

Evaluation of Case Report Publications on Naturopathic Medicine

Masa Sasagawa, ND^{a,b,*}
Jennifer L. Cornell, ND^c
Heather A. Flood, ND, MS, LAc^d
Paul S. Amieux, PhD^a

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ABSTRACT

Objectives: The aims of this article are to evaluate case report publications on naturopathic medicine and to suggest improvement in the content of these case reports to ensure that they appropriately capture the philosophical underpinnings of this type of medicine.

Methods: Articles were obtained by a National Library of Medicine query on “naturopathic” and “case report” in September 2015, and results were evaluated according to the CARE guidelines. The intraclass correlation coefficient (ICC) of the rating scores was calculated.

Results: Nearly half of the case reports were about clinical adverse events. Though it is essential that adverse events be reported, it is imperative that successful cases are also reported to fully understand the impact of naturopathic medicine. The ICC (using single-measure absolute agreement) of the 18 selected articles was 0.669. Question-based improvement checks for writing naturopathic cases are proposed to capture some of the most important tenets of naturopathic medicine, including social and environmental determinants of health and the focus on an individualized treatment approach.

Discussion: Evaluation of currently published naturopathic cases revealed both successful cases and cases involving adverse events. The reliability of rating by three naturopathic clinicians using the CARE guidelines was sufficiently high to confirm that the CARE guidelines are a valid instrument; however, to increase their utility as an educational tool for use in actual cases, additional information that is not part of the CARE guidelines can be included to more adequately describe naturopathic clinical case reports as a part of whole-systems research.

Keywords: Naturopathy; Case reports; Integrative medicine; Holistic health; Evaluation studies

*Corresponding author: Bastyr University Research Institute, 14500 Juanita Dr., NE, Kenmore, WA 98028, USA, Tel.: +1-425-602-3164, Fax: +1-425-602-3079, E-mail: msasagawa@bastyr.edu

^aBastyr University Research Institute, 14500 Juanita Dr., NE, Kenmore, WA 98028, USA

^bUniversity of Washington, School of Nursing, 1959 NE Pacific Street, Seattle, WA 98195, USA

^cBastyr University Clinic, 4110 Sorrento Valley Blvd., San Diego, CA 92121, USA

^dBastyr Center for Natural Health, 3670 Stone Way N., Seattle, WA 98103, USA

INTRODUCTION

In the hierarchy of quality in evidence-based medicine, case reports represent information in the lower tier of the pyramid. This contributes to the assumption of their inferior position in science while demonstrating their foundational role in the development of larger studies and reviews.¹ Despite this inherent weakness, journals recognize the value of case reports. The instructions to authors in *BMJ Case Reports*, a division of the *British Medical Journal*, state, “We want to publish cases worthy of discussion particularly around aspects of differential diagnosis, decision-making, management, clinical guidelines and pathology. The advantage is that we learn from real cases.”² Another journal editor has stated that case reports by novice authors tend to be focused on the novelty of an unusual or complex case, an unusual presentation of a common problem, or an innovative treatment; however, this person also expressed concern that this de-emphasizes the educational value of case reports presenting pragmatic exemplars.³

In an effort to ensure that case reports are adequately rigorous in design and to provide educational value, the CARE (CAse REport) guidelines were established to provide a productive means of disseminating information.⁴ In their own words, “the CARE guidelines provide a framework that supports transparency and accuracy in the publication of case reports and the reporting of information from patient encounters.”⁵ The CARE guidelines represent an excellent foundation for naturopathic case reports.

Naturopathic medicine is a system of medicine that uses education, natural therapies, and natural products to support and stimulate the patient’s intrinsic self-healing processes, or the *vis medicatrix naturae*, in order to prevent, diagnose, and treat human illnesses and injuries. The American Association of Naturopathic Physicians (AANP) defines naturopathic medicine as “a distinct primary health care profession emphasizing prevention, treatment and optimal health through the use of therapeutic methods and substances which encourage the person’s inherent self-healing process” (position paper by AANP)⁶. The emphasis on an individual’s self-healing process is a fundamental component of naturopathic medicine.

This paper evaluates a sample of currently published case reports on naturopathic medicine, discusses issues surrounding the content of naturopathic case reports, and argues for the need to provide information supplemental to the CARE guidelines that will better capture naturopathic philosophy and practice.

METHODS AND MATERIALS

For clinicians interested in looking up a particular case, a MEDLINE/PubMed search using medical subject headings is probably the single most useful biomedical and life sciences research method. Peer-reviewed case report articles were searched in the National Library of Medicine (NLM) database using the query “naturopathic” and “case report.” The articles were critically evaluated by three licensed naturopathic clinicians independently using the CARE guidelines.⁴ The 13 checklist items of CARE are summarized in Appendix A. Using CARE guidelines as a foundation, the three evaluators synthesized consensus recommendations for case report publications in naturopathic medicine.

RESULTS

A PubMed query “naturopathic” and “case report” was made to identify published case reports in September 2015. The query returned 24 articles. Two were eliminated as non-English-language articles; two were eliminated because they were review articles; and two more were eliminated because they reported aggregate cases. Two types of case reports emerged: (1) the clinical outcome of naturopathic treatment with follow-up report (10 cases) and (2) naturopathic treatment that resulted in adverse events (eight cases with two deaths) (Figure 1).

A total of 18 articles were evaluated by authors JC, HF, and MS. Numerical values of A=3, B=2, C=1, and D=0 are averaged in Table 1. Using 13 evaluation criteria, the mean scores of therapeutic intervention between cases presenting favorable outcomes and

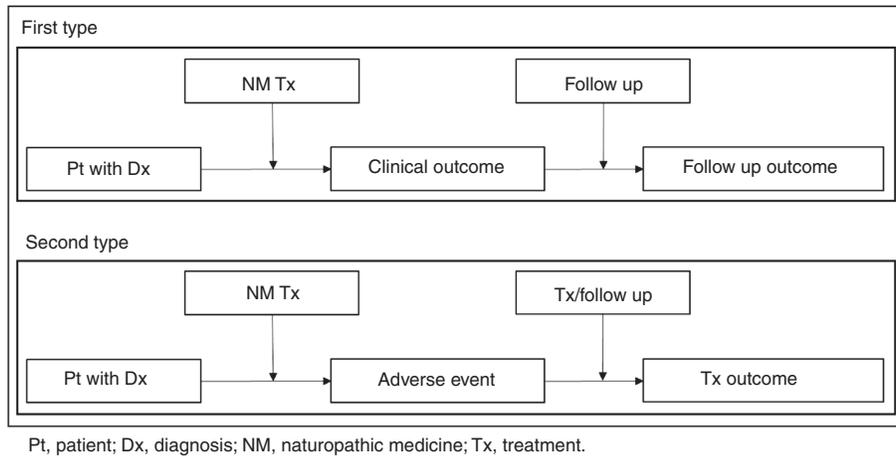


Figure 1: After a PubMed search was performed using “naturopathic “ and “case report” as the query terms, two types of case reports emerged.

The first type of case describes the clinical outcome of naturopathic treatment with follow-up report (10 cases), and the second type of case describes naturopathic treatment that resulted in an adverse event with follow-up report (eight cases with two deaths).

cases presenting adverse events were significantly different [$F(1,16)=8.984, P=0.009$]. It is possible that evaluators were inconsistent about dealing with the description of the original therapeutic naturopathic intervention or subsequent treatments for the adverse event resulting from naturopathic treatment.

The patient, diagnosis, treatment, clinical outcome, and average CARE score for each publication are summarized in Table 2. The means of evaluation

between cases involving favorable outcomes and cases involving adverse events were significantly different [$t(16)=3.835, P=0.001$]. Whether this difference is due to the bias of evaluators being naturopathic clinicians is unknown.

Of the items evaluated for each case, the patient’s perspective and patient’s consent were the most poorly reported items (16.7% for both types of cases). As stated earlier, all case reports evaluated

Table 1: CARE guidelines checklist of articles found by National Library of Medicine query on “naturopathic” and “case report”.

	Reference																	
	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
Title	3.0	0.7	2.7	1.3	3.0	1.0	3.0	2.7	1.0	0.7	1.3	1.0	2.3	2.3	2.7	3.0	2.7	3.0
Keyword	0.0	2.3	3.0	3.0	0.0	0.0	3.0	0.0	2.7	2.3	3.0	0.0	2.3	3.0	2.7	3.0	3.0	0.0
Abstract	3.0	3.0	3.0	1.7	1.7	2.3	2.3	2.0	2.3	2.3	2.7	1.7	2.0	2.3	2.7	2.0	2.0	2.7
Introduction	1.3	3.0	2.7	2.7	2.3	1.3	2.7	0.0	2.3	2.0	3.0	2.7	2.7	2.0	3.0	2.7	2.7	3.0
Patient information	2.0	1.7	3.0	1.3	2.3	2.3	2.3	1.7	2.7	2.0	2.7	2.0	1.7	2.0	2.3	2.3	3.0	2.7
Clinical finding	3.0	2.7	3.0	0.3	3.0	2.3	1.3	2.0	3.0	2.0	2.7	2.7	2.3	1.0	2.7	2.3	3.0	3.0
Timeline	2.0	2.0	2.7	2.7	2.7	2.3	3.0	1.7	2.3	2.0	3.0	2.3	2.0	1.0	2.3	2.7	2.0	3.0
Diagnostic assessment	2.0	2.7	2.7	2.0	2.7	2.7	2.3	1.7	2.7	2.3	2.3	2.3	2.3	1.7	2.3	2.3	2.7	2.7
Therapeutic intervention	2.7	3.0	3.0	3.0	1.7	2.0	3.0	2.3	1.0	1.3	3.0	2.0	1.3	1.0	2.7	2.7	2.7	2.3
Follow-up and outcomes	2.0	1.7	2.7	1.3	1.5	2.3	2.7	1.7	2.0	2.0	3.0	2.0	1.7	1.5	2.7	3.0	1.7	2.0
Discussion	2.3	2.3	2.7	2.0	2.0	2.7	2.7	2.0	2.3	2.7	3.0	1.3	1.3	1.7	2.0	3.0	2.3	2.7
Patient perspective	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	3.0	0.0	0.0	0.0	1.0	0.0	0.0	0.3
Informed consent	3.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.0	0.0	0.0	0.0	3.0	0.0	0.0	0.0

Using the CARE guidelines, 3 authors graded 18 referenced case reports on naturopathic medicine. For grading criteria, see Appendix A. The mean value was obtained by converting A=3, B=2, C=1, and D=0. The means of each evaluation category between the two types of cases (favorable vs. adverse event) were compared, and it was observed that the average of overall categories was significantly different [$t(16)=3.835, P=0.001$].

Table 2: Summary of 18 case reports.

Ref.	Patient age, sex	Health Condition	Treatment focus	Results	CARE
6	56 years, M	Parkinson's	Electroacupuncture	Favorable	2.0
7	65 years, F	Torsade de Pointes	Cesium chloride	Adverse events	1.9
8	11 months, M	Elevated metal burden	DMSA	Favorable	2.4
9	55 years, M	ALS	EDTA and DMSA	Favorable	1.6
10	43 years, M	Dissecting aneurysms	Neck manipulation	Death	1.8
11	66 years, F	Sepsis	Vitamin C IV	Adverse events	1.6
12	56 years, M	Type 2 diabetes	Integrative care	Favorable	2.2
13	50 years, F	Hyperpigmentation	Heated mustard compress	Adverse events	1.4
14	47 years, M	Intravascular hemolysis	Vitamin IV	Adverse events	1.9
15	63 years, M	Venous thrombosis	Dietary supplement with Rx	Adverse events	1.7
16	45 years, F	Hypertension	MBSR and integrative care	Favorable	2.7
17	39 years, M	Hepatic mucormycosis	Botanical supplements	Adverse events	1.5
18	55 years, M	Nasal polyp	Neti kriya yoga and naturopathy not limited to nasal irrigation and dietary change	Favorable	1.7
19	2 years, F	ALL	Delay in conventional treatment due to parental preference of NM	Death	1.5
20	63 years, F	Urinary incontinence	Yoga	Favorable	2.5
21	61 years, F	Asthma	Dietary change	Reduced sxs	2.2
	12 years, M	Asthma	Dietary change	Reduced Rx	
22	53 years, M	Migraine	Integrative traditional European, Indian, and Chinese medicine approaches	Favorable	2.1
23	28 years, F	Cervical dysplasia	Escharotic and anticarcinogenic HPV protocol	Favorable	2.1

ALL, acute lymphoblastic leukemia; ALS, amyotrophic lateral sclerosis; DMSA, dimercaptosuccinic acid; EDTA, ethylenediaminetetraacetic acid; HPV, human papillomavirus; IV, intravenous infusion; MBSR, mindfulness-based stress reduction; NM, naturopathic medicine; Rx, prescription medication; sxs, symptom.

were retrospective clinical anecdotes; thus, the informed consent was not mandatory, with the exception of the report of Vinchurkar and Arankalle, which was a research project.²¹ The mean CARE scores of the two different types of cases were statistically different ($P=0.001$); the reliability of the ratings analyzed by the intraclass correlation coefficient (ICC) using IBM SPSS Statistics version 24 software (IBM, Armonk, NY) was borderline inconsistent ($P=0.09$). For each article, ICC was calculated for the 13 criteria by 3 raters. The ICCs of the type 1 (naturopathic case report) and type 2 (naturopathic case report involving adverse events) were compared. The mean ICC, standard deviation, and number of sample cases (using a single measure, absolute agreement) were (0.733, 0.119, 10) for type 1 and (0.582, 0.250, 8) for type 2. An independent t -test showed that the ICC of the two types of case reports was not statistically different [$t(16)=2.143$, $P=0.09$]. The average ICC of 18 articles by 3 raters was 0.669 for single-measure absolute agreement.

DISCUSSIONS AND RECOMMENDATIONS

Adding information to the standard CARE guidelines may improve their utility in application to naturopathic case reporting. These suggestions include an emphasis on the naturopathic clinician's evidence- or theory-based practice. Additional questions for writing case reports on naturopathic medicine in addition to those outlined in the CARE guidelines are summarized in Appendix B.

ACCURATE REPORTING OF DIAGNOSTIC ASSESSMENT

Appropriate reporting of diagnostic assessment is crucial for naturopathic cases because algorithms of treatment are not standardized to a symptoms-based approach. The clinical thinking of the physician must be reproducible and succinct. Naturopathic

doctors often encounter patients with extensive treatment histories compiled by different practitioners unable to provide the desired outcome to the patient. As such, these patients have already undergone significant workup to identify the etiology of the disease to which the naturopathic doctor is privy and that the reader of the case report should be as well. In addition to previous diagnosticians' treatment approaches, imaging, laboratory values, and other advanced diagnostic information needs to be included.

PROVIDE INFORMATION PERTAINING TO THE PATIENT'S INTEREST IN NATUROPATHIC MEDICINE

Obtaining information about a patient's motivation and knowledge of naturopathic medicine will help to define the role of naturopathic medicine in the overall healthcare system. This includes but is not limited to (1) fee structure, (2) insurance coverage, (3) ethnic or religious compatibilities with the clinician, and (4) feelings about past treatment experiences in conventional medical settings. Naturopathic patients tend to be self-selected, affluent individuals who are likely educated about self-care and highly motivated to help themselves.²⁵ This disparity in who seeks out naturopathic care may stem from variability in insurance coverage due to a geopolitical environment that may be for or against naturopathic medicine. Patient motivation in seeking naturopathic care could help direct its utility in the current healthcare paradigm.

ACCOUNTING FOR THE SYSTEMS OR NONREDUCTIONIST APPROACH

Reductionist approaches tend to be focused on the function of individual components, but they often miss how the components operate in relation to each other as a functional system. Specialization in medicine is an example of a reductionist approach that enhances greater understanding of individual components. Naturopathic medicine uses a systems-based or nonreductionist approach. It is defined not by a single treatment modality but by the philosophy and therapeutic intent as it pertains to the individual patient, encompassing their totality of parts. Considering each individual as a whole and

using a systems-based approach means examining an individual not only from a physical standpoint but also from a mental, emotional, and spiritual standpoint. What is clear is that these holistic views are not generally captured in the electronic medical record (EMR), and thus case reports may be the only existing scientific methodology that can capture the benefit of the therapeutic effect of this systems-based, whole person-centered, patient-empowering approach to medicine.

IMPACT OF THE THERAPEUTIC ALLIANCE

The concept of the "therapeutic alliance" has evolved as a usable skill taught to therapists with a premise that includes agreeing on treatment goals and establishing a bond based on reciprocal positive feelings of regard. The ability to develop mutual goals with patients is paramount.²⁶ In placing the emphasis on a trainable skill, however, one might risk losing the authenticity of a fundamental human interaction. Naturopathic medical training includes collaborative goal setting, participatory decision making, and motivational interviewing as tools to encourage the formation of a therapeutic alliance, combined with 30–90 minutes of face-to-face time with the patient.²⁷ Currently, there is very little scientific research that addresses the importance of time, authenticity, or skill in forming a therapeutic alliance. Documentation of the patient's experience and a definition of the therapeutic alliance from the patient's perspective could contribute to the knowledge base and inspire trials to understand how to make patient outcome-oriented medicine more effective.

USING SELF-INTEGRATION SCALE FOR MEASURING HEALING

Meza and Fahoome define healing as "the human experience of self-discovery and transformation that results in a sense of being whole and connected."²⁸ Developing a therapeutic relationship with a person who has socially constructed power, a healer or doctor, can initiate the healing process and can facilitate discovering and naming emotions that can contribute to repairing and improving relationships with oneself, others, and one's spirituality. The idea of providing optimal healing environments by using the relationship between healer and

patient, as well as among healers themselves, is an important component of integrative medicine.²⁹ The Self-Integration Scale is a tool used to measure the process of healing.²⁸ Naturopathic medicine is considered integrative medicine,³⁰ and the process of healing may be captured through using such an instrument.

DOCUMENT THE QUESTIONS USED TO ASSESS THE INDIVIDUAL'S STAGE OF CHANGE

The transtheoretical model is a robust theory that conceptualizes stages of change pertinent to addictive behaviors (precontemplation, contemplation, preparation/determination, action, relapse, and maintenance).³¹ Numerous sets of short questions have been published for assessing the stage of different types of behavior change, including smoking,³² exercise,³³ opioid drug use,³⁴ and oral self-care.³⁵ Naturopathic doctors prescribe an individualized treatment plan that is based on and targets these stages of change. The stage must continually be reassessed and treatment plans reevaluated in order to consistently meet the patient at the patient's level of change and to optimize the therapeutic effect and progression. Emphasis is placed on the practitioner identifying and meeting a patient where the patient is rather than drawing a line of expectation that may not be realistic or achievable by the patient. When publishing a case report, sharing the individualized assessment questions serves two purposes: (1) It describes key components of health-related behavior change in this particular patient, and (2) it adds credibility to the case for further study.

LIMITATIONS

We chose to use the CARE guidelines for evaluation because we found them to be the most robust and concise set of guidelines. Other limitations include the search criteria used (NLM only) and the fact that acupuncture, physical medicine, and other eclectic modalities were not captured.

List of abbreviations: AANP, The American Association of Naturopathic Physician; BMJ, British Medical Journal; CARE, CAse REport;

CIH, Complementary and Integrative Health; EBM, Evidence-based Medicine; EHR, Electronic Health Record; ICC, Intraclass Correlation Coefficient; IRB, Institutional Review Board; NCCIH, National Center for Complementary and Integrative Health; NLM, National Library of Medicine

DECLARATIONS

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Not applicable.

CONSENT FOR PUBLICATION

Not applicable.

DATA DEPOSITORY

Data are available for 7 years from the time of publication by sending a request to Bastyr University. A data use agreement is required.

COMPETING INTERESTS

The authors declare they have no competing interests.

FUNDING

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AUTHORS' CONTRIBUTIONS

MS conceptualized the study, performed statistical analysis, participated in evaluation of articles, and drafted the manuscript. JC and HF participated in evaluation of articles, contributed to the list of additional information to improve the utility of naturopathic case reports, and edited the manuscript. PA performed substantive editing and approved the manuscript submission.

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APPENDIX A: CARE GUIDELINE EVALUATION TASK

Instructions:	Ratings:	
This package contains 18 case report articles. A case report tells a story in a narrative format that includes information useful to other professionals. There are 13 checklist items for the CARE guideline on the back of this page. Please rate the quality of each publication based on the checklist item as A, B, C, or D.	A=Excellent or all component present B=Moderate or some component present C=Poor or minimally present D=Absent	
Checklist # =	1 2 3 4 5 6 7 8 9 10 11 12 13	
Arankalle and Nair, 2013 ⁷ Chan <i>et al.</i> , 2009 ⁸ Crinnion and Tran, 2010 ⁹ Crinnion, 2011 ¹⁰ Dunne <i>et al.</i> , 1987 ¹¹ Engelhart <i>et al.</i> , 2003 ¹² Grise <i>et al.</i> , 2015 ¹³ Linder <i>et al.</i> , 1996 ¹⁴ Livshits <i>et al.</i> , 2011 ¹⁵ Newey <i>et al.</i> , 2013 ¹⁶ Oberg <i>et al.</i> , 2013 ¹⁷ Oliver <i>et al.</i> , 1996 ¹⁸ Rastogi <i>et al.</i> , 2009 ¹⁹ Usumoto <i>et al.</i> , 2014 ²⁰ Vinchurkar and Arankalle, 2015 ²¹ Virdee <i>et al.</i> , 2015 ²² Wilson <i>et al.</i> , 2011 ²³ Windstar <i>et al.</i> , 2014 ²⁴		
The CARE guidelines checklist (4, page 3, Table 1)		
#	Item name	Brief descriptions
1	Title	The words ‘case report’ (or ‘case study’) should appear in the title along with phenomenon of greatest interest (e.g. symptom, diagnosis, test, intervention)
2	Keywords	The key elements of this case in 2–5 words.
3	Abstract	a) Introduction–What does this case add? b) Case Presentation: – The main symptoms of the patient – The main clinical findings

APPENDIX A (continued)

#	Item name	Brief descriptions
		– The main diagnoses and interventions – The main outcomes c) Conclusions – What were the main ‘take-away’ lessons from this case?
4	Introduction	Brief background summary of this case referencing the relevant medical literature
5	Patient information	a) Diagnostic methods (e.g. age, gender, ethnicity, occupation) b) Main symptoms of the patient (his or her chief symptoms) c) Medical, family, and psychosocial history—including diet, lifestyle, and genetic information whenever possible, and details about relevant comorbidities including past interventions and their outcomes
6	Clinical finding	Describe the relevant physical examination
7	Timeline	Depict important dates and times in this case (table or figure)
8	Diagnostic assessment	a) Diagnostic methods (e.g. PE, laboratory testing, imaging, questionnaires) b) Diagnostic challenges (e.g. financial, language/cultural) c) Diagnostic reasoning including other diagnoses considered d) Prognostic characteristics (e.g. staging) where applicable
9	Therapeutic intervention	a) Types of intervention (e.g. pharmacologic, surgical, preventive, self-care) – Administration of intervention (e.g. dosage, strength, duration) – Changes in intervention (with rationale)
10	Follow-up and outcome	a) Summarize the clinical course of all follow-up visits including: – Clinician and patient-assessed outcomes – Important follow-up test results (positive or negative) – Intervention adherence and tolerability (and how this was assessed) – Adverse and unanticipated events
11	Discussion	a) The strengths and limitations of the management of this case b) The relevant medical literature c) The rationale for conclusions (including assessments of cause and effect) d) The main ‘take-away’ lesson of this case report
12	Patient perspective	The patient should share his/her perspective or experience whenever possible.
13	Informed consent	Did the patient give informed consent?

APPENDIX B: PROPOSED NM CASE REPORT CHECKLIST QUESTIONS FOR AUTHORS (MODIFIED FROM CARE GUIDELINE)

- 1. Title.** Can readers distinguish between the reporting of favorable outcomes or adverse events? Is the phenomenon of interest included in the title (e.g. symptom, diagnosis, test, intervention, or outcome)? Can the title distinguish between a single case and multiple cases?
- 2. Abstract.** What is the rationale of this publication? Is this a prospective or retrospective study? Is the following information present (diagnoses, intervention, outcome or adverse

- event, follow up, main outcome)? What is the main “take-away” lesson from this case?
- 3. Key words.** Do key words correspond to MeSH terms?
- 4. Introduction.** Does sufficient background information with citations bring the case into context? Are the geopolitical and social circumstances of providing naturopathic care included? What is the training level of the clinician, the care environment, and the understanding of naturopathic principles by the care team?
- 5. Patient information.** Does the demographic include occupation and other relevant information? What are the main symptoms and/or history of diagnoses? What other treatments have been given previously? What is the medical, family, and psychosocial history including diet, lifestyle, and genetic information, if

- available? What is the level of self-care and empowerment, for example as measured by staging in the Transtheoretical Model?³¹ Why does this patient choose to receive NM care?
6. **Clinical finding.** What is the relevant or baseline clinical finding? What are the adverse findings?
 7. **Timeline.** Are important relative events linearly described? Is an absolute date/time useful for the case?
 8. **Diagnostic focus and assessment.** What is the diagnostic method (PE, laboratory, imaging, questionnaire, referral)? What was the challenge of diagnosis, deviations or unusual circumstances (financial, cultural, adverse finding)? What is the standardized prognosis (grade and staging) where applicable? Can you identify an external diagnostician who is blinded to your clinical care?
 9. **Therapeutic focus and intervention.** What are the types of intervention (preventive, pharmacologic, surgical, lifestyle, self-care)? What are the dosage, strength, duration and frequency of the intervention? What are the interventions that possibly led to the adverse event? In the case of an adverse event, were other possible causes acknowledged and ruled out? What is the specific product or proprietary procedure used? Who supplied intervention supplements—marketing disclosure of the conflict of interest?
 10. **Follow up and outcome.** What is the clinical course of this patient? How was the intervention modified, interrupted, or discounted and for what reason? What adverse effect or unanticipated event occurred? How were the adverse events treated? What is the outcome? Can the objective diagnostician participate in the follow-up examination?
 11. **Patient perspectives.** How does the patient describe the treatment experience? Can a direct quote be included in the report? Are standardized surveys such as satisfaction or Self-Integration Scale results shared? Has the vested interest of the patient toward naturopathic medicine changed? What does therapeutic alliance mean to your patient?
 12. **Discussion.** What are the strengths and limitations of this case? Can relevant medical literature support your claim? How do you respond to the potential criticism that may include claims such as the placebo effect, clinician bias, and the non-specific effect of naturopathic medicine? How does this case advance the science of naturopathic medicine? What is the take-away message? Why is this case worthy of discussion?
 13. **Disclosure and informed consent.** Was the patient's consent obtained? Are there any competing interests such as the sale of dietary supplements or use of proprietary products? Did an ethics committee approve this study? Was the case sufficiently de-identified?