Aim, Objectives and Methods

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This Health Technology Assessment (HTA) report on naturopathy was developed to provide an evidence-based summary of naturopathic practice and the safety, economics and effectiveness of naturopathic care. The scope of the HTA was informed by research conducted by the international naturopathic community over the last thirty years.

Aim

The aim of this HTA is to provide the data and research necessary to inform evidence-based decisions regarding the inclusion of the naturopathic workforce in contemporary health care systems, which reflects their ability to reduce the burden of global illnesses such as non-communicable diseases. It is our intention that this HTA will be used to support the global implementation of appropriate and robust regulation of the naturopathic profession and to increase access to training for naturopaths/ naturopathic doctors that is commensurate with their role in delivering primary care health services.

Objectives

The objectives of this HTA are to describe:

- 1. The international landscape of the naturopathic profession
 - How widespread is the practice of naturopathy/ naturopathic medicine globally?
 - What is the foundational basis of naturopathic practice?
 - What are the educational standards underpinning naturopathic practice?
 - What regulation is in place for the naturopathic profession?
- 2. The safety and risks associated with naturopathic care
 - What adverse effects or complications can occur or have been observed so far associated with naturopathic practice?
 - What safety precautions are required in naturopathic practice?
- 3. The economics of naturopathy/naturopathic medicine
 - What are the economic considerations when evaluating naturopathic care?
 - What is the cost-effectiveness of naturopathic care?

- What are the economic factors influencing naturopathic practice and research?
- 4. The implementation and practice of naturopathy/ naturopathic medicine in real-world settings and health systems
 - How widespread is the use of naturopathy/naturopathic medicine by the general population?
 - What is the access and equity of naturopathic health services?
 - What role do naturopaths/naturopathic doctors play in health promotion and community education?
- 5. The naturopathic profession's contribution to knowledge generation
 - What types and quantities of scientific publications have been produced by naturopathic researchers?
 - What is the scope, breadth and quality of naturopathic research?
- 6. The research evidence-base for naturopathic practice
 - What conditions are commonly treated by naturopaths/naturopathic doctors?
 - What are the volume and outcomes of clinical studies examining the efficacy and effectiveness of naturopathic therapeutics, practices and treatments?
 - How are naturopathic treatments and practices studied in clinical research?

Context

For five years, the WNF undertook essential foundational work to inform this HTA. During that time, the WNF conducted seven international surveys involving naturopathic organizations, naturopathic educational programs, naturopaths and naturopathic doctors to ensure an appropriate and impartial representation of the breadth and complexity of naturopathic practice globally (see Figure i). An outline of the surveys conducted are as follows:

2015: The first international survey of the global naturopathic profession was conducted outlining characteristics of naturopathic practice in each country. Responses were received from 22 national naturopathic organizations which spanned all World Health Organization (WHO) Regions [1].

2016: A detailed international survey examining the characteristics of naturopathic education, regulation, and practice frameworks was initiated. The survey included responses from 65 naturopathic organizations (educational institutions, professional associations, regulatory bodies) from 29 countries. Data collection for this survey was completed in 2020 [2, 3].

2016: The international naturopathic educational institutions were surveyed. Thirty responses were received spanning 17 countries from five WHO Regions outlining what was taught in their naturopathic educational programs [4].

2016: A bibliometric analysis of research conducted by the naturopathic profession was undertaken from 2016 to 2018. The results of this international naturopathic research coalition project identified over 2200 naturopathic research papers which provided the basis for a substantial part of this HTA [5].

2019: An international practice survey was conducted to confirm the practices, health conditions and treatment modalities used by naturopaths/naturopathic doctors. This survey was sent to members from fourteen full WNF members (national naturopathic organizations) with an established history of naturopathic practice and included feedback from 859 naturopathic patient visits [6, 7].

2019: An international survey was conducted to identify the degree that naturopathic educational institutions provide free or low-cost naturopathic care to the underprivileged, low income or specialized groups through naturopathic community clinics [8].

2019: A detailed analysis of program content provided by naturopathic educational institutions around the world was initiated and completed in 2021. The analysis identified 131 naturopathic educational programs located across five WHO Regions [9].

2020: An international survey of naturopaths/naturopathic doctors was conducted to identify the degree that naturopathic clinicians engage with and educate the public through various community education and health promotion activities. The survey was translated into five languages and over 800 responses were received from naturopaths/naturopathic doctors spanning all WHO Regions [10].

2020: A detailed knowledge mobilization survey was translated into five languages and shared internationally, resulting in over 500 responses from naturopaths/ naturopathic doctors from around the globe. This survey examined naturopathic clinicians' approach to sharing and using knowledge and information related to naturopathic practice [11].

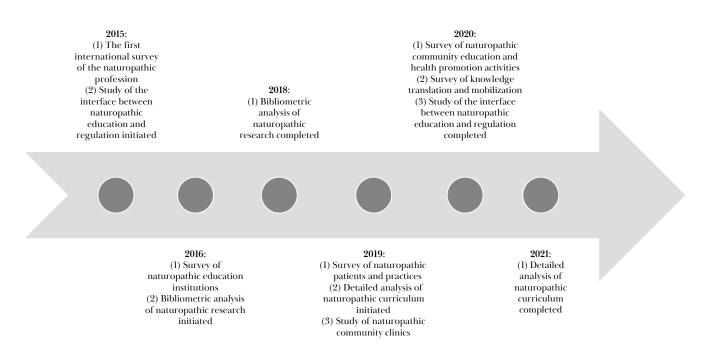


Figure i: Timeline of international research undertaken by the WNF in preparation for the Health Technology Assessment

Declaration of Astana

In 2018, the global health community came together for a Global Conference on Primary Health Care to review the 1978 Alma-Ata Declaration in the context of the WHO Sustainable Development Goals. Both Dr Iva Lloyd, ND and Professor Jon Wardle were invited to contribute to this event as representatives of the WNF, the outcome of which was the Declaration of Astana [12]. With the aim of achieving universal health coverage and meeting the WHO Sustainable Development Goals, the Declaration represents a commitment from Heads of State and Government, ministers and representatives of States and Governments to promote a Health for All policies approach, build sustainable primary health care, empower individuals and communities, and align stakeholder support to national policies, strategies and plans. The success of primary health care has been determined to be driven by knowledge and capacity building, human resources for health, technology, and financing. This Declaration is a pivotal document to guide the focus and activities of all areas of primary health care, including the naturopathic profession, especially as many of the recommendations (e.g., focus on prevention, person-centered care, teaching self-responsibility and healthy lifestyle) are congruent with naturopathic care. This HTA should be considered within the context of the Declaration of Astana's important global vision for primary care.

Full details of the Declaration of Astana can be accessed here: https://www.who.int/docs/ default-source/primary-health/declaration/ gcphc-declaration.pdf.

Resourcing

The HTA was primarily funded by the Naturopaths and Herbalists Association of Australia (NHAA), a full member of the WNF and by the WNF itself.

Materials and Methods

The scope of the HTA was outlined in 2017, approved by the World Naturopathic Federation Research Committee and involved a five-year in-depth analysis of the global naturopathic profession as foundational work for this HTA.

Protocol

The protocol for this HTA was structured in accordance with WHO HTA guidelines [13] and informed by previously published HTAs [14-16] with consideration of the specific context and features of the naturopathic profession and its practice.

Definition of the term "naturopathy" for the HTA report

For the purpose of this HTA report, naturopathy is defined as a system of healthcare with a deep history of traditional philosophies and practices and with medically trained practitioners who utilize a breadth of natural treatment modalities and practices in the provision of person-centered healthcare [17]. The term naturopathy includes both naturopathy and naturopathic medicine.

The foundational basis of naturopathic care includes the philosophies of "vitalism" and "holism" and the guiding principles of naturopathic practice include:

- The Healing Power of Nature (vis medicatrix naturae)
- Treat the Whole Person (*tolle totum*)
- Treat the Cause (tolle causam)
- First, Do No Harm (primum non nocere)
- Naturopathic Doctor as Teacher (docere)
- Health Promotion and Disease Prevention
- Wellness

Naturopathic practice is known for its multifaceted approach to treatment. The therapeutic modalities practiced by naturopaths and naturopathic doctors vary to some degree. A strength of naturopathy/naturopathic medicine is that it is an integrated system; as such, each jurisdiction incorporates modalities based on regional traditional health care practices and on the level of education and regulation in the Region. Other modalities integrated into naturopathic practice include acupuncture, and therapies associated with additional education such as intravenous therapies, prescribing rights for pharmaceuticals, regenerative injection therapies and minor surgery (See Chapter 1 *Naturopathic Practice* for more information).

Literature Search and Choice of Literature

The literature informing this HTA was drawn from the extensive bibliometric analysis of naturopathic research [5] expanded upon in Chapter 16. The full list of citations identified through the bibliometric study was divided into topic areas based on the coding allocated to each manuscript during the bibliometric analysis.

The results of the bibliometric analysis were separated into two sections for the HTA. The first – *Section 5: Effectiveness of Naturopathic Clinical Practice* – presents a summary of the evidence describing the conditions supported by naturopathic research including cancer, cardiovascular conditions, complex immune conditions, endocrine conditions, gastrointestinal conditions, mental health conditions, musculoskeletal conditions, neurological conditions, women's health, skin conditions, among others. The second – *Section 6: Research in Naturopathic Therapeutics and Practices* – presents the clinical outcomes associated with naturopathic treatment modalities and practice including complex naturopathic interventions, applied nutrition, clinical nutrition, herbal medicine, lifestyle and exercise, bodywork, mind-body medicine and counselling, hydrotherapy, acupuncture, yoga, and pharmaceuticals. The topic areas for each chapter were selected by the editorial team based on the number of articles available, and the frequency with which the treatment(s) was used, or the condition was reported as treated by naturopathic practitioners.

In total 51 authors from ten countries in six WHO Regions contributed to the literature review and the writing of chapters for this HTA. Authors selected for each chapter were primarily naturopathic researchers, or research-active naturopaths/naturopathic doctors and, in many instances, were affiliated with naturopathic educational institutions. Authorship of all chapters was led by a naturopathic researcher, however authors from other fields were invited to contribute specialist knowledge or skills where the editorial team deemed it of value to the overall rigor of the report. The authors assigned to a chapter were provided with the full list of citations relevant to their topic, following which they filtered the citations to exclude any manuscripts not reporting original clinical research. Manuscripts were retained if they reported the results from clinical research. This was defined as any retrospective or prospective study designs examining clinical outcomes following an intervention including case reports, clinical audits, and clinical trials. Authors were also invited to undertake pearling and citation-checking to verify if any additional relevant articles produced by naturopathic researchers met the criteria for inclusion.

Analysis of observational studies was also undertaken to summarize the survey research, qualitative studies, and other non-clinical research conducted by naturopathic researchers. Manuscripts meeting this criterion were identified through the bibliometric analysis based on two groupings: (1) health condition; (2) therapy or treatment. Descriptive statistics for each group were analyzed and reported. For the health conditions group, the two most prevalent health conditions examined in the included manuscripts were identified, and the manuscripts were thematically categorized according to their content. The same process was applied to the two most prevalent therapies or treatments covered in the therapy or treatment group. Review and meta-analyses published by naturopathic researchers were similarly examined in accordance with this method.

Data extraction and presentation of results

Data were extracted from all relevant articles for each topic and summarized into tables. Authors for each chapter then provided a written summary of the overall characteristics of the included articles. The written summaries presented in *Section 5: Effectiveness of Naturopathic Clinical Practice* focused on the clinical outcomes of the naturopathic interventions studied. For the topics included in *Section 6: Research in Naturopathic Therapeutics and Practices*, the summaries focused on the specific details about the variations in the types of treatments used within the category, their application, and the conditions they were used to treat.

Due to the substantial number of included studies, full details of all studies could not be presented in the written text and, as such, an overview of selected studies was presented with an overview of relevant papers included in the tables for each chapter within the corresponding section.

Review

A staged peer-review process was employed for each topic. The first stage of review was conducted by at least two members of the editorial team who provided feedback to the authors for quality and compliance with methodology and format requirements of the project. Once completed, members of the WNF Research Committee undertook a second stage of review which was checked by the editorial team and then provided to the authors for further edits and refinements, with a focus on consistency and accuracy of content. A final review was then conducted by the editorial team to check for consistency and accuracy of content. All final versions were approved by authors and editors prior to publication.

Literature Cited

- 1. World Naturopathic Federation. World Naturopathic Federation Report. Findings from the 1st World Naturopathic Federation survey. 2015; Available from: <u>http://</u> worldnaturopathicfederation.org/wp-content/ uploads/2015/12/World-Federation-Report_June2015. pdf.
- 2. Dunn, J., et al., *Characteristics of global naturopathic education, regulation, and practice frameworks: results from an international survey.* BMC complementary medicine and therapies, 2021. **21**(1): p. 1-19.
- 3. World Naturopathic Federation. *Global Naturopathic Regulation*. 2018; Available from: <u>http://worldnaturo-pathicfederation.org/wp-content/uploads/2019/11/</u> Global-Naturopathic-Regulation_Nov-2019.pdf.
- 4. World Naturopathic Federation Roots Committee. *WNF – Naturopathic Roots Report.* 2016; Available from: <u>http://worldnaturopathicfederation.org/wp-content/</u> <u>uploads/2015/12/Naturopathic-Roots_final-1.pdf.</u>
- 5. Steel, A., et al., *Knowledge Dissemination by the Naturopathic Profession: A Bibliometric Analysis of Naturopath-Authored, Peer-Reviewed Publications.* Journal of Alternative and Complementary Medicine, 2021.
- Steel, A., et al., Overview of international naturopathic practice and patient characteristics: results from a cross-sectional study in 14 countries. BMC Complementary Medicine and Therapies, 2020. 20(1): p. 59.
- Steel, A., et al., *Integrative physiology and traditional naturopathic practice: Results of an international observational study*. Integrative Medicine Research, 2020. 9(4): p. 100424.
- Lloyd I, Gerontakos S, and Cardozo V, *Global naturopathic community clinic reach: an international cross-sectional survey.* BMC Health Services Research, 2021.
- World Naturopathic Federation Education Committee. WNF Naturopathic Educational Program Report. 2021; Available from: <u>http://worldnaturopathicfederation</u>.

org/wp-content/uploads/2021/03/WNF_Naturopathic-Programs_final_March_2021.pdf.

- 10. Steel, A. and I. Lloyd, *Community education and health promotion activities of naturopathic practitioners: results of an international cross-sectional survey.* BMC Complementary Medicine and Therapies, 2021.
- 11. Steel, A., et al., *Naturopaths' mobilization of knowledge and information in clinical practice: an international cross-sectional survey.* BMC Complementary Medicine and Therapies, 2021.
- 12. World Health Organization and the United Nations Children's Fund (UNICEF). *Global Conference on Primary Health Care Declaration of Astana*. 2018; Available from: <u>https://www.who.int/docs/default-source/prima-</u> <u>ry-health/declaration/gcphc-declaration.pdf</u>.
- World Health Organization. *Health Technology Assessment*.
 2021; Available from: <u>https://www.who.int/teams/</u> health-product-and-policy-standards/access-to-assistive-technology-medical-devices/medical-devices/ assessment.
- Kienle, G., H. Kiene, and H.-U. Albonico, *Anthroposophic medicine: effectiveness, utility, costs, safety.* 2006: Schattauer Verlag.
- 15. Bornhöft, G. and P. Matthiessen, *Homeopathy in healthcare: effectiveness, appropriateness, safety, costs.* 2011: Springer Science & Business Media.
- 16. Baggoley, C., *Review of the Australian Government Rebate on Natural Therapies for Private Health Insurance*, Department of Health, Editor. 2015, Australian Government.
- 17. World Naturopathic Federation. *Defining the Global Naturopathic Profession*. 2017; Available from: <u>http://</u> worldnaturopathicfederation.org/wp-content/ uploads/2016/03/Defining-the-Global-Naturopathic-Profession_WNF-2017_.pdf.