"Naturopathic Medicine in the 21st Century" has been written to help educate healthcare policymakers and regulators at both federal and state levels about the naturopathic profession and what it has to offer the healthcare system in the 21st century. The case is presented for how naturopathic medicine can contribute to resolving a major healthcare crisis in the United States — the costly epidemic of chronic disease.

In order to do this, the naturopathic profession calls upon state and federal healthcare policymakers and regulators to support and achieve three important goals:

- Implement licensure for naturopathic physicians in every state;
- Level the playing field in reimbursement for naturopathic care and funding for naturopathic educational programs; and
- Substantially increase funding for research in alternative medicine and integrated care.

This document also details how naturopathic medicine addresses the need to hold its physicians and organizations accountable to the public for safety and efficacy through a variety of well-accepted mechanisms that are common to all the regulated healthcare professions.

- Accredited schools and programs
- Standardized professional education
- Scientific research on safety and effectiveness
- Rigorous, validated licensing examinations
- State licensing laws that define a clear scope of practice and establish oversight and resource procedures
- Professional standards of practice and peer review through national and state organizations
- Credentialing and reimbursement processes
- Malpractice insurance
- Co-management of care

Naturopathic approaches to four common conditions are described and referenced. We hope — through these examples — to give the reader a flavor for the amount and depth of research that is available today to document the effectiveness and safety of naturopathic medicine. The four conditions covered are:

- Diabetes
- Menopause
- Hypertension
- Gastric and Peptic Ulcer Disease

I wish to thank all who have contributed to the writing of this document, especially Ms. Sheila Quinn.

Michael T. Aub, ND
President, American Association of Naturopathic Physicians
# Table of Contents

## The Case for Naturopathic Medicine
- A Crisis in American Health Care .................................................. 4
- State Licensure ............................................................................. 4
- Leveling the Playing Field ............................................................ 5
- Funding for Research ................................................................. 6

## The Profession Today
- Introduction .................................................................................. 7
- The Profession ............................................................................... 7
- History .......................................................................................... 7
- Education ....................................................................................... 7
- Clinical Practice Today ................................................................. 8
- Public and Community Service ...................................................... 10
- Accreditation ............................................................................... 11
- Testing .......................................................................................... 11
- Licensing ....................................................................................... 11
- Credentialing and Reimbursement ................................................ 12
- Professional Standards of Practice and Peer Review ..................... 12
- Malpractice Data ......................................................................... 13
- Co-management of Care ............................................................... 13
- Scientific Research and Efficacy Documentation ............................. 13

## The Evidence
- Introduction .................................................................................. 14
- Naturopathic Medicine in the Treatment of Diabetes ................. 14
- Naturopathic Medicine and the Management of Menopause ........ 18
- Naturopathic Medicine in the Treatment of Gastroesophageal Reflux Disease .......................................................... 22
- Naturopathic Medicine in the Treatment of Hypertension .......... 26

## The Resources
- National and State Professional Organizations ............................. 30
- Educational Institutions ................................................................. 30
- Accrediting Agencies ................................................................... 30
- Federal Research Funding ............................................................. 30
- Malpractice Information ................................................................. 30
- Licensing and Testing Authorities and Agencies ........................... 30
- Naturopathic Specialty Societies .................................................. 31

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A Crisis in American Health Care

The Centers for Medicare and Medicaid Services (CMS) are projecting that health care spending in the United States will more than double within the next 10 years — from $1.4 trillion in 2001 to $3.1 trillion in 2012 — with spending on prescription drugs still the fastest growing sector.1 What's wrong with this picture?

Health care in the 20th century took on — and almost mastered — the challenge of acute care: infectious disease, trauma, and sudden onset crises. Today, the incidence of diaphoria, tetanus, smallpox, rheumatic fever, pneumonia, tuberculosis, and other scourges that threatened the lives of so many of our citizens one hundred years ago has been drastically reduced.2 Our response to medical crises (heart attacks, traumatic accidents) has never been better. Why, then, are healthcare costs so extreme? Why do so many people seek out providers of complementary or alternative medicine?

For the last 25 years, the American people have been forging ahead of healthcare policymakers. They understand that the challenge of 21st century care is preventing and treating chronic disease.3 Never before have so many of our citizens suffered diseases, neurodegenerative diseases like Alzheimer's and Parkinson's, unusual new conditions such as chronic fatigue syndrome and fibromyalgia, allergies and asthma, headaches and heart disease. People live long enough today to understand that the quality of life for aging patients with chronic disease can make the added years more of a burden than a joy, and no one wants to live that way.

In the exhilaration of discovering the drug and surgical therapies that so significantly improved the most immediate threats to human life earlier a century ago, we lost sight of the intimate (and ultimate) connections between health and lifestyle and the powerful effects of the social and economic determinants of health. Pushing the bacteria-borne diseases aside has given us a much clearer view of what's left: the chronic and debilitating effects of poor nutrition and diet, an increasingly polluted environment, sedentary lifestyle, loss of community, visual and auditory overload, and a nation that works harder and longer than any other industrialized country. Every system in our bodies is stressed by normal American life: immune system, digestive system, energy and hormone production, brain and nervous system, skeleton and musculature, respiratory and cardiovascular systems. Equally stressed are our minds, our emotions, and our spirits. And the conventional American healthcare system is ill-equipped to take on a challenge of this magnitude, because it has a completely different focus. That's why patients — in ever-increasing numbers — seek alternative care.

"The doctor of the future will give no medicine, but will interest his patient in the care of the human frame, in diet, and in the cause and prevention of disease."

— Thomas Edison

That future Edison spoke of is now, and naturopathic physicians — family doctors whose primary focus is exactly this kind of patient-centered care — are delivering medicine for the 21st century to a rapidly expanding patient population. It is appropriate and timely for healthcare policymakers, at the state and national levels, to do everything possible to secure access to this health-promoting care for their citizens. There are three levels at which vital action is needed.

A. State Licensure

The two subsequent sections of this document provide detailed information about two important aspects of naturopathic medicine that will be of interest to state legislators and policymakers who are considering enacting laws to license naturopathic physicians:

- A description of the profession itself (history, education and training, scope of practice, public accountability, professional organizations, status of currently licensed states), and

- An examination of the evidence underlying naturopathic care in four conditions (diabetes, menopause, hypertension, and gastric and peptic ulcers).

The evidence is indisputable that this is a profession with well-established and effective approaches to patient care, as well as excellent mechanisms for ensuring public safety. The currently licensed states provide successful models for demonstrating and documenting the importance and benefit of integrating naturopathic medicine into each state's healthcare community.

Patients already understand a lot about the benefits of alternative care in general, and are clearly willing to pay for expanding their access.4 However, patients do not understand how our nation's state-by-state healthcare regulatory system can leave them vulnerable — in the unlicensed states — to the claims of untrained or poorly trained practitioners. They rely on the judgment and knowledge of state legislators and policymakers to ensure that naturopathic care is accessible within the safety net provided by state licensing:

- appropriate education,
- testing for competence,
- scope of practice boundaries,
- continuing education for currency.
B. Leveling the Playing Field — Reimbursement for Care

In many ways, the last 25 years have seen a disturbing trend toward a two-tiered healthcare system — one for those in the middle class and above, and another for the poor. As long as alternatives to the conventional healthcare system are available only for those who can afford to pay extra for them, the poor — those in greatest need — will have the fewest options. Where are the rates of diabetes and heart disease the highest? Where does the impact of poor diet make itself felt most urgently? Among the poor and the underserved. The poor (and the underserved) generally do not get preventive care, often are not seen in a doctor’s office when many conditions are still reversible with lower-cost interventions. They are seen in emergency rooms and intensive care units when disease has progressed to acute and crisis proportions. This is an extremely costly way of delivering care to millions of our citizens, and we continue to pay for that expensive level of care through many decades of life.

Leveling the playing field for reimbursements is an investment in both long-term health for our citizens and a more economically viable healthcare system. It is highly consistent with our competitive, entrepreneurial economy that reducing the ability of one profession to control the delivery and reimbursement of care is likely to increase options and reduce costs for everyone — particularly when the profession holding the near-monopoly (conventional allopathic medicine) is inextricably entwined with the industry that is driving the steep increase in costs (the pharmaceutical industry). Our citizens have suffered from the shortsightedness of investing so heavily in after-the-fact treatment and so little in non-drug-dependent prevention and interventions, but the poor have suffered more than most. As a nation, we can no longer afford to marginalize the very professions that are providing leadership in preventive, patient-centered, primary care natural medicine.

Equality in reimbursement will provide the data needed to compare both costs and therapeutic efficacy across different interventions, different providers, different patient populations, and different diseases for millions of people over long periods of time. These elements require study on a prospective basis for many years, to assess the determinants of the decline that often precedes the actual diagnosis of chronic disease and to assess the effectiveness of natural medicine interventions for acute as well as chronic conditions. These factors can’t be studied unless the reimbursement systems — both public and private — consistently cover many different kinds of medical approaches. The efficacy of single-agent interventions in research settings is studied, of course, but that is not the same as studying actual care, delivered by licensed providers, to real patients, equitably reimbursed.
C. Funding For Research

There is a substantial body of research literature now documenting the effectiveness of many natural medicine interventions (see section of this document). However, the level of funding for such research is still incredibly small when compared to the funding for drug interventions. The very numerous botanical medicines, lifestyle, dietary and nutritional interventions that need to be evaluated demand more balanced research funding. Despite the strong evidence available that drugs cannot prevent or cure most chronic diseases, and that their use often entails significant undesirable side effects, and that the spiraling costs of prescription drugs are driving the reimbursement system ever closer to bankruptcy, we have yet to embrace fully the need to study other approaches to care.

Recent recommendations from the White House Commission on Complementary and Alternative Medicine Policy and the National Policy Dialogue to Advance Integrated Care focus heavily on the need to allocate much more substantial funding to researching both integrated care models and specific interventions from the alternative medical communities. Among the recommendations endorsed by the American Association of Naturopathic Physicians are the following:

A. Significantly increase federal research allocations for health promotion and disease prevention, and examine the role of complementary and alternative medicine (CAM) and integrated approaches in these areas.

B. Assure widespread access to CAM and integrated health care in rural and underserved communities. (This absolutely requires revising the reimbursement system to the Medicare, Medicaid, and third party payers will be able to reimburse for naturopathic care.)

Achieve regulatory recognition for each profession seeking it, in every state and within federal programs, based on competency standards set by the profession.

Summary

Naturopathic medicine has much to contribute to 21st century health care in the United States:

A. A long history of dedication to providing effective health promotion and treatment of disease through natural medicine and lifestyle interventions;

A. An effective and economically viable approach to health care;

A. Leadership in integrated care models; and

A. Responsiveness to on-rushing trends in chronic disease.

In order to make these contributions effectively, the naturopathic profession calls upon state and federal healthcare policymakers and regulators to support and achieve three important goals:

1. Implement licensure for naturopathic physicians in every state;

2. Level the playing field in reimbursement for care; and

3. Substantially increase funding for research in alternative medicine and integrated care.

Naturopathic Medicine: Consumers want it...Patients need it...The economics of health care require it!

1 http://cns.nhs.uk/statistics/wha/

2 "We spend over $1 trillion a year on health care – the same size as the federal budget. And what do we get in return? We are number 37th in the world for the quality of our health outcomes and 28th for the quality of our child survival." – Kathleen O’Connor, The Seattle Times, 6/7/02.


4 "Estimated expenditures for alternative medicine professional services increased by 43.2% between 1990-1997 and were conservatively estimated as $27.2 billion in 1997, with at least $12.2 billion paid out of pocket. This exceeds the 1997 out of pocket expenditures for all US hospitalizations." (Sherding D. JAMA 1998;280:1569-1575.)

5 From, op. cit.

6 Diabetes, as one example among many, has increased to epidemic proportions: one million new cases of type 2 diabetes diagnosed each year, with direct costs to the healthcare system of $44 billion annually and indirect costs (disability, work loss, premature mortality) of $64 billion annually (1997 data). "Research studies in the United States and abroad have found that lifestyle changes can prevent or delay the onset of type 2 diabetes among high-risk adults.... The development of diabetes was reduced 43% to 60 percent during these studies that lasted 3 to 6 years.” — http://www.ncbi.nlm.nih.gov/pubmed/19582338 [National Institutes of Diabetes and Digestive and Kidney diseases of the National Institutes of Health].

7 "For true diseases contributing importantly to mortality in Western populations, epidemiologists have long known that nongenetic factors have high attributable risk, often at least 80 or 90%, even when the specific etiologic factors are not clear... For example, we have been able to identify modifiable behavioral factors, including obesity or diet, overweight, inactivity, and smoking that increase for over 70% of stroke and colon cancer; over 60% of coronary heart disease, and over 90% of adult-onset diabetes." Willett W. Balancing life-style and genetics research for dietary intervention. Science 2000;290:615-619.

8 Most people 65-74 believe the availability of alternative care is an important selection criterion in their choice of a health plan. Nearly one-half of adults in the US say that they would be willing to increase their monthly health care expenses in order to have access to alternative care. Landmark Report on Public Perceptions of Alternative Care, 1999, Landmark Healthcare, Inc.

9 Audits of naturopathic service and surveys of insurance companies have indicated that naturopathic medicine is less expensive than conventional care, perhaps by as much as twice the actual savings may be much higher, because some of the audits measured the long-term effect of the naturopathic preventive approach in reducing costs associated with serious chronic disease. Naturopathic Medicine: Community to Health Care Reform, 1993 American Association of Naturopathic Physicians.
The Profession Today

Introduction

Naturopathic medicine is a distinct system of primary health care - an art, science, philosophy and practice of diagnosis, treatment and prevention of illness. Naturopathic medicine is distinguished by the principles that underlie and determine its practice. These principles are based upon the objective observation of the nature of health and disease, and are continually reexamined in the light of scientific advances.

Methods used are consistent with these principles and are chosen upon the basis of patient individuality. Naturopathic medicine emphasizes promotion of health, prevention of disease, patent education and individual responsibility. Naturopathic doctors (NDS) are trained as primary care physicians of natural medicine.

United States Department of Labor, Dictionary of Occupational Title

Definition of a Naturopathic Doctor

Diagnoses, treats, and cares for patients, using system of practice that bases treatment of physiological functions and abnormal conditions on natural laws governing human body. Utilizes physiological, psychological, and mechanical methods, such as air, water, light, heat, earth, physiotherapy, food and herb therapy, psychotherapy, electrotherapy, phototherapy, minor and artificial surgery, mechanical therapy, naturopathic correlations and manipulation, and natural methods or modalities, together with natural medicines, natural processed foods, and herbs and nature's remedies. Excludes major surgery, therapeutic use of x-ray and radiation, and use of drugs, except those assimilable substances containing elements or compounds of body tissues that are physiologically compatible to body processes for maintenance of life.

The Profession

History

Naturopathic medicine is one of the oldest continuously licensed healthcare professions in the United States. Its origins can be traced back to late nineteenth-century European physicians, who wanted to re-orient medicine toward healthful living. It was brought to the United States (and Canada) in the 1890s and quickly drew many physicians with an interest in diet, exercise, physical medicine (hydrotherapy and manipulative therapies), and natural medicines (herbs and homeopathy). In the middle years of the twentieth century, the development of miraculous drugs such as antibiotics, and the large-scale funding that became available from pharmaceutical companies, combined to create a near-monopoly of health care by conventional medicine.

That stage lasted until the mid-1970s and resulted in the suppression of many alternatives to the mainstream system.

In the last quarter of the twentieth century, the American public became increasingly aware of the costs and consequences of relying primarily on drugs and surgery for health care. There began a large and growing demand that natural medicine alternatives be accessible in a consistent, effective way. The result has been the revival and modern development of naturopathic medicine (as well as osteopathic medicine, chiropractic, oriental medicine, homeopathy and midwifery).

Today, thanks to the public's insistence on having real choices in health care, naturopathic medicine is a vibrant, growing field. It's practitioners and inspirations are at the forefront of efforts to develop functional models of integrated care. Today's naturopathic profession includes physician-level, accredited education, expanding state licensure, participation in many reimbursement plans, and leadership in public policy initiatives at the both state and federal levels.

Education

The foundation of all safe healthcare practice is thorough training and competent testing in the scope of practice. All states that license naturopathic physicians (NDs) require a doctoral-level resident course of at least 4100 hours of study from a college or university recognized by the state's licensing board. Over the last thirty years, the naturopathic profession has worked to develop the highest standards of education and professional accountability. Naturopathic medical colleges provide the rigorous training that produces doctors who practice the kind of integrated health care the public is demanding.

Naturopathic medical students usually attend four-year, graduate-level naturopathic medical schools, whose mission is educational excellence in the prevention, diagnosis, and treatment of disease and promotion of optimal health. The education also emphasizes skill in bridging both conventional and natural medicine perspectives, providing patients with knowledgeable advocates in making informed healthcare choices.

Students of naturopathic medicine learn the medical sciences as a foundation on which to build a thorough knowledge of naturopathic and conventional evaluation and treatment approaches. They develop skills in diagnosis and treatment of disease, prevention, and wellness optimization. Like conventional medical schools, the first two years of ND training concentrate on the basic biomedical sciences: anatomy (from gross anatomy and dissection to neuroanatomy), physiology, histology, embryology, pathology, and biochemistry. During this period of study, students also begin their training in diagnostic procedures (physical examination, laboratory testing, and
diagnostic imaging), and are educated in the principles of naturopathic medicine through courses such as Naturopathic Clinical Theory, The Determinants of Health, and The Healing Systems. Therapeutic modalities are introduced, although the major emphasis on these comes later.

The second two years integrate the basic biomedical sciences with the clinical sciences through courses in endocrinology, gastroenterology, gynecology, cardiology, pediatrics, and other organ systems and disease entities. The focus on therapeutic interventions intensifies, covering the broad range of diverse natural treatment modalities that make naturopathic medicine so effective: clinical nutrition and diet, botanical medicine, homeopathy, naturopathic physical medicine and hydrotherapy, counseling and health psychology, including spirituality in medicine. During this clinical phase, students are also trained in pharmacology consistent with a naturopathic scope of practice and in minor office procedures, such as removal of superficial lesions and suturing of minor lacerations.

Students apply their knowledge in supervised outpatient clinical settings, preparing them for the office-based private practice typical of naturopathic physicians. Licensed naturopathic physicians supervise clinical training in teaching clinics at naturopathic medical schools and in the community. In this phase of clinical training, students may preceptor with NDs, MDs and other appropriate medical specialists in private practice, conventional clinics or increasingly in hospitals. Residencies are available for many graduates and are expanding as the profession actively seeks federal financial support for continued development of residency opportunities for all graduates. Residency programs receive certification through the Council on Naturopathic Medical Education (CNME) Committee on Postdoctoral Medical Education.

Clinical Practice Today

Unlike most other health care systems, naturopathy is not identified with any particular therapy, but rather 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. Six powerful concepts provide the foundation that defines naturopathic medicine and create a unique group of professionals practicing a form of medicine that fundamentally changes the way we think of health and illness. [Fitzsimons & Snider, Fundamentals of Complementary and Alternative Medicine, Ed. M. Miccetti. Churchill Livingstone: 1996, p. 173]

Principles

The six guiding principles of naturopathic medicine are:

- **The Healing Power of Nature**
  Trust in the body's inherent wisdom to heal itself.

- **First Do No Harm**
  Utilize the most natural, least invasive and least toxic therapies first.

- **Treat the Whole Person**
  View the body as an integrated whole in all its physical and spiritual dimensions.

- **Identify and Treat the Causes**
  Look beyond the symptoms to effectively address the underlying cause(s) of illness.

- **Doctor As Teacher**
  Educate patients in the steps to achieving and maintaining optimal health.

- **Prevention**
  Focus on promoting health and wellness, and preventing disease.

Scope of Practice

Naturopathic physicians are trained as primary care providers. They blend centuries-old natural and non-toxic therapies with current advances in the study of health and human systems, covering most aspects of family health from prenatal to geriatric care. NDs make a conventional Western diagnosis using standard diagnostic procedures such as physical examination, laboratory tests, and diagnostic imaging, as well as state-of-the-art functional testing to assess nutritional status, metabolic function and toxic load.

Patient education and lifestyle modification form the foundation of naturopathic medical practice. A considerable amount of time is spent evaluating patients' mental, emotional, social, and spiritual status, inspiring them to find greater balance in their lives.

Therapeutically, NDs use virtually every known natural therapy: dietary change and therapeutic nutrition, botanical medicine, naturopathic manipulative therapy, lifestyle counseling, exercise therapy, homeopathy, acupuncture, psychological and family counseling, and hydrotherapy. They select from a range of natural therapeutics to stimulate the body's natural healing mechanisms and to provide symptom relief. Each of the major therapies used by naturopathic physicians has considerable scientific literature devoted to it, and long traditions of clinical use. Modern naturopathic medicine has incorporated advances in science into its traditional body of knowledge.

(Ref: The American Association of Naturopathic Physicians Definition of Naturopathic Medicine Position Paper, 1999)
Diet and clinical nutrition. The dietary approach to prevention and treatment of chronic degenerative disease, championed for more than a century by naturopathic physicians, has recently gained the attention of conventional medicine. Dietary intake studies have shown that the majority of Americans do not consume even the RDA for most nutrients. Nutrient deficiencies accelerate the progress of aging and the development of many illnesses. For example, research has demonstrated that just providing a multivitamin with additional vitamin E, zinc and folic acid could save over $20 billion annually in hospital charges for just three conditions: heart disease, birth defects, and low-weight premature births. (Ref. Benich, A. Malick, R. Issler, S. Potential Health Economic Benefits of Vitamin Supplementation West. J. Med. 1997;166:306-312). Similar examples abound in the current peer-reviewed literature.

Naturopathic physicians are the primary care doctors best trained to integrate clinical nutrition and dietary recommendations into clinical practice, because of the extensive training they receive during their medical education, and because these practices have been part of naturopathic philosophy since the profession began.

Botanical medicine. Medicinal plants and plant extracts have been the backbone of medicine around the world for most of human history. They continue to be the primary medicine for the majority of people in the developing world, according to the World Health Organization. Botanical medicine has succeeded in remaining an effective tool in modern medicine, with the strongest traditions occurring in Europe and Asia. Much of pharmaceutical medicine emerged from botanical medicine, with many of the earliest drugs being botanical constituents (e.g., digitals, glycosides, quinines) or semi-synthetic derivatives of botanical constituents (e.g., aspirin), and with important new drugs continuing to be discovered in or synthesized from herbs today (e.g., paclitaxel, artemisinin). A growing body of scientific research supports the efficacy and safety of various herbs for preventing and treating many health conditions. Numerous double-blind clinical trials have shown, for example, that (a) Serrata reines (saw palmetto) berry extracts are effective and safe for relieving symptoms of benign prostatic hyperplasia; (b) Hypericum perforatum (St. John’s wort) extracts are safe and effective for mild-to-moderate depression; and (c) Echinacea spp. extracts are safe and effective for shortening the duration and lessening the severity of the common cold. Many other examples exist. Like any other field of medicine, not all trials agree on all herbs, and some herbs have not shown efficacy. This does not diminish the value of those herbs and herbal extracts that are showing great promise as economical, safe, and effective approaches to a variety of health concerns.

Homeopathy. Homeopathy is a healing system that is more than two hundred years old. It is based on the principle, “Let likes be cured by likes,” in which each homeopathic medicine matches different symptom patterns or “profiles” of illness and stimulates the body’s own natural healing forces for recovery. Homeopathic medicines are high dilutions of natural substances such as plants, minerals, and animals. In the most significant and comprehensive review of homeopathic research ever conducted, The Lancet (September 20,1997) published a meta-analysis of 89 double-blind, randomized, placebo-controlled clinical trials and concluded that the homeopathic medicines in the studies had a 2.45 times greater effect than placebo. Two surveys of medical doctors in the United States Journal of the American Board of Family Practice, 1995, 8, 361-6) revealed their high interest in receiving training in homeopathy. A major reference book on homeopathic research is Homeopathy: A Frontier in Medical Science (Hollander & Signorini, North Atlantic Press, 1995).

Hydrotherapy. Hydrotherapy is the use of hot and cold water to stimulate circulation for the maintenance of health and treatment of disease. Naturopathic medicine is rooted, in part, in the European hydrotherapy movement, centuries old and still thriving. The best-known American Hydrotherapist of the last century was John Harvey Kellogg, a medical doctor who approached hydrotherapy scientifically and performed many experiments to determine the physiological effects of hot and cold water. His book, Rational Hydrotherapy, considered one of the definitive texts on the therapeutic effects of water, is used in naturopathic medical schools today. In its broadest sense, the term hydrotherapy includes both internal and external uses of water. Hydrotherapy is often utilized by naturopathic doctors because it is a gentle treatment that can produce powerful benefits on the immune system. Internal hydrotherapy stimulates the elimination of metabolic wastes. External hydrotherapy produces reflexive changes in the flow of blood and lymphatic fluid to increase the ability of cells to absorb oxygen and nutrients. Studies indicate that hydrotherapy treatments can boost immune function, eliminate excess fluids and reduce the frequency of colds and flu by over 50 percent (Annals of Internal Medicine, 1990; 22:225-27).

Naturopathic physical medicine. Physical medicine modalities have been an integral part of the practice of naturopathic medicine since the founding of the profession. Every naturopathic medical school curriculum and every naturopathic licensing law includes these approaches to health. Naturopathic physical medicine is the therapeutic use of physical agents (air, water, heat, cold, pressure, sound, light and electromagnetic non-ionizing radiation) to promote health and treat disease. Specific modalities include electrotherapy, diathermy, ultraviolet light, ultrasound, hydrotherapy (see above), non-invasive meridian therapy, therapeutic exercise, and treatment of body structures or tissues to normalize and balance the musculoskeletal system of the body. Naturopathic physical medicine is distinct from the practice of chiropractic, physical therapy and physical rehabilitation.
Behavioral change. Naturopathic physicians are trained in various psychological techniques, including basic counseling, stress management, hypnotherapy, biofeedback and methods of lifestyle modification. A growing body of scientific literature points to the interrelationship of the mind, body and spirit in the treatment of many illnesses, and to the importance of addressing all these elements in a holistic approach to clinical care. Naturopathic physicians frequently refer to psychotherapists and psychiatrists for assessment and treatment.

Oriental medicine. All naturopathic physicians are trained in the basics of Oriental medicine and about one in five receives further training and specializes in it. Many go on to receive board certification by the national accrediting agency for acupunctureists in the U.S. (NCCAOM). Oriental medicine has been in continuous use for more than three thousand years in Asia and coexists along with conventional medicine today in China and Japan as a primary form of health care. Several dozen journals are devoted to the scientific evaluation of Asian methods, including both acupuncture and botanical medicine.

Prescriptive medicine. The curriculum at all naturopathic medical schools includes extensive training in clinical pharmacology. Courses cover the use of legend drugs as well as nonprescription agents, botanicals, antibiotics, hormones, vitamins and minerals. A naturopathic formulary lists those prescriptive substances which naturopathic physicians use in practice. Much of the prescriptive pharmacy is based on naturally derived substances, such as certain hormones and antibiotics. Prescriptive privileges for naturopathic physicians saves consumers money and time by not requiring a visit to another physician when a simple prescription is indicated. Naturopathic physicians are also trained in the critical understanding of interactions between conventional prescription medications and natural therapies such as herbs, to a greater degree than any other profession at this time.

Minor office procedures. Naturopathic physicians receive training in minor office procedures during their 4 years of schooling. Procedures include removal of suspicious skin lesions for biopsy, repair of lacerations, and removal of superficial foreign bodies. These skills become essential when practicing in underserved communities such as rural farm towns, Indian reservations, and low income clinics. Naturopathic physicians do not perform major surgery and refer to appropriate surgical specialists when surgery is clinically necessary.

Public and Community Service
Naturopathic physicians are providing key leadership roles in local, state, and federal health care advisory arenas:

- Joseph E. Pizzorno, Jr., ND, co-founder and President Emeritus of Bastyr University, served on The White House Commission on Complementary and Alternative Medicine Policy, 2000-2002. He also serves on the Seattle-King County Board of Health.
- Two naturopathic physicians currently serve on the Advisory Council to the National Institutes of Health, National Center for Complementary and Alternative Medicine (NCCAM), guiding the research agenda in natural medicine. (Several other NDs have occupied comparable positions over the past ten years.)
- A naturopathic physician has recently been appointed to the National Academies, Institute of Medicine – "Use of Complementary and Alternative Medicine by the American Public" committee
- Two naturopathic physicians have recently been appointed to the Medicare Coverage Advisory Committee (MCAC).
- NDs played an active role in the National Policy Dialogue to Advance Integrated Health Care (held at Georgetown University in November 2001).
- A naturopathic physician serves as a member of the Washington State Health Professional Loan Repayment and Scholarship Program Advisory Committee.
- An ND serves on the Board of Harborview Medical Center (Level One Trauma Center) in Seattle, Washington.
- Naturopathic physicians have been appointed to hospital medical staffs in Hawaii, Arizona, Oregon, Washington, Rhode Island, and elsewhere.
- Naturopathic physicians have occupied key leadership roles on collaborations such as the Building Bridges Between Provider Communities Group (USPHS Region X), and the King County Integrated Health Care 2010 group (later NorthWest Integrated Health Care 2010), both in Washington State.
Public Accountability

Naturopathic medicine addresses the need to hold its physicians and organizations accountable to the public for safer and efficacious care through a variety of well-accepted mechanisms that are common to all the regulated healthcare professions.

- Accredited schools and programs
- Standardized professional education (see above)
- Scientific research on safety and effectiveness
- Rigorous, validated state licensing examinations
- Sole licensing laws that define a clear scope of practice and establish oversight and resource procedures
- Professional standards of practice and peer review through national and state organizations
- Credentialing and reimbursement processes
- Malpractice insurance
- Co-management of care

Accreditation

Regional accreditation. All four naturopathic medical schools in the U.S. are accredited or candidates for accreditation through a U.S. Department of Education-recognized (regional) association of schools and colleges. The Commission on Colleges of the Northwest Association of Schools and Colleges (nASC) accredits Bastyr University (Seattle) and has granted candidate status to the National College of Naturopathic Medicine (Portland, OR). The ASC is one of seven regional accrediting bodies recognized by the U.S. Department of Education, and is the only body that accredits the University of Washington and Oregon Health Sciences University. Southwest College of Naturopathic Medicine and Health Sciences is a candidate for accreditation with The Higher Learning Commission of the North Central Association of Colleges and Schools. The college received this favorable assessment during a recent site visit: "The (SONM) faculty, students, alumni, and board members support the values of critical inquiry, lifelong learning, and service to the profession and community inherent in higher education. This is evident in the curriculum, the work of the faculty, and the behavior of students and alumni." [Report of an Initial Candidate Visit to Southwest College of Naturopathic Medicine and Health Sciences, September 10-12, 2001.] The University of Bridgeport, which has a naturopathic college, is accredited by the New England Association of Schools and Colleges and by the Board of Governors of the Connecticut Department of Higher Education.

Programmatic accreditation. The Council on Naturopathic Medical Education (CNME) is the recognized programmatic accrediting agency for naturopathic medical education in North America. All four naturopathic medical programs in the United States (and one in Canada) hold accredited or candidate status from the CNME. The CNME is a member of the American Specialty Professions Association (ASPA).

Testing

Pre-doctoral Assessment. During their clinical training, naturopathic medical students are assessed for clinical competency through a series of skills that are identified, taught, and tested in order to graduate.

Naturopathic Physicians Licensing Examination (NPLEX). A rigorous, statistically validated, standardized licensing examination is used in all states that license naturopathic doctors. Graduates of the recognized schools are eligible to sit for the national licensing exam, the NPLEX (Naturopathic Physicians Licensing Examination). NPLEX prepares a series of sixteen examinations (five basic sciences and eleven clinical sciences) that are given twice a year. NPLEX has banded the examinations on a practice analysis, laid the fundamental foundations, and had 17 years of experience in producing examinations specific to the naturopathic scope of practice. All NPLEX clinical examinations are based on sound psychometric principles and have exhibited good reliability. A criterion-related validity study of the examinations produced high validity coefficients.

The NPJX Part I - Basic Science Examinations (BSE) are comparable to the basic science examinations in other health care professions, covering Anatomy, Biochemistry, Microbiology and Immunology, Pathology, and Physiology. The NPLEX Part II - Core Clinical Science Examination (CSE) tests Physical and Clinical Diagnosis, Laboratory Diagnosis & Diagnostic Imaging, Botanical Medicines, Pharmacology, Emergency Medicine, Clinical Nutrition, Psychology, and Physical Medicine. The NPLEX Part II - Clinical Science Add-On Examinations (CLAQ) are required by specific jurisdictions. These examinations cover: Homeopathy, Minor Surgery, and Acupuncture. Every state or province that currently licenses naturopathic physicians requires that candidates take the eight examinations in the CSE. All jurisdictions but one also require the five examinations in the BSE and most require one or more of the three examinations in the CLAQ.

 Licensing

Professional licensing in the United States is a function reserved to the individual states. This is true for medical doctors, nurses, dentists, and all other healthcare disciplines. That means that each state decides for itself whether to license a specific profession and, if so, what scope of practice will be permitted and how oversight will be handled. Licensure of naturopathic physicians increases public safety by requiring the highest level of accountability among the various regulatory models used by the states. (Other models such as certification or registration normally carry less public accountability; although there are a few states in which certification standards are the equal of licensing standards.) Establishing high standards for licensure means that, as more consumers turn to natural
Other important issues arise when a profession is not uniformly licensed in all states:

- Lack of licensure leaves the public vulnerable to the claims of unqualified individuals. People are understandably confused about who is qualified to practice as an ND and who is not.
- Patients often find it much more difficult to obtain reimbursement for services, as most third party payers require patient to see a licensed provider.
- Lack of licensure acts as a disincentive for professionally trained NDs to practice in unregulated states where there is no legal protection for the scope of practice, thereby limiting access to the skills of well-trained practitioners.

As of 2002, NDs were licensed to practice as doctors of naturopathic medicine in 12 states, 4 Canadian provinces and the US Virgin Islands and Puerto Rico.

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Legal provisions allow the practice of naturopathic medicine in several other states and the District of Columbia, but lack of licensure standards in DC and elsewhere create a burden for patients, who must individually assess a practitioner’s training and competence. Active legislative campaigns to license NDs are underway in California, Florida, Idaho, Massachusetts, Missouri, North Carolina, New York, and Washington DC.

**Credentialing and Reimbursement**

Credentialing is a process conducted primarily by insurers and payers and by hospitals and group practices, although credentialing can be delegated to professional organizations such as Independent Provider Associations (IPAs). As NDs are included in more reimbursement plans, and as integrated care creates opportunities for NDs to work in hospitals and conventional clinics, credentialing is gradually being implemented for the profession. Credentialing is an asset for public accountability because the provider’s education, scope of practice, licensure history, malpractice history, and reputation among his or her colleagues are all investigated thoroughly.

In 1996, the Washington State Dept of Health approved the Washington Association of Naturopathic Physicians (WANP) Coordinated Quality Improvement Plan, which provides a framework for credentialing and quality improvement for payers, regulators and health care systems that can serve as a model for other states. Peer review also occurs through payers who employ naturopathic medical directors. These directors consult with peer advisory committees in making reimbursement and case management decisions.

**Reimbursement.** Most people (47%) believe the availability of alternative care is an important criterion in their choice of a health plan. Nearly one-half of the public say they would be willing to increase their monthly health care expenses in order to have access to alternative care (Landmark Report on Public Perceptions of Alternative Care, 1998, Landmark Healthcare, Inc.). Audits of naturopathic services and surveys of insurance companies have suggested that naturopathic medicine is less expensive than conventional care, perhaps by as much as half. The actual savings may be even higher, because none of the audits measured the long-term effect of the naturopathic preventive approach in reducing costs associated with serious chronic disease (Naturopathic Medicine: Contribution to Health Care Reform, 1993 American Association of Naturopathic Physicians).

Over 70 companies, unions and state organizations have health plans that cover naturopathic medical services. Reimbursement is another factor in public accountability, as payers perform utilization reviews and have access to a great deal of data about patient outcomes.

**Professional Standards of Practice and Peer Review**

The American Association of Naturopathic Physicians House of Delegates has approved position papers for a variety of conditions and detailed practice guidelines for the profession. These are important guiding frameworks for the profession and they establish a basis for peer review issues at both state and national levels.

On a state level, peer review occurs through disciplinary or advisory boards that license naturopathic physicians. The primary responsibility of these state agencies is to protect the public. Thus, they approve regulations that facilitate the care and consistent implementation of state law they investigate complaints made against practitioners, and they discipline those who have violated statutes or regulations. Action taken may include dismissal or revocation of license, depending on the severity of the infraction.
Malpractice Data
The licensed naturopathic profession has an extraordinary safety record. A review of the twelve United States Naturopathic Physicians Licensing Boards conducted in late 2002 reveals only a handful of disciplinary actions taken nationally. The research firm Jury Verdicts Northwest has conducted reviews on the results of health-related lawsuits. No malpractice judgments have been found against a naturopathic physician since they began keeping records in 1983. A review of similar research firms in other licensed states revealed the same result: there has not been a single case of an ND going to trial for malpractice/negligence in the United States. These databases report only cases going to trial and do not record out-of-court settlements.

An examination of malpractice insurance rating scales for claims shows naturopathic physicians have the lowest incidence of malpractice claims of all licensed primary health care professions. Washington Health Cassidy rates NDs as .7 at the bottom of the scale of risk, below dermatologists and family practitioners who do not do surgery.

Co-management of Care
Naturopathic physicians cooperate with all other branches of medical science, referring patients to other practitioners for diagnosis and treatment when appropriate. Because NDs are specifically trained in drug-nutrient and drug-herb interactions, they are a valuable resource for other clinicians and patients seeking to understand this complex field.

In addition to referring complex cases to specialists, more and more NDs are being incorporated into standard care programs, working shoulder to shoulder with other healthcare professionals to improve the quality of patient outcomes. Examples include the Natural Medicine Clinic at the Kent Community Health Center (King County, WA), the four facilities of Cancer Treatment Centers of America, the North Hawaii Community Hospital, and numerous integrated group practices around the country.

Co-management is a key mechanism in public accountability. Providers co-managing a patient’s case must explain the basis of their diagnostic and treatment recommendations to their colleagues and cooperate in reviews of patient outcomes. Significant mutual education takes place about the diverse provider educational backgrounds and scope of practice, and about the efficacy and mechanisms of action of therapeutic modalities. Patients benefit significantly from co-managed care, not only because there is more built-in review but also because a broader range of therapy options is made available.

Scientific Research and Efficacy Documentation
The naturopathic medical colleges and professional organizations are committed to scientific evaluation of the medicine. The Scientific Affairs Committee of the American Association of Naturopathic Physicians has established a profession-wide research agenda, the Naturopathic Medical Research Agenda (NMPH), to promote practice-based research, and makes an award each year for the best in-office research performed by an ANAP member.

All naturopathic medical schools have research departments and controlled studies are being conducted and published in peer-reviewed literature. Bastyr University was the first naturopathic school in the country to receive a grant from the NIH for research on the treatment of AIDS. National College of Naturopathic Medicine is now a collaborating institution on a multi-institution NIH grant in the Portland, OR, area.

Financial constraints have limited the amount of specifically naturopathic research that is funded and performed. The profession and its schools simply have not had access to the billions of dollars spent by the pharmaceutical industry on drug research, nor to the additional billions in governmental research subsidies provided to conventional healthcare schools and programs. That situation is beginning to change, with increased funding for the National Center for Complementary and Alternative Medicine at NIH. However, the total funding available to NCCAM remains a minuscule portion of the NIH budget, and none of it is focused on examining the whole system of naturopathic practice. Single-agent research has attracted the interest of other NIH institutes, and increased funding is examining the effects of nutrients and herbs under particular conditions. An in-depth discussion of this burgeoning field of research will be provided separately.

Resources: Contact information for professional organizations, educational institutions, accrediting and testing agencies, licensing authorities, and specialty societies are provided in the final section of this document.

References
Introduction
The scientific literature addressing the effectiveness and safety of naturopathic therapies can be found in many different forms and places:
- Publications include thousands of books and journal articles.
- Research methodologies include laboratory studies looking at the active ingredients of herbs or nutrients, in both animal studies and human trials.
- Clinical case studies can be found in the literature for over a hundred years.
- Nutrition researchers study everything from vitamins to therapeutic dietary interventions.
- Lifestyle researchers examine exercise, normal diet, stress, and spirituality.
- Other investigators have looked at homeopathy, acupuncture and oriental medicine, and hundreds of other herbs.

There has not yet been a well-funded, long-term study of the actual clinical practice of naturopathic medicine in all its diversity. Naturopathic physicians are trained in, and practice, all the basic disciplines of natural medicine: nutrition, diet, herbs, homeopathy, physical medicine, lifestyle change, counseling, and, increasingly, acupuncture and oriental medicine. Depending upon the needs of the patient, the nature of his/her condition, and the expertise of the practitioner, a naturopathic approach to treatment includes multiple interventions, addressing the problems from a variety of pathways, to gain synergistic and more comprehensive effects. Examining the research base, therefore, involves collecting citations from many different sources and perspectives, and integrating the analysis of findings to create a logical and intelligent picture of how naturopathic medicine works.

The four conditions briefly described here represent some of the most common complaints that patients bring to their doctors' offices. We hope — through these examples — to give you a flavor for the amount and depth of research that is available today to document the effectiveness and safety of naturopathic medicine. The four conditions covered are:

1. Diabetes
2. Menopause
3. Hypertension
4. Gastric and Peptic Ulcer Disease

Naturopathic Medicine in the Treatment of Diabetes

"Dramatic new evidence signals the unfolding of a diabetes epidemic in the United States. With obesity on the rise, we can expect the sharp increase in diabetes rates to continue. Unless these dangerous trends are halted, the impact on our nation's health and medical care costs will be overwhelming."
— Jeffrey P. Kaplan, MD, MPH
Director, Centers for Disease Control and Prevention
1998-2002

Background
Diabetes is a serious, costly disease that is on the rise. Among U.S. adults, diagnosed diabetes increased 49% from 1990 to 2000. Similar increases are expected in the next decade and beyond. Seventeen million Americans have diabetes, although 6 million of those do not know they have it. Over 200,000 people die each year of diabetes-related complications. Diabetes is a leading cause of heart disease, stroke, blindness, kidney failure, leg and foot amputations, pregnancy complications, and deaths related to flu and pneumonia.

Type 2 diabetes mellitus affects 9% - 95% of people with diabetes and most often appears after age 40. However, it can no longer be considered an adult-onset disease, as it is now found commonly in obese teenagers. The diagnoses of type 2 diabetes, impaired glucose tolerance, and impaired fasting glucose are based on both the World Health Organization and the American Diabetes Association (ADA) guidelines. According to these criteria, type 2 diabetes can be diagnosed either by an oral glucose tolerance test (2-hour post-75-gm load) with a value of 200 mg/dL or greater, or by a fasting glucose concentration of 126 mg/dL or greater. In addition, there are intermediate categories of glucose tolerance. Impaired glucose tolerance is diagnosed by a 2-hour post-load oral glucose tolerance test of 140 mg/dL or greater but less than 200 mg/dL, and impaired fasting glucose is diagnosed by a fasting glucose of between 110 and 125 mg/dL. Both individuals with impaired glucose tolerance and those with impaired fasting glucose are at high risk of developing diabetes.

Diabetes is now the sixth leading cause of death in the United States. One in five adults over age 65 have diabetes. Among adults aged 20 or older, African Americans are twice as likely as whites to have diabetes, and American Indians and Alaska Natives are 2.6 times more likely to have diabetes.
Cost of Treatment, Morbidity and Mortality

Diabetes is a significant public health problem resulting in substantial morbidity and mortality. Direct medical and indirect expenditures attributable to diabetes in 1997 were estimated at $98 billion. Each year, diabetic complications have tragic effects on human suffering and system costs:

- 12,000-24,000 people develop blindness;
- close to 32,000 people develop kidney failure (over 100,000 are treated for this condition);
- about 82,000 people have diabetes-related leg and foot amputations;
- an estimated 135,000 expectant mothers are diagnosed with gestational diabetes;
- 10,000-30,000 people with diabetes die of complications from flu or pneumonia (diabetes are roughly three times more likely to die of these complications than non-diabetics); and
- it is estimated that heart disease and stroke cause about 65% of deaths among people with diabetes.

Overall, direct medical expenditures attributable to diabetes in 1997 totaled $44.1 billion, of which $7.7 billion was spent for diabetes and acute glycaemic care, $11.8 billion for the excess prevalence of related chronic complications, and $24.6 billion for the excess prevalence of general medical conditions. The majority of attributable expenditures were for inpatient care (62%), followed by outpatient services (25%) and nursing home care (13%). Two-thirds of all medical costs for diabetes were borne by elderly people. Attributable indirect costs totaled $54.1 billion—$17.0 billion from premature mortality and $37.1 billion from disability. In 1998, medical expenditures for people with diabetes totaled $10,071 per capita, compared with $2,669 for non-diabetics. With all that, the full burden of diabetes is probably still under reported; death records often fail to reflect the role of diabetes, and the costs related to undiagnosed diabetes are unknown. It is clear the economic burden of diabetes mellitus in the U.S. is enormous. Anything that can be done to improve this disastrous trend is extremely important. (Statistics available at http://www.cdc.gov/diabetes.htm.)

Naturopathic Treatment

Naturopathic treatment for diabetes focuses primarily on diet, lifestyle and nutritional supplementation, for which there is substantial validation in the research literature. Significant progress could be made against this rising epidemic if these specific interventions were aggressively pursued. Individualized treatment from a naturopathic physician might include the following:

A. Diet and lifestyle counseling to prevent diabetes in at-risk patients.

Most studies show that intensive lifestyle changes can have a profound effect on the occurrence and progression of diabetes. Reductions have ranged from 30% to 50% in compliant individuals, as reported in the following studies (among many others):

- Lifestyle intervention was more effective than metformin in preventing diabetes (9% lower incidence).2
- Lifestyle intervention resulted in a 38% reduction in the incidence of diabetes in high-risk subjects.1
- Diet and lifestyle interventions were not effective because of poor compliance in this study. However, in those individuals who were compliant and had only modest weight loss (4.5 kg/yr. 4.2% of initial body weight), there was a reduced risk of NIDDM (non-insulin-dependent diabetes mellitus) by 30%.2

B. Diet and/or lifestyle counseling to improve glycemic control in diabetic patients.

Many studies show that intensive lifestyle changes improve glycemic control (the primary goal in diabetes management) and thereby reduce some complications in diabetic patients.

- Lifestyle changes improved glucose tolerance in newly diagnosed NIDDM.4
- Lifestyle changes improved glucose control in NIDDM patients but had no effect in preventing cardiovascular complications.4
- Low fat, vegan diet in NIDDM patients was associated with significant reductions in fasting glucose and body weight.6
- Meta-analysis suggests exercise training will reduce HbA1c (a key marker of glycemic control) even without change in weight.7

C. Specific dietary modifications.

Many studies show specific dietary modifications can have a positive effect in improving glycemic control and reducing diabetic complications.

- Fats
  - Substituting saturated fat with polyunsaturated fat changes abdominal fat distribution and improves insulin sensitivity.4
  - A 5-year study showed no difference on a reduced-fat of 4 g diet vs. standard diet in glucose control of patients at risk to develop NIDDM. However, those participants who were more compliant maintained lower fasting and 2-h glucose.9
• Meta-analysis supports high monounsaturated (MUFA) diets over high carbohydrate (CHO) diets for NIDDM patients. High MUFA diet decreases triglycerides, increases HDL and improves glycemic control. 10
• A high MUFA/low CHO diet improves glycemic control and triglyceride levels vs. standard diet. 11

Fiber
• Increasing fiber beyond ADA recommendations may be important. A diet rich in soluble and insoluble fiber (50g/day of a 30%/50% blend) improved glycemic control, decreased hyperinsulinemia, and lowered plasma lipid concentrations in NIDDM patients. 12
• Soluble fiber specifically may be of particular importance. 10 grams of psyllium supplemented in NIDDM patients improved glycemic and lipid control. 13
• 20 grams of guar gum improved blood glucose, HbA1C and LDL-cholesterol in NIDDM patients. 14

Low Glycemic Index (GI) Diet
• Epidemiological studies suggest that increasing GI and glycemic load are associated with increased risk for diabetes. 15, 16
• A low GI diet (58) compared to a high GI diet (86) improved blood glucose and lipid control in overweight NIDDM patients. 17, 18
• GI did not improve glycemic control in patients who lost weight. Therefore, GI may be most important in NIDDM who are maintaining weight. 19
• A low GI diet lowered the glucose and insulin responses throughout the day and improved the lipid profile and capacity for fibrinolysis in NIDDM patients. 20
• High-GI meals promoted excessive food intake in obese non-NIDDM patients. 21

D. Specific nutritional supplementation. There is growing evidence that specific nutritional supplementation can have a positive effect in improving glycemic control and reducing diabetic complications.

Chromium
• Chromium at 200 mcg and 1000 mcg significantly improved HbA1C, glucose, insulin and cholesterol in NIDDM patients. The higher dose appeared more effective. 21
• Chromium may be beneficial in individuals who have mild glucose intolerance as well as overt Type 2 diabetics. 22

• Alpha Lipoic Acid
• 600 to 1800 mg/day of alpha lipoic acid (ALA) improved insulin sensitivity in patients with Type 2 diabetes. 23
• 600-1200 mg/day of ALA may improve microcirculation and diabetic polyneuropathy. 23, 24

Coenzyme Q10
• 120 mg/day of Coenzyme Q10 (CoQ10) improved glycemic control and blood pressure in NIDDM. 25
• 200 mg of CoQ10 daily improved HbA1C and blood pressure in NIDDM patients. 26 However, results were inconsistent in other studies. 26

Omega 3 Fatty Acids
• Meta-analysis suggests eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) lowers triglycerides by 30% in NIDDM patients with no adverse effects on HbA1C and blood sugar control. 27
• 2.5 grams of EPA/DHA improved CVD risk factors of platelet aggregation, blood pressure and triglycerides with little effect on glucose and total cholesterol. 27

Magnesium
• 600 mg/day of magnesium lowered BP in IDDM (insulin-dependent diabetes mellitus) only. 30
• 400 mg/day supplemental magnesium lowered systolic BP but did not improve glycemic control or other CVD risk factors in NIDDM patients. 31

Vitamin C
• 2 grams/day of vitamin C may have a beneficial effect in NIDDM subjects on both glycemic control and blood lipids. 32
• 1.25 grams of Vitamin C and 680 iu of vitamin E significantly lowered urinary albumin excretion rate, a marker of progression to end-stage renal disease. 33 1 gram of Vitamin C lowered the urinary albumin excretion in diabetic subjects. 35
• 1 gram of Vitamin C had beneficial effects upon glucose and lipid metabolism in NIDDM patients. 36
• 100 or 600 mg/day of Vitamin C reduced sorbitol accumulation and therefore may be useful in preventing diabetic retinopathy complications. 37

Vanadium
• 100 to 125 mg/day of vanadium improved insulin sensitivity in Type 2 diabetes. 38, 39
• It is important to note that the upper limit for vanadium has been determined to be 1.8 mg/day, and long-term studies on high dose vanadium have not been performed, so supplementation should be strictly monitored.
Antioxidants
- Tomato juice and Vitamin E both reduced LDL-cholesterol oxidation and therefore may decrease cardiovascular risk in NIDDM patients. \(^\text{1}\)
  
- Supplementation of Type 2 diabetic individuals with antioxidant vitamins (beta-carotene, C, E) may help with cardiovascular risk by decreasing LDL-oxidation. \(^\text{11}\)
  
- Supplementation with zinc and chromium may improve lipid peroxidation. \(^\text{2}\)
  
Fenugreek
- 15 grams of fenugreek seed powder significantly reduced postprandial glucose levels in NIDDM patients. \(^\text{11}\)
  
- 1 gram of hydroxy-alpha-cholic extract of fenugreek seeds improved glycemic control, HbA1C, insulin resistance, and hyperglycemia in NIDDM patients. \(^\text{12}\)

Contributed by Dan Lukascek, ND, Director of Clinical Services: Functional Medicine Research Center, Metagenics, Inc., Gig Harbor, WA; Ryan Bradley, third year ND student, Bastyr University


Naturopathic Medicine and the Management of Menopause: Safety and Effectiveness

Background

By the year 2015, nearly 50% of the women in the United States will be menopausal. Between 1990 and 2020, the menopausal population in the U.S. will double. This dramatic increase in the number of menopausal women is changing the way health care providers work with women, and changing medicine itself.

One of the most complicated and difficult health care decisions that menopausal women face today is whether to use hormone replacement therapy (HRT). Women look to their health care providers for definitive answers to their questions. Practitioners are faced with an even greater challenge, evaluating the benefits and risks of hormone replacement therapy, and alternatives to hormone replacement therapy, for individual patients.

In the year 2000, 46 million prescriptions for Premarin® were written in the United States. An additional 22.3 million prescriptions were written for PremPro®. Almost one in three women given a prescription for HRT never fills it. Of those who do start HRT, the majority will discontinue its use shortly after starting therapy. Reasons given for discontinuation include uterine bleeding; side effects (including mood changes, breast tenderness, bloating and weight gain); fear of breast cancer; and not understanding or believing in the need for long-term use.

Definitive evidence regarding the benefits and risks of hormone replacement have recently been clarified by the publication of the results of the Women's Health Initiative (WHI)1. The WHI trials have clarified that the risks of HRT for coronary artery disease, breast cancer, strokes, clots, and heart attacks outweigh the benefits of slowing bone loss, reducing fractures, and reducing the incidence of colon cancer. Women and their health care providers are faced with trying to make the best decision possible in the face of what we do know, what we don't know, and what we're still uncertain about.

Many women report using complementary and alternative medicine therapies for menopause symptoms.2 Although the science underlying natural therapies for menopause symptoms still needs further investigation, decades (and in many cases centuries) of safe historical use, and a growing body of research including randomized, controlled clinical trials, provide compelling evidence of effectiveness and safety. Thus, naturopathic approaches to menopause provide an appealing option for millions of menopausal women.

Menopause and Perimenopause: What Changes?

The decline of endogenous (produced within the body) estrogen leads to numerous tissue and organ changes that can cause problems. In addition to the reproductive and urinary tracts, estrogen-sensitive tissues include skin, bone, vascular lining, teeth and gums, eyes, the brain, and central nervous system.

Fifty percent to 80% of women in the U.S. report menopause-related hot flashes, night sweats, vaginal dryness, insomnia, mood swings and depression. During the first 5 to 10 years of menopause, vulvovaginal symptoms begin to appear. Later, as the other mucous membranes of the urogenital tract become affected, increasing rates of incontinence and infection result.

Sex steroids also affect sleep, libido, cognitive function, motor coordination, and pain sensitivity. Data are mixed regarding the role of menopause in depression and mood swings, but in perimenopause (early menopause), depression and mood disorders do appear to be more common than in the reproductive years.

Naturopathic Treatment

A. Symptom Relief

Natural therapies are typically very well suited for the perimenopausal patient. Conventional HRT is not the only option. Women who should not or do not want to take hormones may turn to herbal and nutritional therapies for managing their menopausal symptoms and risk factors. These natural therapies are increasingly popular and have a growing body of scientific evidence to support their efficacy. Naturopathic doctors are familiar with the research documenting the effects of alternative therapies and are well trained in helping women make wise choices.

A. Soy Isoflavones

• Eight published studies report improvements with soy protein rich in isoflavones.2,12-15,18 In general, reduction in hot flashes and night sweats is in the range of 30% to 55%.

• Other soy studies demonstrate that increasing the soy foods in the diet stabilizes bone density,14,15,16 and reduces cholesterol.17

• Precautions and Contraindications: Adverse effects associated with soy isoflavones are largely related to mild allergic reactions and indigestion. Extremely rare problems such as the inhibition of thyroid hormone production may occur. Women using tamoxifen for breast cancer should avoid high dosages of soy.
Red Clover Isoflavones
- At least four clinical trials have been conducted on the effect of red clover isoflavones on vasomotor symptoms. Two show benefit and two do not.10,11 In the two positive studies, users had approximately 50% reduction in hot flashes.10,11
- Precautions and Contraindications: The PDR for Herbal Medicines lists no precautions or adverse reactions known in conjunction with the proper administration of therapeutic doses of red clover.

Black Cohosh
- There have been six well-publicized studies.12
- In one of the largest studies, clear improvement in menopausal complaints was seen in 80% of the women, and complete disappearance of symptoms occurred in approximately 50%.13 Symptoms included hot flashes, night sweats, headaches, insomnia and mood swings.
- The other studies reported improvement in fatigue, irritability, hot flashes and vaginal dryness.
- A recent study on black cohosh included eighty-five women diagnosed with breast cancer who were experiencing hot flashes.14 Both the black cohosh and placebo groups had a decline in the number and intensity of hot flashes during the first month of about 27%. Women in the black cohosh group did report a greater reduction in sweating.
- Precautions and contraindications: The PDR for Herbal Medicines lists no health hazards or side effects known in conjunction with proper administration of therapeutic dosages of black cohosh. Other reports have included occasional and mild stomach complaints, headaches, dizziness.

Ginseng
- Panax Ginseng can reduce mental or physical fatigue15 by enhancing the ability to cope with various physical and mental stressors by supporting the adrenal glands.15 It may be used to treat atrophic vaginal changes due to lack of estrogen.16
- Precautions and contraindications: Patients with cardiovascular disease or diabetes are cautioned about the use of ginseng. High blood pressure has been associated with prolonged high dose gingseng and concomitant use of caffeine. General side effects have included breast tenderness, two cases of vaginal bleeding with gingseng face cream, headache, inomnia and nervousness. Caution should also be taken when using ginseng and any antidiabetic agent or insulin, blood thinning medications, Phenelzine and selected diuretics.

Combination products
Most of the herbal combination products available contain five or more plans. Other combination products contain a mixture of plants and nutrients. Most of these combination products have not been researched, even though individual ingredient have been.
- One herbal combination product that has been the subject of a clinical trial contains dang gui, motherwort, licorice root, kudzu root, and wild yam root.16 One hundred percent of the women taking the botanical formula had a reduction in their symptom severity; 71% of women taking the herbal formula reported a reduction in the total number of symptoms.
- Combination products are thought to be most effective in treating hot flashes, mood changes, and insomnia.
- Insomnia is the most commonly reported sleep problem in industrialized nations and women are at increased risk. Changes in hormonal levels in the brain cause many women to have insomnia problems during perimenopause and menopause. Valerian is one of the most well known herbal therapies for insomnia and several clinical trials have documented the efficacy of valerian on sleep latency, quality and sleep structure.17,18,19,20
- Other significant menopause symptoms include mood changes, anxiety and cognitive changes. There has been considerable research on St. John's Wort for relief to moderate depression, although not specifically in menopausal women. A systematic review of 8 randomized controlled and double-blind clinical trials of St. John's Wort extract demonstrated a statistically significantly higher response rate in the herbal treatment group versus the placebo group.21
- An extract of kava has been studied for anxiety and hot flashes in menopausal women,17 as well as anxiety syndromes in non-menopausal women. A systematic literature review and meta-analysis of randomized controlled trials utilizing only kava extract identified seven double-blind placebo-controlled studies, six of which met criteria for quality in research methodology.22,23 Three of the trials showed a significant reduction in baseline Hamilton Rating Scale for Anxiety scores after treatment for 4-24 weeks. The other four studies also demonstrated superiority of kava extract over placebo using a variety of anxiety measurements. Kava can be an excellent herbal choice for perimenopausal women who have hot flashes, anxiety, lower threshold for stress than prior to menopause, and escalating problems with sleep disruption.24
Numerous botanicals have been used historically in the practice of traditional herbal medicine for the treatment of menopausal symptoms. Although some have been researched (see above), others have no research, no confirming research, or only a small study showing some efficacy. They include wild yam, dong quai, licorice, chaste tree, kava, sage, hops, and more.

Selected Nutrients for Symptom Relief

- Individual nutrients have been used for specific perimenopausal symptoms. Supplements such as vitamin E, bioflavonoids, and vitamin C have been shown to reduce hot flashes.6,8
- Melatonin, L-tryptophan and 5-hydroxytryptophan have been used for insomnia; vitamins B6, folic acid and B12 for depression; and glucosamine sulfate, borage oil, and chondroitin sulfate for joint pains.

Natural Progesterone Cream

- A transdermal natural progesterone cream was studied for its ability to control vasomotor symptoms (hot flashes) and to prevent bone loss.60 Twenty five of 30 (83%) women in the treatment group experienced improvement or resolution of their hot flashes and five of 26 (19%) placebo subjects showed improvement or resolution. The number of women who showed a gain in bone mineral density did not differ between the treatment group and the placebo group.

Hormone Replacement Therapy

- Naturopathic physicians also utilize prescription natural hormonal therapies for symptom relief when appropriate.

B. Osteoporosis

Osteoporosis is the most common bone disease and is characterized by low bone mass and microarchitectural deterioration of bone tissue. This leads to fragility of the bone and an increase in the risk of fractures. Between 13% and 18% of postmenopausal Caucasian women in the U.S. (4.6 million) have osteoporosis. An additional 30% to 50% (13 to 17 million) have low bone density of the hip. One out of every two Caucasian women will experience an osteoporotic fracture at some point in her life. Fractures and their complications place a heavy economic burden on individuals and on the health care system. Direct medical expenditures alone for osteoporotic fractures are estimated at over 14 billion dollars per year. It is estimated that this number will triple by the year 2040.

Lifestyle

Exercise has numerous health benefits, but near the top of the list is weight-bearing and muscle-strengthening exercise to improve agility, strength, and balance. Reducing the risk of falls and modest increases in bone density will reduce bone loss and fractures.

- Osteoporosis is largely a preventable disease. Maximizing and preserving bone mass have not only multiple health benefits but are cost-effective in preventing this disease and, even more important, in reducing the risk of fracture. Appropriate measures include an adequate intake of calcium and vitamin D, regular weight-bearing exercise, avoidance of tobacco use and alcohol abuse, and treatment of risk factors for fracture such as poor vision.
- Regular exercise, including strength training, slows bone loss and increases bone mass.64,65 Balance training has been shown to reduce fracture risk without any change in bone density by reducing falls.

Dietary counselling

- Dietary counselling is also a fundamental tool in preventing osteoporosis. Postmenopausal women in the U.S. consume about 600 mg of calcium daily, well under the 1200 mg recommended by the National Academy of Sciences. Dairy products, calcium-fortified foods, and foods high in phytoestrogens (soybeans) are not only important sources of calcium, but have other constituents that build bone and slow bone loss. The isoflavones in soy foods may reduce the risk for osteoporosis and may also have therapeutic value for women with osteoporosis.42

Nutritional Supplementation

- Research on the relationship between calcium and bone mass clearly indicated that levels higher than the (former) RDA for calcium are needed to maintain bone mass and reduce the risk of fractures.47
- Recommended intake for women 51 and older is 1200 mg.47
- It is estimated that over half of women consume only about 400 mg of daily calcium.
- Other minerals and nutrients including vitamin D, magnesium, copper, zinc and vitamin K also play key roles in bone physiology, affecting density, architectural structure, and strength.
- Naturopathic medicine recognizes the value and importance of FDA approved drugs for preventing and treating osteoporosis: estrogen replacement therapy, bisphosphonates, selective estrogen receptor modulators, and calcitriol. These may be used in conjunction with a naturopathic treatment protocol.

C. Heart Disease

Women are particularly searching for menopause options since the recent publication of three significant trials showing that conventional hormone replacement therapy (HRT) not only does not reduce their risk of heart disease, but actually increases the risk of heart disease, clots and strokes.1,13 This research has utterly and rather abruptly changed the management of menopause. Many conventional physicians, who have been prescribing HRT to women without hesitation for the last 40+ years, are now looking to short-term HRT for symptom relief. Their attention is turning toward herbal and nutritional
therapies for long-term symptom relief, and toward nutritional, botanical, and pharmaceutical interventions for preventing and treating heart disease.

Basic lifestyle changes – regular aerobic exercise, not smoking, stress reduction, lower fat and whole foods diets – have long been able to demonstrate their association with lower rates of cardiovascular disease. Conventional medical journals contain decades of published research on simple nutritional supplements that lower cholesterol, prevent atherosclerosis, reduce clotting, and prevent oxidative damage to the arteries supplying the heart without requiring potentially harmful HRT. Ensuring that both our health care system and our physicians pay greater attention to nutrition, exercise, and simple supplementation with safe and effective therapies can reduce the risk of the number one killer of women: heart disease.

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Naturoopathic Medicine in the Treatment of Gastritis and Peptic Ulcer Disease

Background

Gastritis is an inflammatory condition of the stomach lining that includes a number of disorders and causes. It is experienced as stomach pain (often severe) and dyspepsia (indigestion). It can cause gastric bleeding which often leads to anemia in the elderly and persons at risk. It is often a precursor to peptic ulcer disease (PUD) which can further lead to gastric hemorrhage and perforation (a life-threatening event requiring surgical intervention). Some forms of chronic gastritis and PUD significantly increase the risk for stomach cancer.

There are approximately 500,000 new cases and 4 million recurrences of PUD yearly in the United States. Approximately 10% of Americans eventually develop PUD. The estimated annual direct costs for PUD are $8-10 billion with additional indirect costs and related gastritis costs of similar (or greater) magnitude.1, 2

There are many causes of gastritis and PUD, including infection with the bacterium Helicobacter pylori (HP), nonsteroidal anti-inflammatory drugs (NSAID) use, severe stress, alcohol use/intoxication, celiac disease, dietary allergic disorders, autoimmune disorders, and others. Of these many causes, NSAID/antispin use and HP infection are the two most common.1, 3, 6, 7

Naturoopathic Treatment

A. Reduce NSAID Use

NSAIDs are used for control of pain and inflammation (both acute and chronic), most commonly in the treatment of arthritis.1

NSAIDs are among the most frequently prescribed drugs worldwide.1

NSAIDs are associated with substantial excess costs and utilization of medical care due to gastritis and PUD caused by their use.7, 8, 11, 12, 13 Although different studies have identified different coefficients for these extra costs, they are always substantial:

- Cost of NSAIDs can be multiplied by coefficients of 1.45 to 3 when treatment costs for associated gastrointestinal complications are considered.13
- Iatrogenic (caused by medical intervention) costs of NSAID therapy add 56% to the cost of NSAID treatment.14
- $0.35 is spent on iatrogenic costs for every $1.00 spent on NSAID therapy with estimated average treatment per NSAID-associated gastropathy episode at $217.20.15

B. Dietary, Botanical, and Nutraceutical Therapies to Reduce Inflammation

Reducing inflammation is an important focus of treatment, because lowering the level of inflammation results in less pain for the patient, and therefore lower doses of NSAIDs to manage the discomfort.

Fish oils/omega-3 fatty acids have been shown in numerous studies to provide substantial benefits in the treatment of inflammatory disorders, resulting in decreased disease activity and a lowered use of NSAIDs.16, 17, 18, 19, 20, 21, 22, 23

Safe and effective botanical medicines that have been shown to have no adverse gastrointestinal effects in the treatment of rheumatoid inflammatory disorders are included in naturopathic therapeutics. Numerous studies indicate substantial benefits of various anti-inflammatory plant compounds (ginger, turmeric, curcumin, and others) in the treatment of inflammatory disorders leading to decreased disease activity and a lowered use of NSAIDs without gastrointestinal complications.24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34

Naturoopathic medicine utilizes dietary therapy in the treatment of rheumatoid inflammatory disorders. Numerous studies demonstrate a significant reduction of symptoms in patients with moderate to severe rheumatoid arthritis (RA) when they periodically fast and are switched to very low-fat, gluten-free, allergen-free, vegetarian diets. These studies strongly suggest that dietary treatment is a "valuable adjunct to the ordinary therapeutic armamentarium for RA."35, 36, 37, 38, 39, 40

Various food supplements and nutraceuticals are used in the treatment of rheumatoid inflammatory disorders. Studies demonstrate that food-based preparations and nutraceuticals can alleviate symptoms and significantly reduce functional disability and NSAID use in patients with osteoarthritis (OA).41, 42, 43, 44, 45, 46

Naturopathic physicians instruct patients in the proper use of exercise and physical therapy for the treatment of rheumatoid inflammatory disorders. Studies demonstrate high-intensity, home-based exercise and strength-training programs can "produce substantial improvements in strength, pain, physical function and quality of life in patients with knee OA" which may help them reduce their use of NSAID.47, 48
E. Treat Diet-associated Causes of Gastritis and PUD

Naturapathic medicine identifies and eliminates various aggravating, intolerant and reactive foods from the diets of patients with gastritis and PUD.

- Certain forms of gastritis and PUD are associated with dietary allergens and require identification and elimination of offending food(s).13, 19, 30, 32, 33
- Long-term exposure to food allergens increases stomach inflammation in allergic patients infected with H. pylori.17
- Certain forms of gastritis and PUD are associated with gluten intolerance (celiac disease) and require testing for celiac disease and dietary elimination of gluten-containing foods.19, 20, 21
- Patients with celiac disease have higher prevalence of HP infection.19

F. Correct Dietary Deficiencies that Increase Risk for Gastritis and PUD

Naturapathic physicians focus on long-term prevention by decreasing patient risks for PUD.

- Reduce alcohol intake.
- Encourage diets rich in fiber and fruits and vegetables that are known to reduce the development of PUD.126
- Supplement with various antioxidants.112
- Correct zinc deficiency.127, 128

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Naturopathic Medicine in the Treatment of Hypertension

Background
The high prevalence and extensive harmful effects of hypertension make it a critical condition to discuss the potential impact of natural medicine on effective management of serious chronic disease. Over sixty million Americans have high blood pressure, including more than half of all Americans aged 65 to 74 years, and almost three fourths of all African-Americans in the same age group. More than 80% of people with hypertension have mild or moderate disease – systolic pressure between 140 and 180 and diastolic pressure between 90 and 110. Hypertension can be implicated in as many as 800,000 deaths per year; as well as non-lethal myocardial infarction, strokes, and permanent damage to the retina and kidney.

Hypertension is found almost exclusively in developed countries and, while environmental, stress and genetic factors undoubtedly play their roles, the standard western diet is strongly linked to essential hypertension. Essential hypertension is virtually nonexistent in undeveloped areas. There, increased blood pressure is not related to advancing age. When people from these primitive societies move into industrialized areas and adopt "civilized" diets (low in fiber and high in protein, fat, sugar, and salt), the incidence of hypertension increases dramatically among them. Other risk factors include smoking, obesity, excessive alcohol or coffee consumption, careless lifestyles, and heavy metal toxicity (especially cadmium and lead). Lifestyle changes and natural therapies can provide a safe and effective way of preventing or reducing hypertension, and can do so without the many side effects associated with conventional hypertension drugs.

Uncontrolled blood pressure (hypertension) can lead to serious medical problems. After a patient's long-term compensatory mechanisms fail and blood pressure keeps rising, there are further serious complications that occur. These include aneurysms, hypertensive heart disease with cardiac hypertrophy and congestive heart failure, cerebrovascular hemorrhage and nephrosclerosis. Also, hypertension is one of the major risk factors for atherosclerosis and the major regional syndromes of atherosclerotic vascular occlusion such as coronary artery disease, occlusive cerebrovascular disease, and peripheral arterial insufficiency.

Naturopathic Treatment
A. Diet and Nutrition
- Short-term reduction in blood pressure by nutritional means translates into improved long-term improvements in morbidity and mortality, including reduced cerebral vascular accidents, coronary heart disease, and myocardial infarctions.1,3,11
- Diets rich in potassium reduced cerebral vascular accidents by 41% in hypertensive subjects.3,10
- A Mediterranean-type diet reduced the incidence of a second myocardial infarction (heart attack or "MI") by 76%.5,12
- The "Dietary Approaches to Stop Hypertension (or DASH-I) Combination Diet" (summarized as sodium restricted, a sodium/potassium ratio of 1 to 7, 75% of the RDA for potassium, magnesium and calcium 31 grams of daily dietary fiber, 8-10 servings of fruits and vegetables daily and 2-3 servings of low fat dairy products daily) was shown to reduce BP to levels that can be achieved by drug therapy in patients with mild hypertension.10,31,42,33
- These and other studies testify to the importance of diet, micronutrients, and specific nutrients in the prevention and treatment of hypertension and its cardiovascular sequelae.13

B. Reducing Side Effects and Interactions with Prescription Drugs
Hypertensive drugs span several drug classifications and can cause an array of side effects and drug-induced nutritional depletions. Naturopathic nutritional supplementation is used to reduce drug side effects while treating the underlying nutrient deficiency states. A few examples from each hypertensive drug class are listed below. [Vasodilators (hydralazine) and alpha agonists have been omitted because they are much less frequently prescribed.]

- Diuretics
  - Calcium is depleted at an increased rate while taking loop diuretic agents.
  - Serious heart dysrhythmias may ensue if magnesium and potassium levels are depleted through diuretic use. Medical doctors check potassium and almost always exclude monitoring for magnesium depletion.
  - Combining high licorice consumption with diuretics has been shown to potentially lower potassium to dangerous levels.
  - Laxatives may potentiate potassium loss when combined with potassium-wasting diuretics, resulting in life-threatening hypokalemia.
Magnesium is depleted at an increased rate while taking loop diuretic agents. This is not conventionally monitored with lab testing.

Loop diuretics in high dosage or with long-term use, may lead to hypokalemia (low potassium).

Diuretics can cause an increased loss of thiamine in the urine, potentially leading to deficiency and cardiac dysfunction.

**Beta Blockers**

- Calcium can reduce blood levels of atenolol up to 50%.
- Apropronol causes serum potassium levels to become elevated in a dose-dependent fashion.

- Beta blockers can cause coenzyme Q10 depletion.

**Calcium Channel Blockers**

- Serum foladipine may become elevated if grapefruit juice is ingested close to administering the drug.
- ACE inhibitors with potassium-sparing diuretics may lead to life threatening hyperkalemia.

- Capoten and inprano can react together to form a complex, decreasing absorption of both.

It is noteworthy that the ALLHAT study, the largest clinical trial on hypertension over undertaken (42,418 patients), recently found that the safest, most effective drugs with the best long-term health outcomes (lowest morbidity and mortality) were thiazide diuretics, chlorthalidone, and reserpine.

In the plant kingdom, diuretics are the most ubiquitous and have a long history of effectiveness in optimal dosages without electrolyte depletion.

**C. Treating Hypertension with Nutritional Supplements, Botanical Medicine and Stress Reduction**

**Natural Diuretics**

The strongest available natural diuretics are taraxconon leaf (dandelion) and petroselium root (parsley). Though both of these agents are potassium-sparing diuretics, high doses are required to achieve optimal diuresis.

**Natural Vasodilators**

The amino acid L-arginine has been shown to be an effective vasodilator through its conversion into nitric oxide. Its effectiveness in human studies of hypertension is well documented.

**Natural Anti-Hypertensive Antioxidants**

Any natural compound that functions as an antioxidant while lowering blood pressure offers additional benefit in stabilizing cell membranes and possibly further reducing long-term morbidity and mortality.

- **Alpha Lipoic Acid (ALA)**

  Alpha lipoic acid helps to reestablish tissue and blood levels of vitamins and antioxidants (such as vitamin C, vitamin E, glutathione, and coenzyme Q10) and improve insulin resistance. It has been shown to improve the effects of ALA on the vasculature and BP.

- **Coenzyme Q10**

  In one study, 26 hypertensive subjects with an average blood pressure of 164.5/98.1 mm Hg were given 50 mg of CoQ10 orally twice daily for 10 weeks. The systolic blood pressure (SBP) showed an 11% reduction, and the diastolic blood pressures (DBP) showed a 12% reduction.

- **Vitamin E**

  The relationship between vitamin E and BP has been studied extensively in animals (sparingly in hypertensive rats, SHR) but limited studies have been done in humans.

- **Celery**

  Animal studies have demonstrated a significant reduction in BP using a component of celery oil, 3-N-butyl phthalide. There was a dose-response relationship in SHR with a 24 mm Hg fall in the Sprague-Dawley hypertensive rat model. Consuming four stalks of celery per day or eight teaspoons of celery juice three times daily seemed to provide a similar antihypertensive effect in human essential hypertension.

- **Hawthorne**

  Hawthorne may reduce systemic vascular resistance and blood pressure, decrease the pressure-rate product in the myocardium, improve ejection fraction and congestive heart failure, improve arrhythmias, lower cholesterol, dilate coronary arteries and improve myocardial perfusion and angiography.

  Doses of about 160 to 900 mg per day of a standardized Hawthorn extract have been used to achieve these cardiovascular effects. No controlled clinical trials in hypertensive individuals have been reported to
L-Carnitine
Clinical and experimental studies demonstrate significant therapeutic benefits of L-carnitine in the treatment of diabetes mellitus, hypertension, ischemic heart disease, acute MI, congestive heart failure (CHF), arrhythmias, and peripheral vascular disease with claudication and dyspnea.128,20,21 Two grams per day was the dose used in the Digieni et al. trial.132

Omega-3 PUFAa (polyunsaturated fatty acids found in cold water fish, fish oils, flax seed and nuts)
A meta-analysis of 31 studies on the effects of fish oil on BP showed a dose-related response in hypertension as well as a relationship to the concomitant diseases associated with hypertension.132,32,43,48
- At fish oil doses of <4 g/day, there was no change in the BP of mildly hypertensive subjects.
- At 4 to 7 grams of fish oil per day, BP fell 1.6 mm Hg to 2.9 mm Hg.
- At 15 grams of fish oil per day, BP decreased 5.8 mm Hg to 8.1 mm Hg.

Potassium
The recommended intake of K+ is 650 mEq per day with a K+/Na+ ratio of over 5:1. Numerous epidemiologic, observational and clinical trials have demonstrated a significant reduction in BP with increased dietary K+ intake.15,14,19,48

Magnesium
A high dietary intake of magnesium of at least 500-1,000 mg per day reduced BP in most epidemiologic, observational and clinical trials, but the results were less consistent than those seen with Na+ and K+.11,20,21,49,43

Calcium
Higher dietary calcium is not only associated with a lower BP, but also with a decreased risk of developing hypertension. A 23% reduction in the risk of developing hypertension was noted in those individuals on greater than 800 mg per day compared to those on less than 400 mg per day.15,41

Combined Supplements
Combined nutrients, vitamins, minerals and antioxidants have clearly been shown to lower BP in the DASH-I, DASH-II, NHANES-III, Vanguard and other studies.13,14,45,46,47,48

- Vitamin C: 100 - 1,000 mg per day
- Vitamin E: 400 - 1,000 IU/day have shown beneficial effects on improving insulin sensitivity, lowering serum glucose, inhibiting TxA2, increasing serum glutathione levels, increasing intracellular magnesium, and improving arterial compliance.
- Vitamin B6: One human study by Abyak et al. reported that high dose vitamin B6 significantly lowered BP. Subjects received 5mg/g/day of vitamin B6 for four weeks. The SBP showed a 9.4% reduction and the DBP showed a 9.3% reduction.

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31