategies are distinctly different. In an unpublished survey of local naturopathic physicians in the Seattle/King county region, 70 ND's were surveyed about their usage of therapies for menopausal symptoms, 31 responses were received (44%). Among respondents, 71% indicated they used combination therapies (11). This supports the generally accepted belief that naturopathic physicians address health issues by utilizing multi-interventional, whole person, individualized therapies. This practice style presents significant challenges to current research design methods. Indeed, some scientists argue that naturopathic medicine by its very nature cannot be fully evidence based (12).

Priority Research Questions for the NMRA

Our group believes the NMRA should consider prioritizing the following research topics regarding women's health and hormone therapy:

1. Whole practice clinical research measuring the effects of multi-interventional therapies on menopausal symptoms for peri and postmenopausal women, and menopausal women with breast cancer or risk for breast cancer.
2. Larger and longer clinical trials testing safety and efficacy of agents such as black cohosh, soy, red clover, human bio-identical plant based steroid hormone formulas, hypericum, ginkgo, damiana, kava, rhodiola, and others for menopausal symptoms, quality of life indicators, effects on serum hormone levels, effects on lipids, bone density, breast tissue, and cardiac risk factors.
3. Clinical trials with other, novel naturopathic approaches for menopausal symptoms, such as botanical or nutritional serotonin agonists, anxiolytics, or homeopathy. Broaden the search for safe and effective therapies for wide range of symptoms encountered during menopausal years.
4. Pharmacokinetic studies to determine bio-availability, absorption patterns, optimum administration routes and dosages of the above agents.
5. In vitro and in vivo studies on the effects of black cohosh, red clover, soy and other botanical medicines used in menopause on breast tissue proliferation and carcinogenicity.
6. The levels of specific environmental toxins in the breast tissue of women with breast cancer compared to controls.
7. Randomized controlled trials to determine if CAM therapies are safe for women at high risk of breast cancer to use for menopausal symptoms
8. Randomized controlled trials on other women's health issues for which there are not adequate conventional therapies such as bacterial vaginosis, interstitial cystitis, vulvar vestibulitis, polycystic ovarian syndrome, infertility due to anovulation, dementia, and sexual dysfunction.
9. Basic research on physiology of female hepatic and endocrine metabolism and functions to determine if detoxification strategies could be effective for women's health issues.

10. Research to determine the validity of commonly used diagnostic tests for women's health issues, such as salivary female hormone panels and liver detoxification profiles.
11. Public health research into CAM therapies for women's health.

Comments on the Prioritization Criteria

Our group used the following criteria to develop the proposed research priorities:

1. **Public health significance.** By 2015, 50% of the women in the US will be menopausal. Up to 60% of them will seek treatment for their symptoms. In addition, one in eight women will be diagnosed with breast cancer in their lifetime. Current conventional therapy is associated with significant health risks for these groups. Use of CAM is prevalent in menopausal women. There is very little safety or efficacy data on CAM therapies for menopausal therapies. Issues of major importance in women's health and public health that are related to the use of HRT are breast cancer, cardiovascular disease and osteoporosis.
2. **Promising preliminary studies.** As of 2002, there were 29 randomized controlled trials of CAM therapies for menopausal symptoms. Of these, soy, red clover, and black cohosh demonstrate benefit.
3. **Need for basic and pharmacokinetic research on natural agents used for menopausal symptoms to measure safety, absorption, and dosage effects.** Very little currently exists
4. **Need for clinical research using whole practice approach.** Very little currently exists.
5. **Need for clinical research on physiology of hepatic, immune, and endocrine issues in women's health.** Naturopathic physicians commonly utilize therapies designed to detoxify the body, stimulate the immune system, and provide adaptogens for the endocrine system. These practices must be subjected to rigorous research to determine their validity.
6. **Need to validate commonly used diagnostic testing methods for women's health issues.** Very little research exists.

Comments on the NMRA Draft, and Priorities Overall

The overall procedure to develop the prioritized list of research specific for naturopathic medicine and women's health created an environment for fusion of innovative ideas and research projects. The proposed NMRA model was inclusive, creating opportunities for experts in naturopathic medicine, researchers, and clinical practitioners from both CAM and conventional backgrounds to collaborate and exchange ideas and thoughts.

Individual Interest or Priority

Our group is strongly interested in prioritizing research to evaluate naturopathic therapies for menopausal symptoms. We believe that the current environment provides an outstanding opportunity for the naturopathic profession to meet a significant public health need as a result of the recent findings about conventional HRT. Research on multi-interventional management of menopausal symptoms will also provide an ideal platform for our profession to document the unique and effective whole practice approach used by naturopathic physicians on an issue that is currently highly profiled in the media. As individuals, our research interests range from in vitro research on the effects of CAM agents commonly used for menopausal symptoms on breast cell lines, to basic clinical research into the physiology of women's hepatic and endocrine functions, to pharmacokinetic research, to randomized controlled trials on CAM therapies for a wide range of women's health conditions, to safety of CAM therapies for breast cancer patients and women at high risk for breast cancer, to test the validity of commonly used diagnostic testing in women's health, and finally, in public health research on major issues such as cardiovascular disease and osteoporosis. Each one of these areas is rich in opportunity, and funding is very likely to be available for these research questions.

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Report on Environmental Medicine for the Naturopathic Medical Research Agenda

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Highlights and Key Trends

Environmental medicine, the diagnoses and treatment of chronic illness from low-level daily exposures to ubiquitous xenobiotics, occupies a unique place in the health care continuum. Common environmental chemicals cause invitro damage to the immune, neurological and endocrine systems and are associated with corresponding health complaints in humans. Sufficient evidence is now available to cause the U.S. Centers for Disease Control (CDC) to begin taking action by identifying the actual body burden of environmental toxins in US residents (1). The CDC has already released two reports and plans to increase the number of compounds being measured in each successive report. The broadest study of xenobiotics to date revealed an average of 91 compounds per person (2). This fact may have implications in the etiology of many health complaints with which each physician is faced. If the physician wishes to treat the cause of the illness and remove the obstacle to cure, how can she or he effectively do that if the patient's toxic burden is not addressed?

For decades epidemiologists have found associations between certain cancers and other chronic illnesses with exposure to certain compounds. An entirely new field of study, toxicogenomics, has recently blossomed to further explore and explain these occurrences. *Toxicogenomics*, which is also the name of a journal published by the National Institute of Environmental Health Sciences (NIEHS), studies genetic differences in certain individuals' ability to efficiently metabolize toxic compounds (3). Those individuals who exhibit genetic differences (genetic polymorphisms) for the clearing of certain compounds exhibit higher rates of toxin-related health issues. This new field shows us that xenobiotic retention, through inefficient clearance, is causally related to a variety of cancers and other chronic health complaints.

In addition to the body burden of toxins that each individual carries, all are further exposed to compounds with daily eating, drinking, and breathing. In certain individuals these compounds lead to chronic health complaints. Conventional medicine is slowly coming to recognize that chronic, low-dose xenobiotic exposures causes ill health. Public health and occupational medicine are the allopathic branches that work with acute toxin-induced illnesses (poisonings). These groups focus on such issues as workplace health, monitoring for unacceptable levels of toxins in the workplace and attempting to prevent acute poisonous exposures. This leaves millions of US residents, burdened with environmental compounds, with virtually no accessibility to health care providers who are trained to diagnose and treat illnesses associated with chronic low dose exposures. Fortunately, the NIEHS, the Environmental Protection Agency (EPA) and the CDC have joined forces to develop 12 centers to study the effect of the environment on children's health (4). These centers are contributing valuable research to this field and will hopefully help to change the way environmental medicine is viewed and applied. In addition to these new centers, numerous institutions have excellent programs in environmental medicine/toxicology research. However, none of these institutions (with the exception of the Southwest College of Naturopathic Medicine and Health Sciences) currently have programs in the treatment of poisoned individuals.

Key Naturopathic Ideas that Differ from Standard/Conventional Medicine

Naturopathic physicians following the principle of *Tolle Causam* (treating the cause) will be compelled to seek or rule out an environmental cause for all of their clients' illness. If the body

burden of solvents or heavy metals is the underlying cause or are main obstacles to cure, these compounds must be cleared before health can be restored. Since the same compounds present in most persons have also been implicated in multiple chronic health problems it is imperative that physicians look into this area.

Traditional “nature cure” techniques have been found effective in reversing a wide range of chronic health problems associated with toxin burden (5). These and other factors combine to make naturopathic physicians the best candidates to pioneer this new and unclaimed field of environmental medicine.

Studying the application of environmental medicine to the problem of neutralizing a very toxic world creates a prototype for utilizing similar methodologies for cleansing the human body of representational bio-waste. This concept is observed in the work at McGill University in Quebec by Dr. B. Volesky (6-7). The technique of “Biosorption” of heavy metals from large water systems is being used as a model to design nutritional supplements for the chelation of heavy metals from humans (6). Bio-waste creates toxic sites on our planet and consequently results in metabolites which cause the impairment of cellular function at the nuclear and mitochondrial levels. Just as the world has repeatedly absorbed much of the human spoilage and waste over centuries, the human body also reflects an ability to be resilient against disease until the total toxic load becomes excessive. With the number of other health care professions who are embracing natural medicine modalities, it is imperative for the future of our profession to clearly establish the field of environmental medicine as the domain of naturopathic medicine.

Priority Research Questions for the NMRA

Numerous other institutions are currently addressing the questions of toxic burden and association with health problems. The naturopathic research agenda should seek to utilize and build on, but not duplicate these efforts. Naturopathic practitioners, as experts in the understanding of “terrain medicine”, offer an opportunity to be advanced through the study and application of the field of environmental medicine. Chronic pathology and cellular deterioration have origins in the emotional, biological, genetic and environmental seeds. Each naturopathic college should prioritize providing advanced environmental medicine training in both basic and clinical sciences.

It is imperative that the naturopathic research agenda study the following:

- Can naturopathic cleansing methods reduce the toxic burden in individuals? With the exception of chelation for certain heavy metals this concept of the ability to reduce the total load of xenobiotics remains unproven and disbelieved. Demonstrating that nature cure techniques can reduce the level of toxins that the CDC is documenting in all US residents will provide safe methods to reduce the body burden of toxins, and provide an answer to one of public health’s great concerns (our toxic burden). [Prioritization Criteria 4.]
- Is the reduction of total toxin load by naturopathic cleansing modalities accompanied by improved health? This should be documented with improvement in signs and symptoms, disease laboratory markers and followed with long-term outcome studies.
 - a. Such studies should be started with chronic illnesses that are highly associated with environmental toxic burden and for which allopathic treatment is currently ineffective (Prioritization Criteria 1,2 & 3).
- Which clinical markers are most associative of toxin burden? Establishing a validated “questionnaire” that can be used by practitioners to identify which clients are most likely to be helped by naturopathic environmental medicine protocols would be of great value.
- Can the mathematical models of biosorption and mechanisms for metal chelation by Biomass be applied to laboratory methodologies for human toxicity analysis?

Conclusion

It is critical for the naturopathic profession to focus its research resources on environmental medicine. Our profession is beset on every side by complementary and alternative professions (CAM)

along with the allopathic medical field who are all intent on claiming the field of natural medicine for their own. To spend our limited research resources on proving that Echinacea does or does not help the immune system only helps our 'competitors' in this field, and fails to distinguish us from all the other CAM professions. With numerous groups claiming ownership over parts of our traditional modalities it would be wise for us to choose a less crowded arena to claim as our own. Environmental medicine provides a logical place for naturopathic medicine to place its flag for the following reasons:

1. All persons are now burdened with multiple environmental toxins.
2. These environmental toxins are causative agents in both acute and chronic illnesses.
3. The chronic illnesses associated with these toxins are common and typically are progressive with serious morbidity and mortality.
4. These illnesses are increasing in numbers and the public wants answers to these problems
5. Currently no health care field has demonstrated efficacy in reducing toxic burden and improvement in toxin-related illnesses except for the use of nature cure techniques.

By focusing our research resources in this arena, we will be able to establish environmental medicine as THE domain of naturopathic medicine. This will solidify our validity and necessity to the rest of the CAM and allopathic medical professions.

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Special Topics Report on Diabetes for the Naturopathic Medical Research Agenda

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Highlights and Key Trends

Statistics in diabetes trends

The number of Americans in 2002 who have diabetes is a staggering 18.2 million, including an estimated 5.2 million undiagnosed. This costs Americans \$92 billion in direct medical costs, and is the 6th leading cause of death in the year 2000 (likely underreported). Heart disease is the most likely cause of death in persons with diabetes. The prevalence of diabetes among adults living in the developed world is expected to increase by 42%, and by 170% in the developing countries by the year 2025. The parallel rise in obesity in the United States reflects the importance of over-fatness in the etiology of diabetes.

Lifestyle intervention prevention trials

There are a number of diabetes trials comparing lifestyle intervention to that of a minimal treatment group (2,3,4,5,6) with the goal of preventing diabetes. While study designs and methods are different, the overall observations are that modifying lifestyle behaviors are effective at reducing the incidence of diabetes compared to minimal intervention. A few of these trials are worth noting.

The Diabetes Prevention Program (DPP) and The Finnish Diabetes Prevention Study (FDPS) were the first randomized controlled trials comparing lifestyle intervention to minimal treatment groups (the control). Each of the studies had an intensive diabetes education program with the goals of weight reduction, dietary modification, and exercise. The result of each trial was a 58% reduction in the incidence of diabetes in the lifestyle intervention group compared to the minimal treatment group. One remarkable distinction which came forth from the FDPS was that none of the participants who had achieved all of the lifestyle goals by the 1st year went on to develop diabetes (either in the treatment or control group), as contrasted by one third of the participants who never reached a single lifestyle goal went on to develop diabetes during the study period.

The DPP also compared lifestyle intervention to drug therapy. When compared to lifestyle intervention, metformin was demonstrated to be approximately 50% as effective in preventing the progression from impaired glucose tolerance to diabetes. Other studies exist, but the inadequacy of the lifestyle education arm of the studies would prevent clear conclusions from being made.

It is not surprising that the metformin arm of the DPP would not prevent as many cases of diabetes as lifestyle intervention since the medication exerts its influence for only a specified period of time with specific modes of action, while exercise, weight reduction and diet addresses the causal factors initiating the natural history of the disease.

The Malmo Feasibility Study suggested the incidence of diabetes might be halved with diet and exercise intervention. The Da Qing study compared diet, exercise, diet plus exercise or a no treatment control and found that all three lifestyle approaches reduced the risk of developing diabetes by 31-46%.

Once an individual has type 2 diabetes, lifestyle intervention has been shown to prevent the deterioration and improve hemoglobin A1c, fasting glucose and weight loss. To date there are no diabetes treatment or prevention studies comparing lifestyle intervention plus natural medicine to that of lifestyle intervention plus drug therapy.

Diabetes Treatment Trials

Dilemma with Alternative Therapy

From guided imagery (15), biofeedback (16), and acupuncture (20, 21, 22, 23, 24, 25) to botanicals (e.g., Chinese, Indian, and European) (26-45), clinical trials and animal studies of various single agent/multiple combinations of CAM therapies that appear to lower fasting/postprandial glucose and/or HbA1c have been reported in the literature. Some are popular (e.g., gymnema, mormordica, vaccinium, chromium, vanadium, and vitamin E,) and others less popular (aloe vera, *Opuntia* species, etc.) in the US. However, these findings have not been repeated using the standards of Western medicine. With recent findings of Chinese and Indian anti-diabetic botanical products containing anti-diabetic pharmaceutical agents and/or contaminated with high concentrations of heavy metals and other toxins, the wide spread use of these formulations in the US is a concern (46-51).

Optimal Botanical and Nutrient Intervention

In addition to lack of research, many of the over-the-counter botanical and nutrient products have not been evaluated for quality/quantity/characteristics of the ingredients listed. Label reliability and consistency of the actual amount of the substance per dose, and quality of the active compound standardized, and the purity and identity of such compounds are more often unreliable and inaccurate (49-51). When the concentrations of active components are not precisely standardized or controlled, conflicting and unusable findings may result. Validity and reliability of outcomes is required for other scientists to reproduce or to further supplement the NMRA-mandated diabetes clinical research, to publish end results on what was actually used in their studies; and to standardize products for future manufacturing. Delivery of naturopathic therapies to the larger diabetic population is one of the long-term goals of our research.

This transfer of safety and efficacy information and knowledge from clinical trials of sample populations to the larger target population has been difficult with botanical products in particular. For example, *Echinacea* is one of the most extensively studied botanicals in the world (54). *Echinacea* has been studied in numerous controlled trials with both positive and negative results pertaining to enhancing the immune system, reducing the symptoms of cold and flu, and increasing recovery time from upper respiratory viral infections (55-59). However, one fact is clear; the immense diversity of the “*Echinacea*” used in the studies. Diversity is in the form of delivery (capsule, tablet, tea, tincture, glycerin), part(s) of plant used (flower, stem, leaf, root), standardized extract vs. whole herb, and, if standardized extract, the concentration and “active compound” also varies, the species of *Echinacea* used (*E. purpurea*, *E. angustifolia*, *E. pallida*), and the dosage used in each study. To address this concern (a regulatory issue beyond the scope of our research agenda), the botanical and nutritional products used in any clinical trials will be identified for quality, purity, and content.

Rationale for Combination Botanical and Nutrient Therapy

While clinical trials using single agents (botanicals and other dietary supplements) for diabetes are found in the literature, the quality of the research is poor. Although some results show positive glucose control, evidence to prove or disprove these therapies is still inconclusive and has yet to be accepted by conventional medicine. Lacking even more evidence are the effects of combination CAM therapy for treating diabetes (67-68). Combination CAM therapy is widely used by CAM practitioners/physicians and reported to be effective and more clinically potent in aiding glucose control than treating with a single herb or nutritional supplement, but clinical trials have yet to be conducted to support or refute these claims.

Current literature suggests that each component of our diabetes protocol has one or more of the following predominant effects, although the mechanism is uncertain (66-68): 1) potentiate the action of insulin, decrease insulin resistance, improve glucose utilization, and reduce hyperglycemia; 2) prevent chronic diseases associated with long-term hyperglycemia, e.g., cardiovascular disease, retinopathy, nephropathy, and neuropathy; and 3) symptomatic relief of complications associated with type 2 diabetes. Combination therapies have the potential to deliver greater glucose control

and insulin sensitivity; therapeutic actions particularly needed for uncontrolled hyperglycemia in diabetes. Combination therapy may also deliver better long-term glucose normalizing effects than monotherapy of each component when therapy is discontinued. Hence, combination botanical and nutrient therapy may be an acceptable alternative choice for uncontrolled diabetes and/or used as an adjunctive supportive therapy with oral pharmaceutical agents such as sulfonylureas and/or insulin. Combination therapy research in diabetes will help improve and develop innovative therapies to prevent the degenerative consequences of diabetes.

Combination botanicals and nutrients may provide stronger and more comprehensive action in glucose control and insulin sensitivity in diabetes unresponsive to current oral agents and/or insulin. The intervention includes botanicals and nutrients that appear to reduce hyperglycemia and improve insulin sensitivity. The glucose controlling effects and prevention/protection against diabetes complication will be followed, such as, risk factors of cardiovascular disease (high blood pressure, hyperlipidemia), peripheral neuropathy, nephropathy, retinopathy, and diabetic cataract. United Kingdom Prospective Diabetes Study Group (UKPDS) and Diabetes Control and Complications Trial Research Group (DCCT) findings show that improved glucose control will prevent and reduce diabetes complications. UKPDS results of 1998 indicate a 1.0 reduction in HbA1c resulted in: 17% reduction in all-cause mortality; 18% reduction in MI; 15% reduction in stroke; and 35% reduction in microvascular endpoints; 18% reduction in cataract extraction. UKPS blood pressure epidemiological analysis found a 10mm Hg reduction in BP resulted in: 11% reduction in all-cause mortality; 11% reduction in MI; 17% reduction in stroke; 13% reduction in microvascular endpoints; and 15% reduction in heart failure.

Important mechanisms

Reduce hyperglycemia: *Gymnema sylvestre* (75-89), *Momordica charantia* (90-103), *Vaccinium myrtillus* (104), *Syzygium jambolanum* (105-107), *Pterocarpus marsupium* (108-110), *Panax ginseng* (111-119), chromium (120-147), vanadium (148-150)

Improve insulin sensitivity and beta cell function: *Gymnema sylvestre*, *Momordica charantia*, *Pterocarpus marsupium*, *Panax ginseng*, chromium, vanadium, magnesium (151-165), vitamin E (173-186)

Synergistic (Improves the function of other botanicals (reduce insulin resistance, anti-hyperglycemia, beta-cell/pancreatic function)): *Glycyrrhiza glabra*, *Panax ginseng*

Prevent oxidative damage: Low density lipoprotein (LDL) oxidation is implicated in cardiovascular damage, and lipid peroxidation is implicated in peripheral neuropathy. Oxidative stress is increased particularly in retinas of diabetic animals and causes increased activation of vascular cell adhesion molecules (VCAM-1) which are associated with vascular damage in type 2 diabetes. The oxidative damage to the retina may be decreased with antioxidants such as vitamin C (166-172), vitamin E, and *Vaccinium myrtillus*. Vitamin E prevents LDL oxidation and microangiopathy, and may also be important in protection of the kidney. In type 2 diabetes controlled trial, patients who had significantly more oxidized LDL also had low LDL vitamin E levels (187-189).

Prevent glycosylation of proteins: Protein glycosylation from glucose auto-oxidation generate free radicals that can cause broad range tissue damage. Vitamins C and E as well as carnosine inhibit glycosylation.

Aldose reductase inhibition: Sorbitol does not diffuse passively into and out of cells and accumulates along with some fructose in the cells resulting in hydropic swelling and cell damage. Sorbitol accumulation is particularly evident in cataract formation, neuropathy, and nephropathy. Inhibiting aldose reductase can block sorbitol accumulation, this inhibition has been found to prevent diabetic cataracts, retinopathy, nephropathy, and neuropathy. *Vaccinium myrtillus*, vitamin C and bioflavonoids inhibit aldose reductase.

Prevent abnormal collagen formation: In diabetic nephropathy abnormal connective tissue deposits in the capillaries cause thickening and blockage, preventing filtration. *Vaccinium myrtillus*, vitamin C and E has preventative action.

Stabilize membrane and protection against vascular damage: Increased vascular permeability and capillary fragility contribute to retinopathy and nephropathy. *Vaccinium myrtillus* and vitamin C has preventative action against vascular damage.

Diabetes Complications and CAM *

Cardiovascular disease

Atherosclerosis, peripheral vascular diseases are linked to LDL oxidation. Elevated lipids, particularly triglycerides, and endothelial cell proliferation in blood vessels are associated with increased tendency for platelet aggregation. Glycosylated proteins cause free radical tissue damage to heart muscles. Atherosclerosis and oxidative damage, through NF-KappaB pathways, are linked with late stage complications. Vitamin E has preventative action.

Peripheral neuropathy

Peripheral neuropathy and associated causes appear to include sorbitol accumulation, lipid peroxidation, and decreased blood flow. A study with 21 subjects with type 2 diabetes in a controlled trial showed that vitamin E for six months significantly improved nerve conduction velocity in median motor nerve fibers and tibial motor nerve distal latency. Niacin slows down the sorbitol induced damage in nerves cells.

Nephropathy

Increased capillary permeability allows protein leakage. Glycosylated proteins and abnormal connective tissue deposits in the capillaries cause thickening and blockage, preventing adequate filtration. Vitamin C have been found to decrease urinary albumin, which is elevated in diabetic nephropathy, as well as susceptibility to urinary tract infection and glomerular sclerosis. Vitamin E increases circulation and reduces free radical damage to the kidneys.

Retinopathy

Suspected causes of retinopathy include increased capillary permeability, vascular fragility, glycosylated proteins, and low nitric oxide (NO) activity in the retinal vascular endothelium (important because NO is responsible for increasing ocular blood flow which may be diminished in diabetes). Vitamin C at 1000 mg a day was found to improve fragile capillaries. Both vitamin C and E have been found to restore glutathione levels to normal in the retina of diabetic animals.

Vaccinium myrtillus contains important anthocyanoside flavonoid compounds, which have a special affinity for the eye. Flavonoids decrease hemorrhage and capillary leakage, especially in retinopathy due to diabetes. Antioxidants strengthen and decrease leakage of retinal blood vessels. Deficiencies in nutrients that are found in diabetic retinopathy include magnesium.

Diabetic cataract

Sorbitol accumulation in the lens, protein glycosylation, and oxidative damage are suspected causes of diabetic cataracts. Aldose reductase inhibitors may be effective in diabetic cataracts. Inhibitors such as vitamin C have shown to be beneficial.

Key Naturopathic Ideas that Differ from Standard/Conventional Medicine

There are many similarities in comparing the naturopathic approach to the treatment of diabetes to that of conventional medicine. Weight management, exercise and nutrition are fundamental to the foundational structure of any rational diabetes control and recovery program. What has

* Citations for this section may be found in References section (pages 98-108)

not been researched in well designed trials is the combined use of natural medicines and lifestyle intervention in preventing or treating diabetes.

Conventional – lifestyle and diet (low fat, higher carbohydrate), plus medications

Naturopathic – lifestyle and diet (moderate fat, low carbohydrate), plus nutrient supplementation and botanical medicines

Where conventional medicine excels, in our observation, is in conducting widely available methodically designed educational classes teaching behavioral lifestyle optimization. Despite ample funding for diabetes education, obesity continues to rise in America and the incidence of diabetes is still climbing.

The Finnish Diabetes Prevention Study was the first well controlled lifestyle intervention trial. This study randomized the 522 participants into a control and intervention group. The intervention group had five lifestyle goals: 1) weight reduction of 5% or more; 2) total fat intake less than 30% of energy consumed; 3) saturated fat intake less than 10% of energy consumed; 4) fiber intake less than 15 g/1000kcal; and 5) moderate exercise for 30 min/day or more. The incidence of diabetes was reduced by 58% in the treatment group during the six year study period. (5)

There needs to be a realistic approach to interventions in both developed and developing nations, and in ethnic groups where a better understanding of the socio-economic, cultural and demographic issues and perceptions surrounding chronic diseases such as diabetes is required. Whether the strategies used in these studies (DPP, FDPS) can be translated into a ‘real world’ scenario is doubtful. In practice, it is more than likely that a number of strategies will be needed to complement the lifestyle approach. These will include pharmacological approaches with metformin, acarbose and other agents used to treat diabetes and its complications, (currently under investigation). Longer-term follow-up studies will also clarify whether both lifestyle and pharmacological interventions actually prevent type 2 diabetes, or merely delay its onset.

Family physicians have an important role in identifying people at risk of developing type 2 diabetes and managing those diagnosed with the disease, yet they struggle to deliver practice-based interventions that promote sustainable behavior change among their patients. **CONCLUSION:** It is evident that supporting patients to make changes in their physical activity and dietary habits can prevent onset of type 2 diabetes. Translating this finding into effective recommendations for clinical practice requires further effort and evaluation.

Priority Research Questions for the NMRA

The number one priority for research of Naturopathic interventions in diabetes mellitus is **whole practice intervention**. No single agent (conventional or alternative) is effective at controlling diabetes. Multiple interventions are required. These are probably best studied via demonstration projects. A reasonable plan to research whole practice interventions of type 2 diabetes mellitus would include:

- a. Survey of practitioners and a Delphi process to develop:
 - A description of the prescribing practices of naturopathic physicians who treat diabetes
 - A standardized nutrient supplement
 - A standardized botanical medicine
 - A naturopathic therapeutic protocol that is implemented stepwise with endpoints measured at baseline and between added interventions
 1. Doctor–patient interaction/motivation programs
 2. Lifestyle – standardized diet, exercise, stress management programs
 3. Standardized nutrient supplement
 4. Standardized botanical medicine
- b. Systematic review of the literature regarding alternative treatments for diabetes

- c. Design and carry out a series of R21 proposals to look at mechanisms, safety and efficacy of components of naturopathic protocols. The following are questions that were derived from the NMRA process.
1. What are the effects of natural agents on glucagon-like peptide 1 and 2 (GLP1, GLP2)?
 2. Are dietary/lifestyle education and demonstration effective tools in reversing an individual's disease course or is psychological intervention necessary?
 3. Which psychological interventions are most effective for treating eating disorders, modify blood sugar disrupting behaviors, improve lifestyles?
 4. Do weekly visits with people with diabetes (PWD) help them understand, agree to and commit to the treatment protocols that are assigned to them?
 5. Can the Naturopathic Glycemic Control Diet (derived from the Delphi process and a modification of the diet promoted by Dr. Richard Bernstein) be an effective tool for having PWD achieve and maintain non-diabetic blood sugar and HbA1C levels?
 6. What exercise types and frequency are the best for PWD to aid in achieving and maintaining non-diabetic blood sugar and HbA1C levels?
 7. What are the best stress reduction techniques to help PWD in keeping their blood sugar normalized?
 8. What is the effectiveness of natural and/or pharmaceutical appetite suppressants and do they have a place in treating diabetes with natural medicine?
 9. What is the best standardized naturopathic nutritional supplement program to put PWD on for treatment and prevention?
 10. What is the best standardized naturopathic botanical medicine supplement program in a naturopathic treatment protocol for aiding PWD in achieving and maintaining non-diabetic blood sugars and HbA1C levels?
 11. Is it possible using naturopathic treatment protocols to have PWD use for their insulin needs only the amount of insulin that non-diabetics make in their bodies daily?
 12. Will long-term maintenance of PWD with normoglycemic HbA1Cs in the low 5s prevent all secondary diabetic complications?
 13. Can naturopathic protocols that have success with upper lower, middle, and upper socioeconomic PWD have the same success with those PWD living in poverty with their unique and devastating problems?
 14. What is the cost comparison for naturopathic protocols to have PWD achieve and maintain normoglycemic and HbA1C levels vs. Conventional drug protocols for six months?
- d. Find a site for a demonstration project (integrated clinic) as a research platform (VA, PHS, military, etc.).
- e. Institute the whole practice interventions that result from the practitioner survey and Delphi protocol process.

Future Studies

There are many topics for future investigation. Many more will be elucidated by the process outlined above. The following were topics that came up frequently in the AANP special topics sessions.

1. Dairy allergy and type 1 diabetes
At three months of age, infants fed cow's milk formula had a significantly higher immune response to cow insulin than infants who received the other formula or were breast-fed. These observations raise the question of whether oral exposure to foreign insulin plays a role in the autoimmune process leading to type 1 diabetes. It is conceivable that in some predisposed children, early exposure to cow's milk could trigger an immune reaction to insulin, they conclude.
2. Mitochondrial damage from xenobiotics has been implicated in contributing to poor glycaemic control. The effect of environmental pollutants on diabetics is not well studied.

3. The effect of naturopathic protocols in maintaining normal glycemic responses in children at risk for developing diabetes (Native Americans, Hispanics, etc.) has not been studied.

Comments on the Prioritization Criteria

1. Focus on diseases with the highest burden of human suffering.
2. Focus on issues with the greatest public health significance. The current epidemic in obesity and diabetes is well documented to fulfill these criteria.
3. Evaluate treatments first which have the greatest likelihood of reducing the burden of suffering—the low hanging fruit among naturopathic treatments. Lifestyle modification is well documented as being the most effective therapy for controlling diabetes. Various previously cited studies support the efficacy of naturopathic nutritional and botanical agents.
4. Focus on methodological evolution and the necessary sequencing of studies to achieve long range goals. The strategy outlined in this document fulfills this criteria.
5. Investigate naturopathic concepts with revolutionary potential for wide-ranging benefit. Drug therapy is not very effective at controlling diabetes or the progression of peripheral manifestations of the disease. Long-term control of glycemia is difficult to achieve. The studies annotated below show that well controlled diabetics do not progress to nephropathy and that natural medicines can be beneficial, too:
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 - e. Brand-Miller JC. Glycemic load and chronic disease. *Nutr Rev* 2003;61(5 Pt 2):S49-55. Observational studies suggest that diets with a high glycemic load are independently associated with increased risk of type 2 diabetes. Lower glucose and insulin levels are associated with improved risk.
6. Attend to questions for which infrastructure exists or can be quickly built and that are fundable. There is funding available for diabetes studies. Most of the naturopathic medical colleges have adequate infrastructure to carry out the trials as planned above.

Comments on the Model/ Figure, and Priorities Overall

The priorities for diabetes research presented in this monograph are consistent with all the other NMRA documents and priorities.

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Special Topics Report on Asthma for the Naturopathic Medical Research Agenda

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Abstract

This report summarizes the state of the science in naturopathic medicine with respect to treatment of asthma. It reviews use of botanicals, acupuncture, diet and nutrition, homeopathy, and manipulation in order to suggest research priorities. Asthma has a high health, economic and societal burden. Naturopathic medicine has successes treating asthma, but the majority of these therapies are not adequately investigated.

Introduction

A survey of CAM (complementary and alternative medicine) use by asthma patients, based on 17,000 questionnaires with a response rate of 27.8% (4741), found 59% used CAM. Breathing techniques, homeopathy and herbs were the most commonly used. The majority of patients felt CAM was moderately useful (1).

Botanicals

A review of English language papers on herbs and asthma found positive effects on bronchodilation, pulmonary function tests, antagonism of asthma mediators (histamine, platelet activating factor (PAF), corticosteroid use and mucus clearance.(2) They concluded there was a lack of quantity and quality controls, fewer side effects than current conventional therapy and a need for more detailed investigations.

Solanum xanthocarpum and *S. triblobatum* (Solanaceae) are widely used in south India with significant positive effect on pulmonary function, but the mechanism requires detailed study.(3) *Astragalus membranceus*, *Codonopsis pilosula* and *Glycyrrhiza uralensis* significantly decreased airway responsiveness over a six week trial.(4) At least 58 plants are used in traditional Hawaiian medicine for asthma including *Piper methysticum*, *Solanum americanum*, *Aleurite molucana*, and *Sophora chrysophylla*.(5) Ayurvedic medicine herbs *Tylophora ashmatica* (*T. indica*) provide significant symptom relief (6,7,8) as does *Boswellia serrata*.(9,10,11) The Greek plant *Petasites hybridus* has been shown effective in quinea pig studies (12,13).

Plant constituents such as quercetin are anti-inflammatory (14,15), and sterols and sterolins may increase Th1 while lessening Th2 response (16,17). Traditional botanicals for asthma such as *Ephedra sinica* (18,19), *Lobelia inflata* (20,21), and *Capsicum frutescens* (22,23) are poorly studied. Eclectic botanicals such as *Asclepias syriaca* (*A. tuberosa*), *Aspidosperma quebracho-blanco*, *Blatta orientalis*, *Cinnamomum camphora*, *Eucalyptus globulus*, *Grindelia robusta*, *Larrea mexicana*, *Peonia officinalis*, *Symphlocarpus foetidus*, and *Tussilago farfara* have not been studied (24,25).

Acupuncture

Martin et al. (26) reviewed published acupuncture trials from 1970-2000, included 11 studies, and concluded there was no evidence to support acupuncture in asthma when bronchoconstriction was induced. Medici et al. (27) conducted a real vs. sham acupuncture trial, found no significant effects except a significantly higher eosinophil count 10 months after the trial. Malstrom et al. (28) tested acupuncture vs mock-TENS with no significant effect on cold induced asthma. Shapira et al. (29) tested acupuncture vs sham-acupuncture without significant effect. Laser acupuncture on real and placebo points in children yielded no significant effect on cold air challenge (30).

Nutrition

Baker and Ayres (31) concluded that supplementation studies of A, C, E, selenium and magnesium are needed to confirm the role of antioxidants, sub-optimal nutrient intake and food allergy on asthmatic inflammation. Ram et al. (32) in a meta-analysis of six randomized, controlled trials in children with a family history of atopy, found reduced risk with avoidance of cow milk protein compared to use of standard cow milk formula. Olge and Bullock (33) found 91% of children less than one year old with a respiratory allergy and negative inhalant skin tests had respiratory symptom improvement. Hodge et al. (34) concluded that elimination/challenge diets had the best success in identifying allergens and preventing asthma. Children with an average age of 12 years old placed on a vegetarian diet for one year had 71% improvement at four months and 92% at one year in objective lung variables.(35) Children with a fresh, oily fish diet had a significant reduction in current asthma.(36) Woods et al. (37) concluded there was little evidence to recommend people with asthma supplement with marine n-3 fatty acids. There are positive trials using probiotics for eczema, but none for asthma. (38)

Erythrocyte magnesium has been found to be lower in acute asthma.(39) Intravenous magnesium in emergency rooms for asthma from nine trials showed statistical benefit.(40) A meta-analysis of seven trials found it safe and beneficial in both adults and pediatrics.(41) High oral magnesium supplementation reduced symptoms but did not improve objective scores.(42) Nebulized magnesium added to salbutamol compared to saline with salbutamol was positively significant for FEV1 at 90 min. (43)

Reduced intake of dietary antioxidants over the past 25 years may be a factor for increased asthma.(44) Vitamin C levels were inversely related to cough and wheeze in young smokers (45), coenzyme Q10 was reduced in asthmatics (46), lycopene reduced exercise-induced asthma (47), antioxidants were low in children with asthma (48), and beta-carotene reduced exercise induced asthma. (49) A Cochrane review of six vitamin C studies found insufficient evidence to recommend its use (50). Wright argues that frequent B12 IM is clinically effective (51) and Gaby (52) found that IV cocktails of magnesium, calcium, B and C vitamins along with B12 IM yielded clinical improvement.

Manipulation

A systematic review of five manipulation trials found no evidence to support its use in asthma (53). Anecdotal information suggests benefit in some patients during acute attacks; the likely mechanism is muscular spasm relaxation.

Homeopathy

White et al. (54) found no evidence for homeopathy in childhood asthma. Linde and Jobst (55) reviewed homeopathy trials and found two positive and one where the effect of homeopathy equaled placebo.

Hahnemann (56) recommended provings as a means of identifying homeopathic medicine clinical properties. His were among the first blinded medical experiments in the late 18th and early 19th centuries. Sherr (57) has put these provings into modern language, added double blinding of the prover and proving supervisor, and conducted and published a number of provings. These proving data add to the literature on asthma when provers develop respiratory symptoms or when homeopathic medicines effectively treat asthmatic patients. Conventional medicine has largely ignored this systematic method of data collection and its potential clinical utility, probably because homeopathic treatment focuses not on a specific diagnosis but rather on the symptoms of the patient in order to select the specific homeopathic medicine. There have been no studies on Herings Law, alternation of symptoms (e.g., asthma and eczema), or other basic homeopathic principles that govern current practice.

Research Priorities

Many botanical medicines in daily use by naturopathic physicians are poorly studied and rely solely on historical and current clinical use results. Mechanisms of the best known or most often used are not well understood, and the actions of some seem contradictory. Research should be done on the more commonly used botanicals to identify mechanism of action and clinical effectiveness.

Acupuncture studies do not mimic individualized patient treatment in point selection and need better design before new trials are conducted. Studies that parallel the clinical practice of acupuncture in point selection and variation during treatment will likely be more beneficial to clinicians than identification of single point(s) that could be of benefit.

Prospective studies of diet and supplementation are needed. Several essential nutrients appear to play a role with some showing more effect than others. These should also be investigated.

Manipulation therapy lacks positive outcomes to date. A polling of practitioners could determine if it is more beneficial in acute versus chronic patient presentation. This could then lead to better study designs and more useful outcomes.

Homeopathy has some positive evidence, but better trial design is required. The most effective current design is experienced homeopaths taking a case and prescribing, but blinding and randomization of whether the patient receives the medicine or placebo. This method remains true to the homeopathic paradigm and tests that paradigm.

Naturopathic physicians should avoid areas such as environmental controls or mind-body interventions. This is a research field where others can do a better job of treatment and research.

Research on the whole practice of naturopathic medicine, including its integration of therapies, is needed for both acute and chronic asthma. Current studies take a dissection approach rather than a holistic approach.

Summary

Asthma is a significant health and economic burden. Some botanical medicines have been studied, but those most commonly used by naturopathic physicians are poorly studied. Clinical trial data showing the benefits of acupuncture and manipulation are absent while those for homeopathy are limited. Research supporting the use of nutrition is positive but limited. There are currently no studies that have examined the integration of therapies as they are used in active naturopathic medical practice. Thus there is an opportunity for considerable quality research on the use of single and integrated CAM therapies for the treatment of asthma.

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Report on Health Services and Workforce Issues for the Naturopathic Medical Research Agenda: *Integrating Naturopathic Physicians into Mainstream Delivery Systems*

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Highlights and Key Trends

The classic health workforce question, “Do we have enough health care practitioners to provide necessary care” has evolved into a series of related and more sophisticated workforce and health services questions driven by changing demographics and delivery models. Today, at least five trends frame the concerns of health care leaders seeking to “grow” the professions, to best match health care demands with workforce supply, and to best integrate promising new health services into mainstream health care in the United States:

- The high – and rising – numbers of individuals without health insurance combined with many health care providers’ reluctance to see new patients with managed care or government insurance coverage make access to care shamefully elusive in the US.
- The aging US population requires considerably more attention to geriatric care for patients, to the career and workplace needs of an aging health care workforce, and to the reality that fewer new workers are entering the workforce.
- The increasingly multicultural population in the US raises questions about providing culturally competent health care to all patients and reaching out to pools of workers from populations underrepresented in the health care professions.
- The evolving role of health care consumers brings new demands for different and higher standards for health care services and qualities in health care professionals.
- The high -and in some cases rapidly growing - rate of preventable chronic disease across all populations suggests that new primary care competencies emphasizing prevention and health promotion are needed.

These trends translate to acute shortages in some professions (1), a growing disconnect between the demographic profile of the health care workforce and the country’s general population (and questions about capacity to deliver culturally responsive care and to reduce disparities in health) (2), ongoing geographic mal-distribution of practitioners (3), interest in complementary and alternative medicine (CAM) and integrated care (4), and the need for professionals competent in geriatric care and the treatment of chronic conditions (5).

Health services and workforce research focused on naturopathic medicine is relatively new and data are sparse. However, in contrast to health professions that are attracting fewer new members, the naturopathic medicine profession appears to be growing (6, 7). This growth, along with that of CAM generally, may offset shortages in some of the other professions and may hold keys to understanding why individuals are choosing CAM careers over mainstream health care work but more research needs to be done.

Naturopathic medicine may have even farther to go in terms of racially and ethnically diversifying the workforce than other professions. A 1998-1999 sample study of naturopathic physicians (or naturopathic doctors, “NDs”) in two states found fewer than 6% of the NDs to be “nonwhite” (8) compared to at least 25% of the US population (9). The decades-long efforts of allopathic medicine to increase the numbers of traditionally underrepresented minorities (not just “nonwhite” populations), resulting in only about 10.5% of medical students coming from these groups compared to 21% of the general population (10), may be difficult to match or exceed.

A 1998-99 sample study of characteristics of visits to CAM providers found that ND patients were more likely to be adult (non-children, non-elderly), female, and white than the general population (8, 11). However, whether NDs are evenly distributed geographically within a given state and the extent to which they are seeing underserved patients (including uninsured, patients covered by managed care or government insurance, and racial and ethnic minorities) is largely unknown.

Although the ability of NDs to provide care to underserved communities is compromised by lack of Medicare and Medicaid coverage for services, between 1990 and 2004, the number of public and community health clinics offering naturopathic services through affiliations with the four accredited naturopathic colleges grew to 30 (12). Beyond these affiliations, better data would help determine whether NDs are providing care to underserved communities - and the costs, extent of and barriers to that care - or are concentrating in areas where access to care is less of a problem but where out-of-pocket payment capacity makes practice possible. For purposes of comparison, in studies of various professions in California, it has been documented that allopathic physicians are even more likely than the population as a whole to choose large urban areas (3), chiropractors tend to practice in rural and suburban areas (13), and acupuncturists tend to practice in the state's wealthiest counties (14). For full integration, naturopathic medicine would benefit from demonstrating that it is more than an add-on option for people who already have access to health care. Health services research is also needed to assist in identifying the impact of policy barriers on access to naturopathic care and the possibility of changing policy to improve provision of services to communities in need.

We have very little data on the competencies of NDs to treat geriatric patients or the experiences of geriatric patients who see NDs for care. The growing cost of care for serious and debilitating disease calls for reassessing the competencies needed to not only treat, but also restore the health of this ailing population. For geriatric populations in particular, the impact of public and private coverage plan policies (including benefit limits, caps and coverage restrictions) on ND services, patient utilization, and referral patterns between conventional and ND insured providers would be valuable.

Key Naturopathic Ideas that Differ from Standard Conventional Medicine

The relative youth, model of care, and unique position of naturopathic medicine in the US provides it with different opportunities compared to mainstream medicine. For example, electronic databases and online capabilities can now easily permit regulatory agencies to query and track practitioners and to provide useful practice information to consumers, employers and insurers. In viewing itself as complementary and alternative to allopathic medicine on the road to integration, naturopathic medicine need not meet all or even most of the health care needs of the country but can focus on determining its greatest contributions as part of an integrated system and on ensuring that naturopathic physicians have the competencies to meet those needs. This shift in perspective from a mere head-count of the workforce to assessing the competencies and contributions a profession brings to an integrated delivery system is revolutionary and welcome.

Priority Research Questions for the NMRA

To better integrate naturopathic medicine into mainstream health care, third-party payers, policy makers, naturopathic medical leaders, consumers and other health care professionals need information about the work of naturopathic physicians (modalities and competencies), costs of that work, how care is accessed and how accessible care is (workforce numbers, demographics and practice patterns), how naturopathic medicine compares to other health care services and how it can be integrated into current systems. In particular, some research areas are priorities (not necessarily in order):

1. Expand geriatric and chronic care research, education and practice.
2. Develop culturally appropriate care, including reaching out to Latino, African-American and Asian communities, both as patient populations and as potential workforce pools.

3. Assess and expand public health and population-based research and education in schools, including curriculum development (practicing in public health settings; providing care to the underserved) and program development to produce researchers with public health skills.
4. Establish ongoing mechanisms to collect workforce numbers, demographics and practice patterns on naturopathic physicians. An excellent, low-cost model is the state regulatory boards that query their licensees at every renewal period.
5. Continue to research and widely publish findings regarding the safety, efficacy, and costs of naturopathic physicians and the modalities they employ.
6. Take advantage of variations in laws and programs among and within the states (e.g., Veterans' Administration sites, public health facilities, and the Health Professional Loan Repayment and Scholarship Programs) for natural experiments to explore practice models that support or hinder integrated, high quality health care.
7. Document capacity of NDs to work in integrated teams of health care professionals, such as the prototype Community Health Centers of King County, Washington.
8. Develop new and expand existing demonstration projects that show the value of integrating naturopathic medical services into conventional care settings.
9. Develop research projects to document and test the application of ND prevention, health promotion, and cost-effectiveness to geographical areas or populations with disparate/high rates of disease.

Comments on the Prioritization Criteria

During the process of setting the Naturopathic Medicine Research Agenda, six criteria were offered as a guiding framework for determining research priorities (15). The criterion most useful in determining health services and workforce research areas is #2 (public health). With access to care being perhaps the most pressing public health issue today, the research areas identified above are geared to collecting baseline and ongoing data, which, if acted upon appropriately, would improve access to care generally, and access to competent, integrated, culturally responsive care in particular. In addition, Criterion #4 (methodological evolution and sequencing) keeps in mind the need to grow the naturopathic profession evenly across fields (practice, teaching, research, policy) and to diversify the profession. Criterion #5 (naturopathic concepts with revolutionary potential) brings attention to naturopathic medicine's perspective of focusing on competencies within the profession and integration of the profession into mainstream health care. Criterion #6 (existing infrastructure and fundability) forwards the potential of licensing systems to gather data at minimal cost and natural experiments that effectively test and compare different practice models. While criteria #1 and #3 focus on disease-based clinical research and are less relevant for health services and workforce research, they too remind us of the need to ensure that the profession develops the capacity to actually conduct, evaluate and incorporate clinical research findings into practice. Finally, all the criteria could be relevant to health services and workforce research in the context of specific disease priorities.

Comments on the Draft NMRA Model/figure, and Priorities Overall

Although the draft NMRA model and priorities are focused on STEPS to a Healthier US diseases or conditions, they are also flexible and inclusive enough to incorporate health services and workforce research questions generally and/or with certain considerations as discussed above. This reality raises the question, however, whether the spirit of the model is to exclude all research questions that are not specifically grounded in clinical disease/condition templates or if the model is meant to be flexible and inclusive of other pressing research needs. We hope and trust in the latter.

In addition, we understand that the model is an evolving document that will benefit from additional context and perspective. Rather than crafted like a grant-making entity's funding strategy, it will be most valuable as a consensus document regarding a research agenda issued by leaders of the profession. As such, we hope final versions will include attention to how the agenda could be implemented, how data and findings from the research would be incorporated into practice,

possible resources for funding, and guidance for researchers as they seek to balance the profession's goals with funding realities and regulatory parameters.

Individual Interest or Priority

Workforce and health services concepts deal with people. Integration of CAM, including NDs into "mainstream" is not just about financing, delivery systems, and evidence-based research but also about how people work together. As such, we need to know who NDs are (demographic profiles, geographic distribution, cultural competence), how NDs work (practice patterns: solo or teams, private offices or institutions; with other CAM providers or mainstream practitioners; insurance and/or medical group affiliations), with whom they can work best (training experiences with other health care professionals; interdisciplinary relationship analyses; practice setting studies), and how those teams of people improve health of patients and the public. In addition to items recommended above, a key, achievable approach would be to establish demonstration projects to research health services and workforce questions in integrated healthcare clinics at VA hospitals, and in rural and urban community public health facilities affiliated with the naturopathic medical colleges.

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15. The six criteria are: 1) Focus on diseases with the highest burden of human suffering; 2) Focus on issues with the greatest public health significance; 3) Evaluate treatments first which have the greatest likelihood of reducing the burden of suffering – the low hanging fruit; 4) Focus on methodological evolution and the necessary sequencing of studies to achieve long range goals; 5) Investigate naturopathic concepts with revolutionary potential for wide-ranging benefit; and 6) Attend to questions for which infrastructure exists or can be quickly built and that are fundable.

APPENDIX F: Naturopathic Medical Science: Examples of Clinical Protocols and Algorithms

Editors note: In presenting these guidelines and algorithms, we wish to emphasize that each of these is one of many possible versions. The challenge in the near term will be to establish definitive and authoritative versions for testing in whole-practice intervention studies.

Naturopathic Intervention for Rheumatoid Arthritis

Carlo Calabrese, ND, MPH

In 2002, a qualitative and a quantitative exploration was launched to develop a 'best practice' naturopathic treatment protocol for rheumatoid arthritis (RA). A group of five naturopathic physicians from Oregon and Arizona (Southwest College of Naturopathic Medicine, Phoenix) was empaneled and led in a modification of the nominal group technique of decision-making (Jones 1995). Each participant was state licensed, met the membership requirements of the American Association of Naturopathic Physicians (AANP), and had clinical experience in rheumatoid arthritis and/or research.

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Before meeting to discuss the problem, a treatment plan for RA patients was solicited from each panel member. These were shared with all members in advance of a day-long meeting in Portland at NCNM in October 2000, at which point a draft intervention was drawn. For this intervention, the naturopathic physicians were told to shape the protocol according to their opinions of naturopathic 'best practice' and congruence with the naturopathic body of knowledge (i.e., safety and effectiveness from a naturopathic perspective). This protocol was then reviewed and commented on by the members for two more rounds. An outline of the essential elements of the intervention is in italics below. The intervention protocol consists of a core set of therapies appropriate for all patients with confirmed RA combined with a short treatment algorithm. The Core Therapy has lifestyle guidance as to rest, exercise, psychospiritual care, stressors, specific diet changes, and dietary supplements to address inflammation and joint preservation. The Therapy Algorithm with particular treatments for different patients is driven by their individual medical histories, disease presentations, and laboratory tests.

A. Core Therapy for All Participants

Adequate rest: 8 hrs men, 9 hrs women. If sleep disruption, treat.

Exercise: Breathing exercises; Tai chi/ROM/stretching or equivalent

Psychospiritual self-care: Affirmations, meditation or prayer related to self-efficacy and stress management.

Diet therapy:

Low fat, especially lower saturated fat; no trans fatty acids.

Increase coldwater fish consumption (not fried)

2 – 3 qts good water/d. (filtered, spring, distilled, not tap, non-carbonated)

Eliminate/reduce in order: 1. Dairy, 2. wheat, 3. peanut, 4. soy, 5. corn. Test if patient refuses to alter diet.

Challenge nightshades.

Emphasize fresh non-starchy vegetables and fruit, 6 servings/d
 Eat at least 3x/day
 Not more than 12 oz coffee/d. Green tea is the recommended beverage.
 Not more than two alcohol drinks/day

Supplements:

Multivitamin/mineral (several acceptable options)
 Omega 3 fatty acids (fish oil with vitamin E) 2 – 3 gms in divided doses
 MSM 1/4 – 1/2 tsp bid phased in due to possible GI effects
 Glucosamine sulfate 1000 mg bid [with a diabetes caution]
 Antioxidant combination: Flavonoids (OPCs 250 mg dose), vitamin A (10,000u), vitamin C (2000 mg), vitamin E mixed tocopherols (800 IU), n-acetyl cysteine (500 mg bid), Selenium 200 mcg, mixed carotenoids (20,000 IU)

Avoidances:

No tobacco
 Avoid NSAIDS which interfere with cartilage healing. Taper off NSAIDS.

B. Therapy Algorithm

Therapeutic changes based on presentation

Depending on severity (pain), the naturopathic anti-inflammatory and analgesic therapies below may be initiated in the following order:

1. Topical Capsaicin PRN
2. Enzymes (mixed proteases) not with food. Wobenzyme 3-4 tid between meals.
3. Botanical therapy including one or more of: Trypterigium, green tea, Coleus, Cat's claw (Samento), Yucca, curcumin, ginger, Boswellia, or the mussel extract Liprinol.
4. Medrol or hydrochloroquine may be acceptable drug therapy.

Therapeutic changes based on testing results

The following baseline tests are done on all subjects:

Chemscreen (include lipids, TSH, free T4, CRP, ferritin)
 CBC (w diff), sed rate, ANA, RF
 Cortisol. Treat appropriately if abnormal.
 Indican (indole); marker as well as secondary outcome marker.
 Challenge nightshades. Eliminate nightshades if positive.

Medical history-driven laboratory tests

1. If digestive difficulties (bloating after eating, diarrhea, constipation), exposure to GI infection, or extensive antibiotic use: do complete digestive stool analysis (CDSA) including Proteus. Treat appropriately.
2. If other allergic/inflammatory conditions, do intestinal permeability test. If positive, treat with gamma oryzonal, glutamine, butyric acid, NAG
3. If history of onset of RA with infection or post vaccine, evaluate for mycoplasma, EBV, amoeba/parasites. Treat if positive.
4. If history of exposure to heavy metals, do DMSA/24 hr urine. Treat to detoxify.

Patient choice-driven lab tests

- If patient refuses elimination trial, test for food sensitivities. If sensitivities, reinforce elimination.
- If participant refuses to eliminate and challenge nightshades, test for nightshades food sensitivity. If sensitivities, reinforce elimination.

Treatment options for food allergy may include sodium cromolyn, Urtica, Ammi visnaga (Khella).

C. Naturopathic Medicine

Naturopathic medicine is considered to be one of the CAM professional practices. It is practiced as either a complement or an alternative to conventional medicine under different circumstances. The American Association of Naturopathic Physicians (AANP) describes the practice as a primary healthcare profession which functions to promote health, and to prevent, diagnose, and treat disease. As of this writing, a naturopathic physician must be licensed to practice in 11 states and three Canadian provinces. The license typically is broad, allowing naturopathic doctors to diagnose any disease by a wide range of diagnostic means and to treat using any natural means, which in some states, including Oregon, is interpreted very broadly. Many consider licensed naturopathic physicians to be the most broadly trained among CAM practitioners; they may be the best prepared for integration into the mainstream healthcare system because of their training in basic and diagnostic biomedicine and their broad range of practice in CAM therapeutics. A naturopathic physician arrives at a functional and constitutional assessment as well as a disease diagnosis. Treatment is individualized for the particular patient's condition rather than for a disease entity. Almost universally in naturopathic medicine, an individualized combination of treatments is applied with the objectives of healing the whole person and of maximizing constitutional potential. The expectation in RA is that by avoiding suppression of symptoms (which leads to further physiological dysfunctions) and individualizing treatment to the patient, a higher proportion of patients will completely respond to therapy. Since the lifestyle changes are expected to be generally salutary and only tolerable and non-toxic supplements are retained in the regimen, this may amount to a higher functional cure rate. Therapeutic strategies may include addressing the antigenic burden, impairments in the regulation of T-cell subsets, influences of the gut and its microflora, hormonal alterations, chronic exposure to environmental toxins, and total level of oxidative stress. Treatments are classically focused on five therapeutic "modalities": nutrition (including both diet changes and dietary supplements), botanicals, homeopathy, psychospiritual approaches, and physical medicine. Except for homeopathy (which will not be used in this study), data supporting the use of each of these modalities in RA is substantial.

Controlled clinical trials, though usually small, provide evidence of some degree of rigor supporting the use of various individual naturopathic interventions in RA. In nutrition, both single dietary supplement agents and specific diet practices have shown benefit in RA. To begin with diets, a vegan, gluten-free diet improved symptoms and laboratory markers but not joint destruction compared to a normal diet among RA patients (Hafstrom et al., 2001). In another single blind trial, a vegan diet following a short fast in a randomized study of 53 RA patients showed that all clinical variables and most lab variables improved with the regimen (Kjeldsen-Kragh et al., 1992). A further recent study of a four week, low fat, vegan diet also showed reduced symptoms in a controlled study of 24 patients with moderate to severe RA (McDougall et al., 2002). A change in fecal bacteria associated with an uncooked vegan diet rich in lactobacilli was associated with improvements in RA activity compared to an omnivorous diet (Peltonen et al., 1997). In a four week trial, a hypoallergenic diet composed of artificial peptides was associated with improvements in pain and the quality of life score compared to a conventional diet (Holst-Jensen et al., 1998). Characteristics common among these diets include their hypoallergenicity, lowering of saturated fat (affecting the arachidonic acid and prostaglandin pathways to immune modulation), and higher antioxidant content (Hanninen et al., 2000). These characteristics are common to therapeutic strategies among naturopathic physicians in autoimmune diseases.

Clinical evidence with specific dietary supplements is substantial. A study of 30 subjects who received conventional therapy or conventional therapy plus antioxidants showed faster improvement with antioxidants (Helmy et al., 2001). A vitamin D analogue has also shown benefit (Andjelkovic et al., 1999) in RA in trial while vitamin E has shown mixed results (Edmonds et al., 1997). Omega-3 fatty acids, commonly from fish oils, have repeatedly been shown in small trials to benefit RA (Astorga et al., 1991, Geusens et al., 1994, Kjeldsen-Kragh et al., 1992, Nielsen et al., 1992, van der Tempel et al., 1990). It has been shown these effects are independent of the vitamin E that commercial fish oils contain. One study showed a combination of fish oil and evening primrose

oil (containing gamma linolenic acid) reduced the need for NSAIDs (Belch et al., 1988). Other sources of alpha and gamma linolenic acids have also shown positive results in RA (Leventhal et al., 1993). Oral proteolytic enzymes have shown positive results in some studies in reducing pain in rheumatic diseases (Klein and Kullich 1999). Two hypothesized mechanisms for this effect of enzymes in RA are current: first the reduction in circulating immune complexes (Kullich and Schwann 1992) and second, a decrease in TGF-beta (Desser et al., 2001).

Botanical supplements also have a role in naturopathic care of RA. Willow bark extract (not just its salicylates) have shown benefit for pain in rheumatic conditions, often with equivalence to NSAIDs (Chrubasik et al., 2001). Other botanicals with clinical trial evidence for a supportive role in RA include *Melothria madraspatana* (Ramakrishna-macharya et al., 1996), *Podophyllum* derivatives (Larsen 1989), *Tripterygium wilfordii* (Tao et al., 1989). Though *Tripterygium* has had a reported association with adverse events, this association is with purified fractions rather than with the whole herb. Although the only controlled clinical trial with *Boswellia serrata* showed no differences from placebo in 37 patients, two open trials show improvement and its clinical reputation among NDs remains strong. Indeed, *Boswellia serrata* showed strong *in vitro* evidence of two pharmacological mechanisms that treat RA (specifically, inhibition of 5-lipoxygenase reducing biosynthesis of leukotrienes (Safayhi et al., 1992) and inhibition of matrix metalloproteinase-9 (Safayhi et al., 1997)). It has also helped suppress elevated glycohydrolases and cysteine proteinases in arthritic animals (Reddy et al., 1987).

Useful topical agents that naturopaths might employ and that have trial evidence in RA include dimethylsulfoxide (DMSO; Abdullaeva and Shakimova 1989) and capsaicin (Deal et al., 1991). Due to the inconvenience of DMSO, many practitioners have changed to the oral use of its metabolite, methylsulfonyl methane (MSM), which is purported to work by the same mechanisms as DMSO, but which does not yet have much data available in RA.

Naturopaths might commonly prescribe gentle exercises, such as Tai Chi, for arthritic patients to preserve range of motion and stimulate circulation. Again, evidence from controlled trials validate versions of this approach in RA with a dance-based exercise (Noreau et al., 1995) and at-home physical therapy (Lineker et al., 2001). Another physical medicine interventions that naturopaths might use is hydrotherapy. In one trial with RA patients, hydrotherapy showed larger and longer-lasting improvements in the Arthritis Impact Measurement Scales (AIMS2) than either exercise or relaxation though patients in all treatment groups improved (Hall et al., 1996). Recently more popular among some practitioners, the use of magnets has also shown benefit in a double-blind trial in 64 RA patients with knee pain (Segal et al., 2001).

Epidemiological work implicates lifestyle choices such as the use of tobacco (Albano et al., 2001) and coffee. Overall coffee consumption (Heliovaara et al., 2000) as well as decaffeinated coffee (Mikuls 2002) have been associated with an increased risk of RA. Coffee and tobacco use are among the lifestyle avoidances that naturopaths may prescribe in cases of RA. Naturopaths will also be attentive to sleep quality which shows disturbances in RA patients (Belza 1995, Pollmacher et al., 2000).

Finally, a holistic approach such as that of naturopathic medicine calls for enlisting the patient's psychological and spiritual resources for maximizing function and healing. Positive clinical evidence for such interventions includes cognitive-behavioral therapy (with biofeedback), which led to lower clinic visits and hospitalizations (Young et al., 1995), and within-person intercessory prayer, which was associated with overall clinical improvement (Matthews et al., 2000). In the latter study, no additional improvements resulted from supplemental distant intercessory prayer. A change in "self-efficacy," induced following a stress management program, showed improvements in pain, health-related quality of life, and disease measures (Smarr et al., 1997). Relaxation training was associated with improved self-care, recreation, and both upper and lower body function compared to a control group (Lundgren and Stenstrom 1999). Another trial showed that a visualization technique was superior to relaxation training (Geissner et al., 1994).

While these trials specific to RA show effects with single agents or practices, NDs expect better results with combinations of treatments shaped for the patient. Beyond these studies, numerous controlled clinical trials show many naturopathic modalities benefit other arthritides, autoimmune diseases, and inflammatory conditions which may be relevant for treating RA.

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Naturopathic Medicine: A Complementary Treatment for Multiple Sclerosis

(Study findings are still under analysis.)

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Background and Significance

MS is an often disabling disease of the central nervous system (CNS) that affects over 350,000 Americans. MS is most likely an immune mediated disease in which CD4+ Tcells, macrophages, and soluble mediators of inflammation cause multi-focal demyelination and axonal injury (1,2). MS causes a variety of symptoms depending on the location and severity of lesions within the CNS. Common symptoms include generalized fatigue, partial or complete paralysis of the legs and arms, spasticity, imbalance, urinary urgency and incontinence, constipation, sexual dysfunction, tremor, loss of vision, double vision, cognitive impairment, and depression. About 85% of patients begin with a relapsing remitting clinical course in which there are relapses or attacks of MS lasting days to weeks followed by improvement and stability lasting months to years. About 50% of patients with relapsing remitting MS develop secondary progressive MS within 10 years of onset of MS; during this phase of the illness, there is steady, progressive worsening of symptoms and patients may continue to have relapses. About 15% of patients have primary progressive MS in which there is progressive worsening from the onset of the illness without relapses ever occurring.

Treatments for MS typically are divided into disease modifying therapies, which seek to alter the course of the illness, and therapies designed to control particular symptoms. Current disease modifying therapies include corticosteroids to treat relapses or attacks of MS and human recombinant interferon-beta and glatiramer acetate, which have been shown to be partially effective in decreasing disease activity in relapsing MS (3,4). There are a number of therapies designed to help alleviate symptoms, such as oxybutinin to control urinary urgency, amantadine to improve fatigue and baclofen to reduce spasticity. Conventional therapies for MS typically entail using one of the disease modifying medications coupled with one or more symptomatic therapies. Despite the availabilities of these conventional treatment modalities, many patients still become disabled from MS and very often have symptoms that decrease their quality of life.

CAM and Naturopathic Therapies for MS

A large and increasing proportion of people in the US are using complementary and alternative medicine (CAM)(5). In a study done in Colorado, 30% of MS patient's surveyed sought treatment from an alternative practitioner (6). Importantly, MS patients that use CAM generally report that the CAM approaches improve symptoms and quality of life and have few side-effects (7). Few of the alternative therapies have been proven efficacious for treating MS although some individual approaches appear to have potential benefit.

A number of alternative therapies that are common among naturopaths, and sometimes fundamental to their practices, have been evaluated by clinical trial and have been shown to have benefits for MS patients. Alternative therapies that show the most promise, as evaluated by clinical trial, include diet, exercise, stress reduction and essential fatty acid supplementation. Lifestyle changes such as diet, exercise and stress reduction have shown a positive trend in improving the sense of well being and quality of life for MS patients (8,9,10,11). One MS specialist has evaluated the long

term effects of MS patient's adherence to a low fat diet (dietary fat equal or less than 20 g/day) and essential fatty acid supplementation regimen showing less mortality and disease deterioration in the treatment group although there was no placebo control group included in this study (9). Outcomes of the four studies on the effects of exercise on MS reviewed here show an overall positive improvement on well-being and quality of life measures (8,10,11,12). One pilot study showed a significant improvement in muscle strength, fatigue, work and power in MS patients after a 10-week aquatic fitness program (8). A study evaluating the effects of aerobic training on gait abnormalities found only minimal effect on gait abnormalities (12). Patients with chronic disabilities (chronic pain, chronic obstructive pulmonary disease, and MS) went through eight 2-hour stress management training programs. After completion of the stress management training there was a significant decrease in state anxiety and somatization. The investigators reported that the subjects experienced less preoccupation with physical symptoms, this study was not placebo controlled (13). Clinical trials treating MS patients with either essential fatty acid supplementation or increased dietary essential fatty acids have reported mixed results (14,15,16,17,18). A re-analysis of three double-blind placebo-controlled trials of linoleic acid supplementation report a small but significant decrease in disability for patients with minimal or no disability at baseline and a significant reduction in the severity and duration of relapses for the treatment group, there was no change in number of relapses of the treatment group compared to controls (18). All of the treatments above are within the scope of practice and philosophy of naturopathic physicians. Clinical trial evidence of the benefits of single naturopathic therapeutic interventions for MS are thus fairly frequent in the literature yet scientific evaluation of naturopathic medicine as a multi-modality system of treatment in MS is lacking.

Naturopathic Medicine (a whole system theory of treatment)

In the US and Canada, naturopathic medicine is a healthcare profession which functions to promote health and to prevent, diagnose and treat disease. Naturopathic medicine may be chosen as a primary health care alternative or as a complement to conventional medicine. Currently, there are 11 US states and three Canadian provinces which require a license for naturopathic physicians to practice. About 1,700 licensed naturopathic physicians who have been trained at in-residence four-year, post-baccalaureate institutions have met the licensing standards.

This study proposes to evaluate treatments used among naturopathic physicians meeting this educational standard. Such naturopathic physicians are well prepared to integrate into the mainstream healthcare system for they are both broadly trained in a range of alternative modalities as well as in the basic and diagnostic sciences of biomedicine. Naturopathic practice is guided by many of the same principles as a conventional medical practice such as: utilizing methods that minimize harm, identifying and treating the underlying cause of disease and using methods that would aid in disease prevention. A naturopath believes that organisms are inherently self-organizing and it is this process of living systems which establishes, maintains and restores health. It is the naturopathic physician's role to support, facilitate and augment this process by identifying and removing obstacles to health and recovery, and by supporting the creation of a healthy internal and external environment. A naturopathic physician recognizes the harmonious functioning of all aspects of the individual as being essential to health therefore environmental, social, physical, genetic, mental, emotional and spiritual aspects of an individual are considered in the restoration of health. Naturopaths are trained in a number of "modalities" or treatment categories: botanicals, diet, nutritional supplements, homeopathy, physical medicine (physiotherapy, hydrotherapy and manipulation), and counseling/psychotherapy.

A naturopath, as a part of a vitalistic tradition, may arrive at a constitutional assessment as well as a disease diagnosis. Treatment is individualized for the particular patient's condition and capacities rather than for just a disease entity. A combination of treatments are frequently applied and are adjusted over time as a patient's condition changes. Naturopathic medicine shares key characteristics with other whole systems of medicine such as traditional chinese medicine, ayurvedic medicine, homeopathy and other traditional medicines which include a global approach to diagnosis and treatment of an individual's condition, use of multi-modalities for treatment, and individualized

rather than diagnosis-based treatment. The inherent complexity of these systems of treatment make them difficult to evaluate scientifically.

There are only a small number of clinical trials evaluating the safety and efficacy of individualized treatments for acute or chronic conditions (19,20,21). Although these trials were able to evaluate individualized treatment, they tested a single treatment modality (homeopathy, chinese herbal medicine). There have also been very few studies evaluating the efficacy of alternative multi-modality treatments, e.g., lifestyle changes which incorporate diet, exercise, stress reduction and psychological support (22,23,24). These studies showed significantly positive outcomes of the combined effects of diet, exercise and stress reduction in altering the course of disease, although these treatment regimens were not individualized. To date there has been no scientific evaluation of the safety and effectiveness of naturopathic medicine that has incorporated the fundamental clinical concepts of treatment individualization and multi-therapy for MS.

Naturopathic Treatment Plus Usual Care

All subjects randomized to the naturopathic treatment intervention will undergo eight visits with Lynne Shinto, ND following their baseline assessments. The course of visits for naturopathic treatment over this six-month period will model the care given in most naturopathic practices. Subjects will be seen at the MS Center of Oregon's outpatient clinic at Oregon Health and Science University, Portland.

The first visit will last approximately 90 minutes and will include an introduction to naturopathic medicine, a review of the patient's neurological and medical history, a psychological, social and spiritual history, constitutional history, assessment of diet, and brief physical exam. At the first visit all subjects will be instructed on the naturopathic treatments and be given a one month supply of supplements. The naturopathic treatments for the naturopathic intervention include: individualized diet intervention, vitamin and mineral supplementation, 1 mg/ml B12 i.m., 1x/wk, and counseling (See "Naturopathic Treatments"). If the subject is currently taking any of the supplements listed in the "Nutritional Supplements" section below, they will be asked to discontinue using those supplements. Subjects may continue taking any supplements that do not overlap with the supplements we are providing as long as taking them along with the study supplements does not create any known health risks or serious adverse reactions. A four-day Diet Recall will be given to subjects at this visit to be filled out by the subject before the second visit. Dr. Shinto will go over the four-day Diet Recall with the each subject to insure the subject's understanding on how to fill out the recall form.

The second visit will occur one week after the first visit and will include a review of the diet recall with an assignment, by Dr. Shinto, of a diet intervention. Dr. Shinto will also go over the treatment intervention with the subject, perform brief physical exam if necessary, and do counseling based on the questions set at the first visit.

The third visit will occur two weeks after the second visit and **visits 4-8** will occur at monthly intervals (See Table 1. Schedule of Evaluations). Visits 2-8 will follow the same format as described for visit two and will last one hour. Supplements for the naturopathic intervention will be dispensed monthly by the Dr. Shinto. Each month the subjects will be asked to bring in their supplement bottles, whether they are empty or not, so that Dr. Shinto may record how many of the supplements they have taken during the month. All subjects will continue their usual care for MS while receiving the naturopathic treatments.

Naturopathic treatments

Nutritional Supplements

- Vitamin E 400 IU/cap ; 1 cap 1x/day with meals
- Fish oil 1,000 mg (EPA 300 mg, DHA 200 mg)/cap; 1 cap 2x/day with meals
- Multi vitamin and mineral without iron; 2 caps 2x/day with meals

- Alpha lipoic acid 200 mg/cap; 1 cap 1x/day with meals
- Buffered ascorbic acid 1000 mg/cap; 1 cap 1x/day with meals

Weekly intramuscular B12

Intramuscular methylcobalamine (vitamin B12), 1 mg/ml/week. Subject should inject B12 at least one hour before or after taking nutritional supplements.

Dr. Shinto will perform the first B12 injection and will instruct the subject and/or a partner, relative, or friend on how to administer the intramuscular injections.

Diet intervention

The level of diet intervention will be determined by evaluation of the four-day Diet Recall on the second naturopathic visit. For each naturopathic visit the subject will be asked to bring in a completed diet recall to check compliance on the diet.

Level I simple intervention

The subject will work on limiting trans fatty acids in the diet (e.g., by decreasing or eliminating consumption of packaged and processed foods). The subject will work on decreasing the amount of artificial sweeteners consumed, coffee and alcohol consumption, and cigarette smoking. The subject will also work on increasing water consumption (ideal would be 6-8 cups/day).

Level II moderately simple intervention

Level I intervention plus the subject will reduce consumption of red meat to two 4-6 oz. servings/week (substitute fish or skinless chicken) and increase fresh vegetables in their diet to six ½ cup servings per day.

Level III moderate intervention

Level II intervention plus the subject will be asked not to consume refined sugar, fried foods, and processed or packaged foods. This diet will require that the subject not consume coffee and alcohol.

Level IV advanced intervention

Hypoallergenic Diet (see handout for this). This type of diet is also called a food elimination and challenge diet and will be explained in detail to the subject if they are assigned to this diet.

Counseling session (up to 20 mins/visit)

Questions asked at first visit which will be address over the eight visits:

Do you have a spiritual practice: If so what does this practice mean to you?

Do you have any fears? Do you have any fears about your MS disease process?

What are your views on faith and healing?

MS-Focused Education Sessions with a Nurse Plus Usual Care

The purpose of this group is to account for outcomes that may occur as a result of extra attention or from doing something “new.” Subjects randomized to this group will receive their usual care for MS plus eight visits with a nurse. The frequency of these visits are matched to the naturopathic intervention visits. Subjects in this group will not be wait-listed to the naturopathic intervention group as these subjects will be receiving an additional “attention” intervention from a nurse, which is different from their usual care. At each visit the subjects will receive an educational pamphlet published by the National MS Society containing information about MS. The subjects will review the information in the pamphlet with the nurse during these sessions. The nurse will instruct each subject that the intent of the session is to focus on the information contained within the pamphlets. If subjects have questions about other aspects of their care, such as advice on medications, specific interventions for MS-related symptoms or alternative therapies, the nurse will instruct the subjects to contact their physicians for answers to these types of questions. Subjects will continue their usual care for MS while participating in this intervention.

Because of budget and resource constraints, the full naturopathic intervention will not be offered to this group but, as compensation for participating in the study, all subjects randomized to this group will be offered a 6-month supply of the following supplements:

- Vitamin E 400 IU/cap; 1 cap 1x/day with meals
- Fish oil 1,000 mg (EPA 300 mg, DHA 200 mg)/cap; 1 cap 2x/day with meals
- Multi vitamin and mineral without iron; 2 caps 2x/day with meals
- Alpha lipoic acid 200 mg/cap; 1 cap 1x/day with meals
- Buffered ascorbic acid 1000 mg/cap; 1 cap 1x/day with meals

Any supplements subjects are taking that do not overlap with the supplements we are providing can be continued throughout the study as long as taking them along with their study supplements does not create any known health risks or serious adverse reactions. If a subject is taking any of the supplements listed above when they receive their 6-month study supply, the subject will be asked to discontinue using supplements that overlap with the study supplements for six months. Adverse events will be monitored for the six months of supplementation as in the “naturopathic” intervention, by a monthly phone call.

Usual Care Alone

After randomization the usual care only group will continue their standard medical care for six months. All subjects in this group will be placed on a “wait-list” and will be offered the naturopathic treatment after the six-month outcome assessment.

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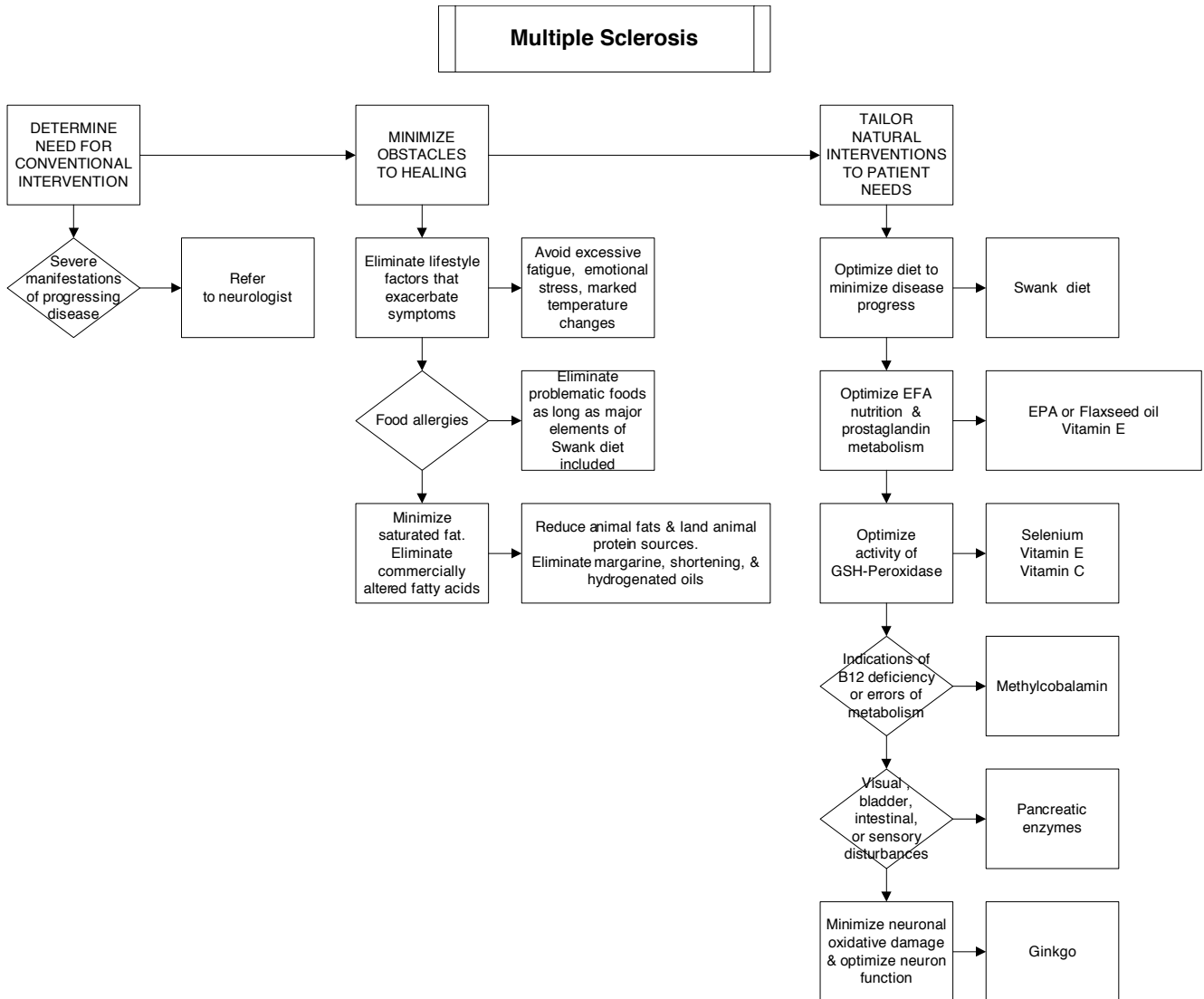
Multiple Sclerosis:

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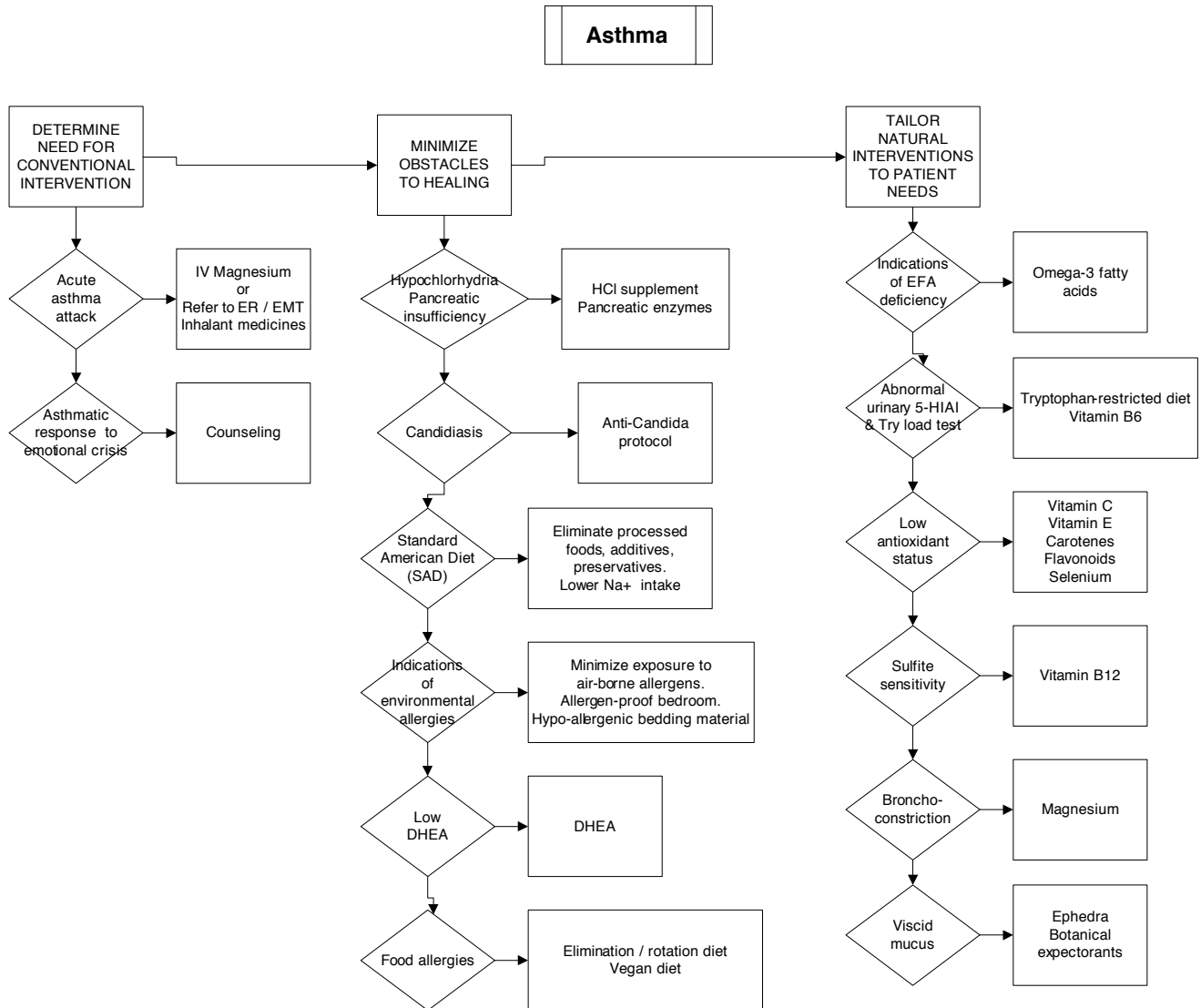
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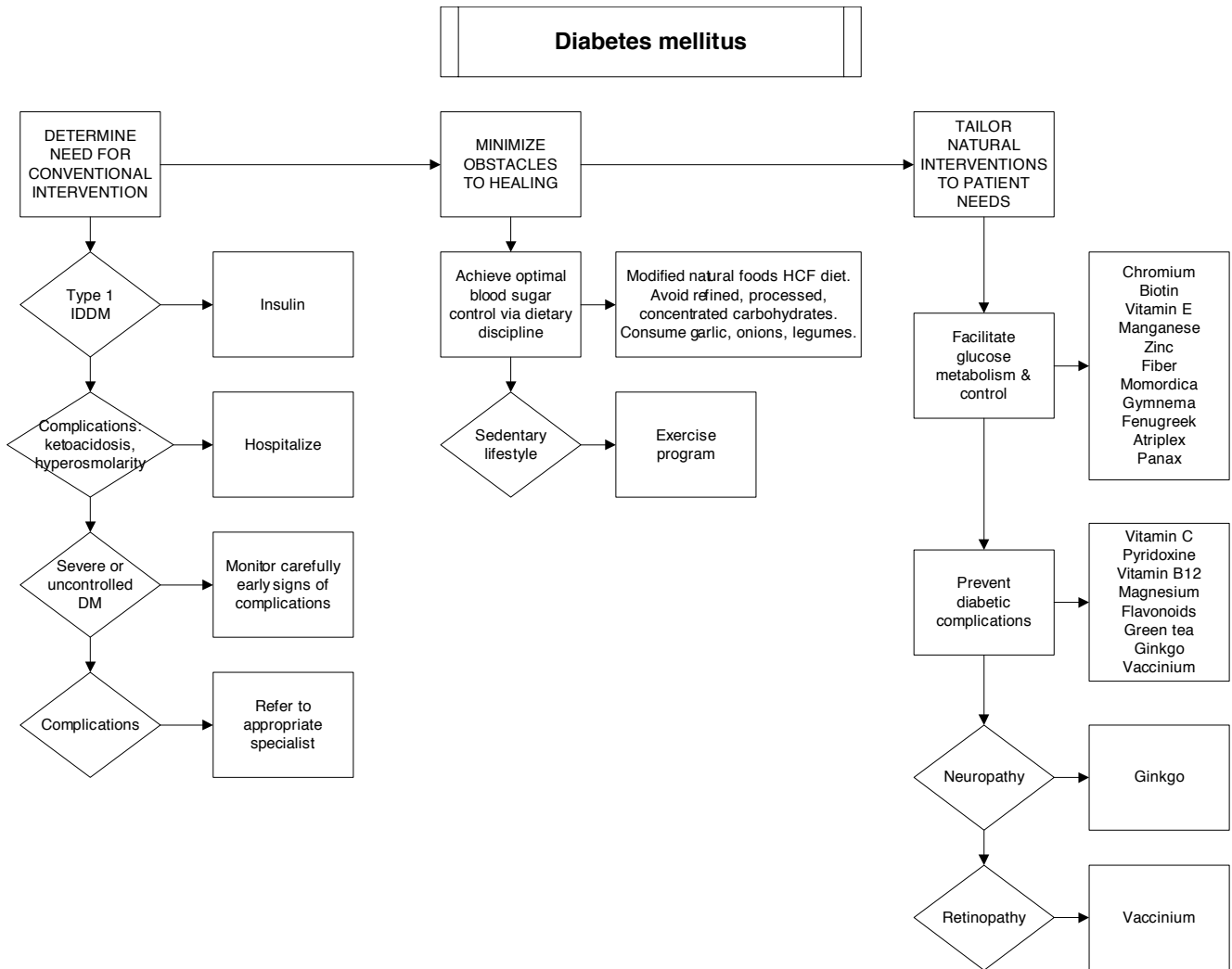
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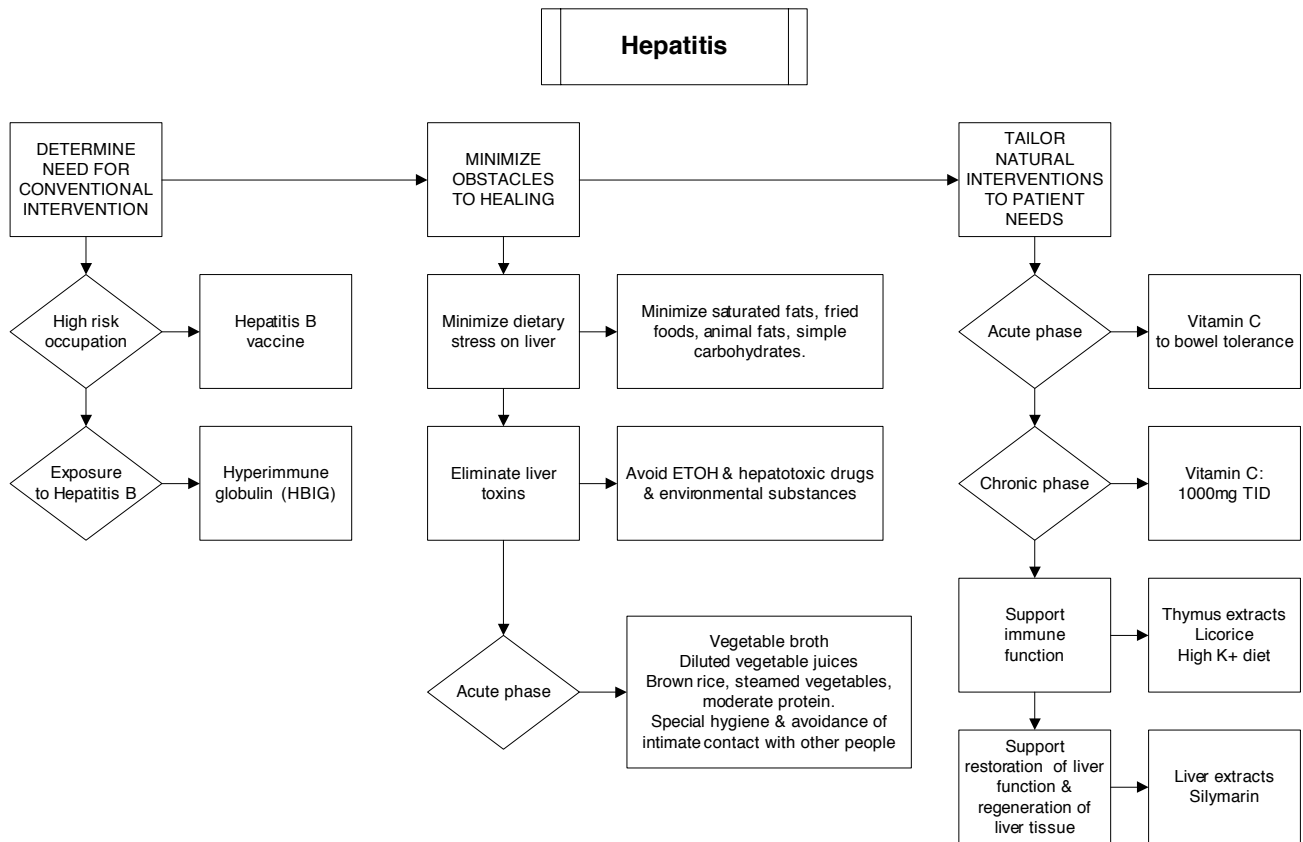
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APPENDIX G: Presentations and Publications by the NMRA Core Team Arising from the 2002-2004 NMRA Process

The North American Naturopathic Medical Research Agenda (2010) Queries from the Heart of the Medicine AANP Panel Presentation & Discussion August 2003, AANP Annual Convention, Portland, Oregon

Leanna J. Standish, ND, PhD
Carlo Calabrese, ND, MPH
Pamela Snider, ND
Konrad Kail, ND, MPH
Edward Mills, DPH
Heather Zwickey, PhD
Peter Martin, ND, DC,
Stephen Myers, PhD, BMed, ND

Objective

- Engage the naturopathic profession in development of the North American Naturopathic Medical Research Agenda
- Present and communicate NMRA's draft working agenda to AANP members
- Present highlights and priorities from college research forums
- Solicit responses, input and guidance on this Draft Agenda from members to be reviewed and incorporated, particularly from practicing clinicians

Methods

Plenary Session Panel-presentation ending with open mike, open survey-comments solicited from participants.

Results

Building participation and consensus in our profession for a scientific agenda for naturopathic medicine. Input will be considered by the NMRA Work Group and will influence the *Naturopathic Medical Research Agenda*.

What are the research priorities for naturopathic medicine for the next decade? What promise does naturopathic medicine hold for public and community health and cost effective healthcare? What research models will be effective in studying the most central questions for naturopathic medicine? How will the federal government effectively integrate complementary and alternative medicine with conventional and public health services and education? What is the nature of the healing process-salugenesis and the healing and transformative power of nature? What are the core assumptions of naturopathic philosophy which invite scholarly and scientific inquiry in order for the profession to determine what does and doesn't work clinically and why?

Through a grant from National Institutes of Health National Center for Complementary and Alternative Medicine, accredited North American naturopathic colleges are creating a research agenda to guide and plan the next decade of naturopathic medicine research. The Naturopathic Medical Research Agenda co-investigators and Work Group members will present to the profession a discussion draft for the Agenda and highlights from Research Forums held at the Naturopathic

colleges this spring. An open mike session will follow where the Research Team invites queries and research priorities where from the heart of the medicine; with an emphasis on practicing clinicians.

The Naturopathic Medical Research Agenda: APHA Panel Presentation & Discussion October 2003, American Public Health Association, San Francisco, California

Leanna J. Standish, ND, PhD
Carlo Calabrese, ND, MPH
Pamela Snider, ND
Bastyr University

Premise

The systematic scientific investigation of naturopathic medicine, an increasingly popular option for consumers, is a public health necessity. An interprofessionally-developed research agenda for naturopathic medicine will have a positive impact on health in the US.

Objective

Engage the American Public Health Association membership in development of the Naturopathic Medical Research Agenda (NMRA) to be delivered to NIH NCCAM in 9/04. Solicit responses, input and guidance on the developing research agenda.

Method

Plenary Session panel presentation ending with open microphone session soliciting scientific, medical and policy feedback from APHA 2003 participants.

- Describe the relationship of naturopathic medicine and public health.
- Summarize NMRA's draft research agenda to APHA members.
- Solicit commentary and questions from audience and participants to refine the research agenda.

Results

Build participation and consensus within APHA in the development of a naturopathic medical research agenda. Input will be considered by the NMRA Work Group and will influence next draft *Naturopathic Medical Research Agenda*.

Learning Objectives

- Understand the role of naturopathic medicine in public health.
- Learn the state of current interprofessional opinion on research targets and methods in naturopathic medicine.

What are the research priorities for naturopathic medicine for the next decade? What promise does naturopathic medicine hold for public and community health and cost effective healthcare? What research models will be effective in studying the most central questions for naturopathic medicine? What are the core assumptions of naturopathic philosophy that invite scholarly and scientific inquiry? What is the nature of salugenesis and how should it be measured? How should the community determine what does and doesn't work clinically and why? Answers to such questions will help the Federal government effectively integrate complementary and alternative medicine with conventional and public health services, education and research. Through a grant from NIH's

National Center for Complementary and Alternative Medicine, accredited naturopathic colleges and medical scientists are creating an agenda to guide the next decade of research for naturopathic medicine. The Naturopathic Medical Research Agenda co-investigators and Work Group members will present a discussion draft of the Agenda. An open mike session will follow where the Research Team invites queries and research priorities from APHA members.

NMRA Special Topics Reports Submitted to the *International Journal of Naturopathic Medicine* for Publication in Fall 2004

Crinnion, W.J., Fitzpatrick, K.M., Snider, P. (2004). Report on Environmental Medicine for the NMRA *Intl J Naturopathic Medicine*, July 2004 in review.

Dower C., Kail K. and, Snider P. (2004). Report on Health Services and Workforce Issues for the Naturopathic Medical Research Agenda: Integrating Naturopathic Physicians into Mainstream Delivery Systems, *Intl J Naturopathic Medicine*, in review.

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Appendix H: NMRA Letters of Support from the Presidents of the American Association of Naturopathic Physicians and the North American Naturopathic Medical Colleges

Nancy E. Dunne, MA, ND, President, American Association of Naturopathic Medicine, Washington DC
 Robert Bernhardt, EdD, President, Canadian College of Naturopathic Medicine, Toronto, Ontario Canada
 William Keppler, PhD, President, National College of Naturopathic Medicine, Portland, Oregon
 Isis van Loon, ND and Cidalia Paiva, PhD, Acting Directors of the Boucher Institute of Naturopathic Medicine, New Westminster, British Columbia, Canada
 Guru Sandesh S. Khlasa, ND, Dean of Naturopathic Medicine, College of Naturopathic Medicine, University of Bridgeport, Connecticut
 John Daley, PhD, Acting President, Bastyr University, Kenmore, Washington
 Paul Mittman, ND, DHANP, President, Southwest College of Naturopathic Medicine, Tempe, Arizona



Monday, July 12, 2004

Leanna Standish, ND, PhD, LAc
 Senior Research Scientist/NMRA Principle Investigator
 Bastyr University
 14500 Juanita Drive NE
 Kenmore, WA 98028

Dear Dr. Standish,

The American Association of Naturopathic Physicians applauds the vision, values, organization and implementation to date of the Naturopathic Medical Research Agenda's Work Group.

Based on review of the June, 2004 draft, I am honored to declare the ongoing and active support of the AANP toward fulfillment of the NMRA's 5 year plan. Specifically, the AANP will facilitate the NMRA by providing a research reporting track at the scientific meeting hosted annually at our national convention. Additionally the AANP will maintain an active liaison with the NMRA Work Group via the participation of the Scientific Affairs Committee NMRA Task Force Chair. We will look for additional opportunities to participate meaningfully as the various projects unfold.

Our thanks to you and the NMRA team, for representing a leading edge of the naturopathic profession, as you move the vital aspect of naturopathic medical research into the best of future health care.

Sincerely,

Nancy Dunne, N.D.

Nancy E. Dunne, MA, ND
 President, American Association Naturopathic Physicians
 3201 New Mexico Ave. NW Ste 350
 Washington, DC, USA, 20016

Cc: Michael Traub, ND, DHANP, CHC
 Carlo Calabrese, ND, MPH
 Pamela Snider, ND
 Karen Howard



THE CANADIAN COLLEGE OF NATUROPATHIC MEDICINE
OFFICE OF THE PRESIDENT

BY FAX 425-823-6222

June 28, 2004

Leanna Standish, ND, PhD, LAcup
Senior Research Scientist/NMRA Principal Investigator
Bastyr University
14500 Juanita Drive Northwest
Kenmore, Washington 98028-4966

Dear Dr. Standish:

This letter is being written to indicate The Canadian College of Naturopathic Medicine's support for *The Naturopathic Research Agenda* as developed by *The Naturopathic Medical Research Agenda Workgroup*.

This report provides a strong framework for the development and assessment of research proposals in the field of naturopathic medicine. In particular I would like to note our strong support for the criteria proposed for establishing priorities with respect to this research:

1. Study conditions with the highest burden of illness.
2. Study problems of emerging health significance.
3. Study the most effective naturopathic treatments.
4. Study naturopathic approaches with revolutionary potential.
5. Foster the development of needed methods and infrastructure.
6. For initial studies, focus on near-term feasibility.

Canadian health officials are becoming increasingly concerned about the growth of health expenditures, particularly when combined with a sense that the country is not effectively addressing the health concerns of its population. There is an increasing recognition that a greater focus must be placed on keeping the population healthy as opposed to simply treating the various symptoms that result when health is compromised. The relevance of naturopathic medicine to this shift may appear obvious, but without the research base to demonstrate the efficacy of the naturopathic approaches it is far too easy for traditional health providers to erect barriers in the interest of maintaining what they perceive as their share of funding. Nonetheless, this occurs in a milieu of individuals and organizations passionately committed to health; I am convinced that when the research results emerge, major shifts in our approach to public health will follow.

1255 Sheppard Avenue East, Toronto, Ontario M2K 1E2

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www.ccnm.edu

Leanna Standish, ND, PhD, LAcup
Senior Research Scientist/NMRA Principal Investigator
Bastyr University
June 28, 2004 - Page 2 of 2

The Canadian College of Naturopathic Medicine applauds the work of *The Naturopathic Medical Research Agenda Workgroup* in establishing a context in which this research agenda can be moved forward.

Yours sincerely,



Bob Bernhardt, EdD (cand)
President & CEO

cc: John Cosgrove, Board Chair
Ed Mills, Director Research

National College of Naturopathic Medicine
& NCNM Natural Health Center Teaching Clinics



10 August 2004

Dr. Leanna Standish, ND, PHD
Research Department
Bastyr University
14500 Juanita Drive NE
Kenmore, WA 98028

Dear Director Standish:

It is a pleasure and a privilege for National College of Naturopathic Medicine to enthusiastically endorse and strongly support the North American Medical Research Agenda.

Without a cutting edge program in ABC research-applied, basic, and clinical-natural medicine cannot take its rightful place to prove the efficacy of our modalities among other health specialists and the general public.

Further, it is imperative that we continue to support the Six Principles of Natural Medicine as our guidelines in conducting research projects.

Finally, no medical institution can ever be a leader in the field without a first rate research program for the discovery and exploration of new knowledge. We fully support the Naturopathic Medical Research Agenda.

With every good wish.

Respectfully,

William J. Keppler
William "Bill" J. Keppler, PhD (University of Illinois)
President and Professor of Public Health Epidemiology

Office of the President

NCNM

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Boucher Institute
OF NATUROPATHIC MEDICINE



Leanna J. Standish, ND, PhD
Principal Investigator
Bastyr University Research
14500 Juanita Dr. NE
Kenmore WA 98028

July 26, 2004

Dear Dr. Leanna Standish;

We recognize and honour the tremendous amount of work and energy that made the Naturopathic Medical Research Agenda possible. The NMRA lays a solid foundation for improving the health of humanity, a goal that has always been fundamental to naturopathic health care. With the development of this agenda, Naturopathic medicine has defined a role in health science research, and is positioned to fundamentally impact the health care system in a very positive way. So saying, the work has only just begun. With the strong foundations of the NMRA, the naturopathic medical community is ready to build, in collaboration with conventional and other branches of medicine, an edifice that reflects a new paradigm in health care. To effectively and efficiently contribute to health care we must have the research to back up and support Naturopathic Medicine. We now have a definition of a research agenda. The next step is to follow through and enlarge the field of naturopathic research in our schools and our communities.

The Boucher Institute of Naturopathic Medicine is a relatively new school, and was just accepted as a candidate for accreditation by the Council on Naturopathic Medical Education in the fall of last year. As such, our research department is still in its developmental stages, and we look forward to having this NMRA to help us in our development. We are excited by the breadth and scope of the NMRA, and we look forward to working with the Naturopathic community in furthering Naturopathic Medical Research, and thereby assisting with the vitally important goals of the NMRA.

On behalf of the Boucher Institute of Naturopathic Medicine, we would like to congratulate you on this tremendous achievement, and eagerly anticipate working with NMRA participants in the future.

Thank you,

Dr. Isis van Loon ND
Dr. Cidalia Paiva PhD
Acting Directors,
BINM Research Department





**University of
Bridgeport**

College of Naturopathic Medicine

August 19, 2004

Loanna Standish, ND, PhD
Bastyr University Research Department
14500 Juanita Dr. NE
Kenmore, WA 98028

To Whom It May Concern:

The University of Bridgeport College of Naturopathic Medicine is proud to lend its support to The North American Naturopathic Medical Research Agenda (NMRA). This is an important endeavor that will advance the effort to adapt and apply modern research protocols to assess the modalities and outcomes of naturopathic medicine.

With the increasing interest of the public, government, and scientific community in naturopathic and other forms of non-conventional medicine, it is important to increase the information available regarding their efficacy and safety. The naturopathic educational community should be in the forefront of this effort. The College of Naturopathic Medicine at the University of Bridgeport is committed to collaboration in this process.

Sincerely,

A handwritten signature in black ink, appearing to read "G. S. Khalsa".

Guru Sandesh S. Khalsa, ND
Dean of Naturopathic Medicine

BASTYR UNIVERSITY

FOR 25 YEARS AT THE HEART OF NATURAL MEDICINE

Office of the President

14500 Juanita Drive N.E.
Kenmore, Washington 98028-4966
(425) 602-3003
FAX (425) 602-3196
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November 9, 2004

NCCAM
National Institutes of Health
Bethesda, Maryland 20892

To Whom It May Concern:

I am writing in support of the Naturopathic Medical Research Agenda. This document is the result of two years of hard work and collaboration by the research directors of the six naturopathic medical colleges and workgroups of senior scientists and professionals representing academic medicine and public health.

This agenda lays out a process to fully research naturopathic medicine in the next few years that has the potential to yield information that can facilitate changes necessary to our health care delivery system.

I endorse the NMRA and hope that it will encourage collaboration of support of NCCAM and the naturopathic medical schools.

Sincerely,



John C. Daley, PhD
Interim President



March 14, 2005

Dear Naturopathic Community,

Publication of the Naturopathic Medical Research Agenda report is a significant moment in the history of our profession. The future of Naturopathic Medicine and its role in the broader health care system will increasingly rely on building a solid research foundation. The collaboration over the past two and a half years between Naturopathic Medical schools' research divisions is a giant first step to building this edifice.

Congratulations to the many participants and supporters of this effort. The planning stage is over, now let the work begin!

Sincerely,

A handwritten signature in black ink, appearing to read "Paul Mittman".

Paul Mittman, ND, DHANP
President/CEO

APPENDIX I: Glossary (including acronyms for organizations and agencies)

AANP: American Association of Naturopathic Physicians

Acupuncture: Acupuncture is a traditional Chinese medical system using very fine, thin stainless steel needles to stimulate/treat specific points and organ systems. Oriental medical practitioners have mapped out more than 350 acupuncture points more than 2,000 years ago. This treatment is used to promote health and treat organic or functional disorders.

Acute disease: An effort to eliminate from the organism waste material, foreign matter, and poisons, and repair injury to living tissue. In other words, acute disease is the result of a cleansing and healing effort of nature (Lindlahr 1913).

Alternative Medical Systems: Alternative medical systems involve complete systems of theory and practice that have evolved independent of and often prior to the conventional biomedical approach. Many are traditional systems of medicine that are practiced by individual cultures throughout the world, including a number of traditional Asian approaches. Examples included traditional Oriental medicine, Ayurveda, homeopathic medicine, chiropractic and naturopathic medicine. Traditional medical systems have also been developed by Native American, Aboriginal, African, Middle-Eastern, Tibetan, Central and South American cultures. (Snider Fall 2000.)

BU: Bastyr University

CAM: Complementary and alternative medicine

Chronic disease: A condition of the organism in which lowered vibration (lowered vitality), due to accumulation of waste material and poisons, with subsequent destruction of vital parts and organs, has progressed to such an extent that nature's constructive and healing forces are no longer able to react against the disease by acute corrective efforts (Lindlahr 1913). "A condition of the organism in which the healing forces are no longer able to react against the disease by acute corrective efforts" (Sensenig 2003, personal communication).

Collaborative health care: Integrated or integrative health care delivery, education or practices based on collaboration between a variety of CAM, conventional medicine and traditional provider types. (National Library of Medicine Health Information Health Info Quest website)

Communities of practice: A practitioner group engaged in health care practices using a common approach, but without uniform organizational, educational or standardized benchmarks or requirements for competence, practice, or delivery of that service. A community of practice may draw from a broad range of non-standardized, non-consensual information for their bodies of knowledge. A community of practice may be recognized by communities by their traditional practices, passed down through individual apprenticeship. Native American healers, curenderas, and traditional shamans represent communities of practice. A community of practice may also be a profession integrating new practices from another profession, without educational requirements, credentialing for those practices, or concerted application of standards and guidelines for these practices.

Complementary and alternative medicine (CAM): According to the NIH's National Center for Complementary and Alternative Medicine, complementary and alternative medicine (CAM) includes those health care practices that are not currently an integral part of Western medicine. The terms "alternative" and "complementary" originated to describe complete systems of care or

specific practices, which were outside of conventional health care and not taught in US medical schools. Today the term is less descriptive because many of these systems and practices are widely used by the public and are entering mainstream health care delivery systems. Some CAM disciplines also incorporate many practices of Western medicine, depending on patient need. Examples of complete CAM systems of care are naturopathic medicine and traditional Chinese medicine. Examples of specific CAM modalities are physical medicine and massage, botanical medicine, and nutrition. Nursing, public health and family medicine are philosophically the closest branches of Western medicine to CAM. Holistic and natural medicine are related terms. (See National Library of Medicine Health Information Health Info Quest website.) Today, CAM practices may be grouped within five major domains: (1) alternative medical systems, (2) mind-body interventions, (3) biologically-based treatments, (4) manipulative and body-based methods, and (5) energy therapies. The individual systems and treatments comprising these categories are too numerous to list in this document. Thus, only limited examples are provided within each medicine.” (NCCAM website)

Complexity science: Complex adaptive systems are defined as a collection of individual agents with freedom to act in ways that are not always totally predictable, and whose actions are interconnected so that one agent’s actions change the context for other agents. Examples include the immune system, a colony of termites, the financial market, and just about any collection of humans, for example, a family, a committee, or a primary health care team (Plsek and Greenhalgh 2001).

Constitutional hydrotherapy: The therapeutic use of water applications, compresses and electrotherapy to balance body functions, strengthen the immune system, and promote healing and regenerating processes. It involves the application of hot and cold compresses to the trunk (front and back).

Cure: Successful remediation, restoration to health; a means of healing or restoring to health.

Disease crisis: An acute reaction resulting from the ascendancy of disease conditions over the healing forces of the organism. Its tendency is, therefore, toward lasting functional damage and tissue destruction (Lindlahr 1913).

Emerging professions: A developing profession that has undertaken and successfully achieved a number of the benchmarks along the continuum, and has evidence that others are being developed. The profession begins to “emerge” as a significant number of the key benchmarks are established. An emerging profession contains the basic characteristics of a profession; these characteristics or benchmarks are in various stages of actual development (Snider 2000).

Healing crisis: An acute reaction resulting from the ascendancy of nature and the organism’s healing forces over disease conditions. Its tendency is toward recovery (Lindlahr 1913).

Health care systems and disciplines, modalities and therapies: A discipline or system of health care is “the structure or whole formed by the essential principles or facts of a science or branch of knowledge or thought: an organized or methodically arranged set of ideas, theories or speculations. . . . This may imply that the component units of an aggregate exist and operate in unison or concord according to a coherent plan for smooth functioning.” (Webster’s Dictionary, 2000). A system of health care is typically titled by its system name, and is usually comprised of modalities. Therapeutic interventions exist within these modalities.

A system or discipline of health care may incorporate a discrete and limited amount of knowledge or a group of strategies from another system, functioning in practice at the level of a modality, rather than incorporating the entire system itself. Examples of disciplines or systems: biomedicine, Ayurvedic medicine, traditional Chinese medicine, naturopathic medicine, chiropractic health care, Tibetan Medicine, Yunani Medicine, homeopathic medicine.

Hering's law of cure: Symptoms disappear from within, out; from the top, down; from the more severe to the less severe, and in the reverse order of appearance (Hahnemann 1921).

Holistic Medicine: Holistic medicine is the art and science of healing that addresses the whole person - body, mind, and spirit. The practice of holistic medicine integrates conventional and alternative therapies to prevent and treat disease, and most importantly, to promote optimal health. This condition of holistic health is defined as the unlimited and unimpeded free flow of life force energy through body, mind, and spirit. Holistic medicine encompasses all safe and appropriate modalities of diagnosis and treatment. It includes analysis of physical, nutritional, environmental, emotional, spiritual and lifestyle elements. Holistic medicine focuses upon patient education and participation in the healing process. (American Holistic Medical Association website)

Homeopathy: A healing process based on the principle of “like cures like” where the remedies match different symptom patterns or “profiles” of illness in which the medicines stimulate and encourage the body’s own natural healing forces of recovery. It is derived from the Greek word *homios*, meaning “similar”, and *Pathos*, meaning “suffering.” Homeopathic remedies are generally agitated serial dilutions of natural substances from plants, minerals, and animals.

Integrated health care: This term describes a collaborative, team care approach between a variety of Western medical, traditional and indigenous, and CAM licensed health care providers. It implies a comprehensive access to a full range of health care systems based on patient need and cost effectiveness. (National Library of Medicine Health Information Health Info Quest)

Integrative medicine: Integrative medicine is a new health care discipline being established by US medical schools seeking to combine ideas and practices of Western medicine and CAM. A less precise use of the term refers to a wide variety of health care delivery models ranging from individual medical doctors, providing an assortment of CAM therapies, to a team of providers, some of whom are licensed or trained in CAM health care and traditional medicine systems. (National Library of Medicine Health Info Quest)

NCNM: National College of Naturopathic Medicine

Palliation: to relieve without curing; mitigate, alleviate (Webster’s dictionary, 2000).

Philosophy: The rational investigation of truths and principles (Webster’s dictionary, 2000).

Principle: Accepted or professed rule of conduct; a primary or general law from which others are derived; A fundamental doctrine or tenet... exemplified in natural phenomena (Webster’s dictionary, 2000).

Recover: to get back or regain something lost or taken away; to regain the strength composure, and balance; to regain health after being sick, wounded or the like (Webster’s dictionary, 2000).

SCNM: Southwest College of Naturopathic Medicine

Suppression: to put an end to the activities of; to do away with or abolish; to keep in or repress; to stop or arrest; to vanquish or subdue; quell, crush (Webster’s dictionary, 2000).

Theory: A system of rules or principles dealing with the methods of a science or art... explaining a class of phenomena (Webster’s dictionary, 2000).

Law of the normal: The “normal” state of the human being (and all living systems) is to be healthy or whole, according to naturopathic medical authors:

-“Once the normal environment has been established nothing of value can be added.” (Spitler, 1948)

-“God made us to be healthy and happy.” (Wendel 1951)

-“Health is normal and harmonious vibration of the elements and forces composing the human entity on the physical, mental and moral planes of being, in conformity with the constructive principle in nature applied to individual life” (Lindlahr 1913).

Mechanistic theory: The theory that everything in the universe is produced by matter in motion; materialism.

Natural hygiene: a natural health care discipline that seeks to understand exactly and precisely the nature and influence of air, water, food, light, exercise, rest, sleep, temperature, clothing, housing, noise, the emotions etc... “...and to apply the knowledge of these things in the process of living, acting ever and always in proper relation to the laws of life. By this means we seek not alone to preserve health, but also to restore it if we have been so unwise as to impair it. It is a comprehensive treatment of the whole problem of living in terms of a valid standard; a synthesis interrelated and correlated living factors productive of a pattern of living normal for human beings; one that covers the total needs of man and not merely one or two of his requirements. *Natural hygiene* is a way of life, not a plan of treatment; it is a mode of living and not a system of therapeutics. Thus understood, the phrase *Natural Hygiene* acquires a real significance, at once novel, startling, intense and delicious.” (Shelton, 1968)

Nature cure: Nature cure was a system for treating disease with natural agents such as water, air, diet, herbs and sunshine that developed in nineteenth century Europe. Naturopathy was the combination of nature cure and homeopathy, spinal manipulation and other natural therapies that were developed in early twentieth-century America. Naturopathic medicine is application of the principles of naturopathy within the context of modern scientific knowledge that has evolved throughout the last half of this century. The term nature doctor has been used to describe the practitioners of these permutations of nature-based medicine (Kirchfield, 1994).

Primary care: The provision of accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community.

Rules of cure: Use determines function

-Early disorder is less severe than late disorder. Early symptoms tend to be more superficial both in terms of each instance, as in acute illness, and in terms of the person’s life.

-Symptoms proceed from outer, less vital layers to deeper, more vital layers.

-Herings Law: Symptoms disappear from within, out; from the top, down; from the more severe to the less severe, and in the reverse order of appearance (Hahnemann 1921).

Theory of the minimum dose:

-The minimum dose of a drug is that which has the least toxic effect on the body when administered (Kent 1979).

-“...so it follows that when medicines act as remedies, they can only bring their curative property into play by means of this their power of altering man’s state of health by the production of peculiar symptoms; and that, therefore, we have only to rely on the morbid phenomena which the medicines produce in the healthy body as the sole possible revelation of their indwelling curative power...” (Hahnemann 1921). Use the fewest number of substances or interventions in the smallest possible dose as infrequently as possible (Hahnemann 1921).

Unity of disease: “The primary cause of all disease is the violation of nature’s laws. “Departures from normal and harmonious vibration result in adaptations which are called disease”(Lindlahr 1913).

Vitalism: The doctrine that ascribes the functions of living organisms to a vital principle, distinct from chemical and physical forces...and which is, in some measure, self-determining (Webster’s dictionary, 2000).

Vital force: The power possessed by the human body of resisting disease and of restoring health. The primary force of all forces, coming from the great central source of all life; an expression of divine intelligence (Lindlahr, 1913). The motive, plan, or spirit animating mind and body expressed as physiological and psychological functionality and adaptability (Calabrese). The self-organizing property of living organisms (Standish 1987).

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- AANP (see American Association of Naturopathic Physicians)
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