

ORIGINAL RESEARCH

# A METHOD FOR DESCRIBING AND EVALUATING NATUROPATHIC WHOLE PRACTICE

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**Context** • Even though complementary and alternative medicine (CAM) is generally practiced as distinct systems of medicine, almost all CAM research has focused on single therapies. In order to more adequately evaluate the effectiveness of these medical systems, studies that evaluate the outcome of intact whole systems are needed. One challenge lies in defining the whole medical system (and any medical system it is compared to) in a way that ensures treatment fidelity.

**Objective** • This paper presents a proposed method to measure treatment fidelity (treatment criteria) in studies of the naturopathic medical system.

**Design** • Illustrative example of the theory-based development and post-hoc “testing” of treatment criteria against an existing database of actual treatments prescribed by a random sample of naturopathic physicians.

**Main outcome measures** • Treatment criteria for 3 conditions—

menopausal symptoms, bowel dysfunction, and fatigue/fibromyalgia—and their comparison to actual treatments prescribed.

**Results** • A set of meaningful, measurable treatment criteria based on the naturopathic practice principles were defined that could have generated the majority (82%-93%) of treatment prescriptions given at visits for these conditions. Several of the treatment criteria components are common across the 3 conditions studied, and might be appropriate for all visits to doctors of naturopathy (NDs). Others are specific to each condition. In addition to ensuring model validity, these criteria help identify critical components of care, enable study replication, provide a measure of quality of care, and are one step toward allowing CAM to be studied as it is generally practiced—as distinct systems of medicine.

**Setting** • Work was performed at Bastyr University and the University of Arizona. (*Altern Ther Health Med.* 2006;12(4):20-28.)

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that characterize and evaluate the outcome of intact whole systems are needed. One challenge lies in defining the whole medical system (and any medical system it is compared to) in a way that ensures treatment fidelity.

Several researchers have recommended that specific medical systems be studied, each as a “black box,”<sup>4,5</sup> often defined minimally as treatment by a practitioner of that medical system with, say, X years of experience. Others recommend that the box be “unpacked.”<sup>1,6</sup> The simply defined “black box” approach offers no assurance that the box contents are a valid representation of the medical system; however, given the number of different diagnosis schemes and treatments available, complete “unpacking” may prove an insurmountable measurement, analysis, and interpretation challenge.

When a study compares 2 drugs (or a drug to placebo), all else is held equal. Often, the same practitioner provides either drug in one facility under strictly defined protocols. As both comparison groups are being treated within the same medical system (conventional medicine), little, if any, effort is given to defining that system. Here, treatment fidelity is ensured through monitoring adherence to protocols that focus on ensuring that the best treatment possible is given, that the only difference between groups is the drug, and that the drug did indeed differ between

**E**ven though complementary and alternative medicine (CAM) is generally practiced as distinct systems of medicine, virtually all CAM research has focused on single therapies.<sup>1,3</sup> In order to more adequately evaluate the effectiveness of these medical systems, studies

groups. When 2 *systems* of medicine are compared, very little can be held equal. Not only will different treatments be offered, but different practitioners with dramatically different training will diagnose and then prescribe those treatments in different clinical settings and under very different philosophies of care. Some method of defining these medical systems is needed to capture and measure these differences to ensure that both interventions are implemented as intended.

The concept of treatment fidelity emerged in the 1960s in psychotherapy when early attempts to sort out design and interpretive problems in outcomes studies proved impossible. (For a brief history and overview of treatment fidelity and its measurement, see Bond et al.<sup>7</sup>) Since then, measures of intervention fidelity have become standard requirements for research in a number of applied fields, including mental health services, criminal justice, education, and medicine. Other terms that are similar to that of fidelity measurement are treatment integrity assessment, process rating scales, manipulation checks, and practice guideline adherence.<sup>7,8</sup>

Attendees of an international workshop on whole systems research (as well as other authors) have delineated a number of challenges for CAM whole systems research.<sup>1,6</sup> Of the 5 areas identified by conference participants as requiring further attention,<sup>1</sup> this paper addresses parts of 2. The first is a need for "model validity" in study designs to evaluate intact whole systems. Determination of model validity as defined by Lewith et al is essentially an assessment of treatment fidelity.<sup>9</sup> Lewith defined model validity as "the likelihood that the research has adequately addressed the unique theory and therapeutic context of the CAM system."<sup>9(p12)</sup> The second area is the need to understand and measure CAM diagnoses and treatment decisions. In order to understand whole medical systems, it is not enough to track what was prescribed; we must also know *why* it was prescribed—how the treatment relates to the diagnosis according to the theory and therapeutic context of the CAM system.

Naturopathic medicine is a CAM system that uses treatment modalities such as botanical medicine, diet, nutritional supplements, homeopathy, counseling, and physical medicine (eg, hydrotherapy, massage) according to a particular medical philosophy and a set of treatment principles. A large number of studies have evaluated the efficacy of individual treatments used in naturopathic medicine.<sup>2,10</sup> However, only 1 published study that examined the effectiveness of naturopathic medicine as a whole medical system was found.<sup>11</sup> It used a "black box" protocol in that it defined the intervention only as treatment at a particular naturopathic clinic staffed by licensed naturopathic physicians.

Other studies of naturopathic medicine include 2 recent publications<sup>10,12</sup> and a book chapter<sup>13</sup> that describe the philosophy of naturopathic medicine, its regulation in the United States, and training requirements for doctors of naturopathy (NDs). Other recent reports have described the history of naturopathic medicine in the United States,<sup>14</sup> the characteristics of naturopathic physicians<sup>15</sup>, their practice patterns,<sup>16</sup> and the characteristics of visits to NDs.<sup>17</sup> Several studies have surveyed naturopathic physicians

regarding the treatment modalities (types of treatments) they prescribe for particular conditions (eg, breast cancer,<sup>18</sup> human immunodeficiency virus<sup>19</sup>) or populations (eg, pediatrics<sup>20</sup>); however, none gives more than a few of the specific treatments prescribed, nor the reasons behind these prescriptions.

This article presents a proposed methodology to ensure treatment fidelity (herein called treatment criteria) for studies of the naturopathic medical system. These treatment criteria must adequately reflect the underlying paradigm of naturopathic medicine in a way that is easily quantifiable (so that fidelity can be measured) and that clearly distinguishes this medicine from that of other systems. We illustrate this concept by simulating the development of a set of treatment criteria based on naturopathic theory for each of 3 conditions treated by NDs: menopausal symptoms, bowel dysfunction, and fatigue/fibromyalgia. We then use an existing database of treatments prescribed by a random sample of licensed naturopathic physicians to "test" these criteria. The goal of this approach in practice would be to create a set of treatment criteria that are measurable, meaningful operationalizations of the practice of naturopathic medicine for use in future studies.

## METHODS

### Study Design

This study examines the feasibility of the measurement of treatment fidelity in studies of the naturopathic medical system. To this end, it presents an example of the development and post-hoc "testing" of treatment criteria for 3 conditions: menopausal symptoms, bowel dysfunction, and fatigue/fibromyalgia. These criteria were developed based on the information available in published documents on the theory and practice of naturopathic medicine. They were then compared to existing treatment data for these conditions as a preliminary test of their ability to measure model validity.

### Development of Treatment Criteria for Each Condition

Whereas in practice these criteria would need to be developed with substantial input from the naturopathic community, for illustrative purposes, the development of treatment criteria defining the practice of naturopathic medicine began with a review of the major texts used to teach naturopathic medical students,<sup>21-26</sup> published articles on the practice of naturopathic medicine,<sup>2,10,12</sup> and the website of the American Association of Naturopathic Physicians.<sup>27,28</sup> Relevant articles cited in these documents also were obtained. These documents were used to identify the underlying theoretical construct of naturopathic medicine (ie, the critical elements that make naturopathic medicine naturopathic medicine). Related aspects of clinical theory and practice also were identified, including the types of treatments prescribed under different situations. From this information, treatment criteria were developed and modified for each condition until consensus was reached between the 2 authors who are NDs. The criteria were then reviewed and confirmed by the remaining authors.

## Data

The “testing” of the treatment criteria developed used a secondary analysis of an existing database that included treatment data from a random sample of 99 licensed naturopathic physicians in Connecticut and Washington.<sup>15,17</sup> Visit data were collected in 1998 from 65 naturopathic physicians in Washington (1,186 patient visits) and in 1999 from 34 naturopathic physicians in Connecticut (631 visits). For more detail on the sampling design see Cherkin, et al.<sup>15</sup> Visit data captured up to 20 consecutive patient visits for each physician. Therefore, the dataset rarely contains more than one visit for an individual patient and includes a mix of first office calls and return visits.

Prescribed treatments were classified by modality (eg, acupuncture, botanical medicine, homeopathy, minerals, vitamins, therapeutic diet, physical therapies) and by specific treatment within each modality (eg, *Echinacea spp* tincture within botanical medicine, magnesium within minerals).

## Study conditions

Up to 5 diagnoses were recorded by the physician either using ICD-9 codes or written in long hand (an appropriate code was manually assigned for these). For this analysis, 3 clusters of conditions were included, and visits within a primary ICD-9 diagnosis code (the first code recorded for each visit) were selected as follows:

- Menopausal symptoms (627.2—Menopause with symptoms including hot flashes; 627.8—Other specified menopausal and postmenopausal disorder symptoms; 627.9—Unspecified menopausal and postmenopausal disorder)
- Bowel dysfunction (555.9—Crohn’s disease, unspecified site; 556.9—Ulcerative colitis, unspecified; 579.0—Celiac disease, nontropical sprue; 564.1—Irritable colon; 564.0—Constipation; 558.9—Noninfectious enterocolitis, other and unspecified; 787.91—Diarrhea, unspecified; 579.9—Intestinal malabsorption, unspecified; 564.11—Dysbiosis; 693.1—Allergies due to food)
- Fatigue/fibromyalgia (729.1—Fibromyalgia or fibromyositis; 780.7—Malaise and fatigue; 780.71—Chronic fatigue syndrome; 780.79—Other malaise and fatigue)

These conditions were chosen because they are commonly seen by NDs. Fatigue was the most common reason given for visits to NDs in the 2 states included in the database, and menopausal symptoms was the third most common diagnosis.<sup>16</sup> Bowel dysfunction was chosen both because it was one of the top 10 reasons for visits given because a basic belief of naturopathic medicine is that many chronic health problems begin in the gut.<sup>24</sup> These diagnoses collectively comprise about 15% of the total sample of 1,817 ND visits. The 3 specific fatigue/fibromyalgia diagnoses (fibromyalgia, chronic fatigue syndrome, and fatigue) were combined due to the large overlap in their symptomology.<sup>29</sup>

## Variation in Therapies Prescribed

To illustrate the complexity of naturopathic medicine and the variation in the treatments prescribed by NDs, visit records in which the primary diagnosis matched the diagnoses defined above were pulled from the database (using ICD-9 codes) for each of the conditions of interest. The data in these records were tabulated to show the number of visits, number of different types of treatments prescribed, and number of individual therapies prescribed across visits.

## Comparison of Treatment Criteria to Therapies Prescribed

If the treatment criteria are an appropriate indicator of naturopathic treatment fidelity (ie, they represent naturopathic medicine), then the treatments prescribed by a sample of NDs should fit these criteria, assuming these NDs are indeed practicing naturopathic medicine—an assumption made in this study. Determination of the validity of the treatment criteria identified ideally would require their use in general practice in the naturopathic community and their evaluation in situ on a number of dimensions. In this study, the treatment criteria are simply compared to the treatments actually prescribed by a sample of NDs (as recorded in the database) to determine whether practicing according to these criteria could have generated those prescriptions.

## Data Analysis

To demonstrate the “fit” between the treatment criteria and treatments prescribed for each condition, the total number of treatment prescriptions “addressed” by the treatment criteria (ie, those that could have been generated by following the treatment criteria) was compared to the total number of treatments prescribed in the database, and a percentage was calculated. Median numbers of treatments prescribed per visit were calculated for each condition, as well as the numbers of prescriptions representing the 25th and 75th percentiles. Data were analyzed using SPSS for Windows Release 9.0.0 Standard Version (SPSS Inc, Chicago, Ill) and Microsoft Excel 97 SR-1 (Microsoft Corp, Redmond, Wash).

## RESULTS

### Development of Treatment Criteria for Each Condition

The most formalized aspect of naturopathic theory available in the documents reviewed was a set of practice principles and a medical philosophy. Licensed naturopathic physicians offer primary healthcare based on 6 principles.<sup>2,10,13,27,30</sup>

1. **The healing power of nature (*vis medicatrix naturae*).** Support, facilitate, and augment the inherent ability of the body to heal itself by identifying and removing obstacles to health and recovery and by gently stimulating the body’s vital force.
2. **Identify and treat the causes (*tolle causam*).** Seek to remove the underlying causes of disease rather than simply eliminating or suppressing symptoms.
3. **First do no harm (*primum non nocere*).** Use methods that minimize harmful side effects, using the least force neces-

sary to diagnose and treat; avoid suppression of symptoms; and respect each individual's self-healing process.

4. **Doctor as teacher (*docere*).** Emphasize patient education and self-responsibility for health and the therapeutic potential of the doctor-patient relationship.
5. **Treat the whole person.** Take into account the complex interaction of physical, mental, emotional, social, spiritual, environmental, and other factors that affect health and disease.
6. **Prevention.** Encourage and emphasize disease prevention.

Naturopathic medicine was founded in vitalism, a medical philosophy that holds that a living system is self-organizing and more than the sum of its parts. This approach to healthcare does not eschew mechanistic therapies. Instead, it holds that any treatment plan intended to remove the agent of disease (a mechanistic approach) should also include therapies to decrease susceptibility to disease.<sup>13</sup> This philosophy directly relates to the first and fifth principles; therefore, the above set of 6 principles was used to represent naturopathic theory.

Simply defining naturopathic medicine as practice according to these principles is of little use to the measurement of treatment fidelity (eg, how would application of the healing power of nature be measured?). Fortunately, several texts discuss the clinical decisions that result from the application of these principles, and 1 in particular provided the clearest connections.<sup>30</sup> Figure 1 shows the relationship between the naturopathic principles and the treatment criteria developed. Several of the treatment criteria components are common across the 3 conditions studied and should be considered in all visits to NDs. Others are specific to each condition.

### Treatment Criteria Components That Apply to All Conditions

Complete naturopathic care includes prescriptions to address deficiencies in any of these areas contributing to the patient's ill health.

- **Healthy lifestyle promotion.** Poor lifestyle choices often are serious obstacles to cure. Naturopathic treatments that promote a healthy lifestyle include eating a healthy diet, getting adequate exercise and rest, managing stress, adopting constructive and creative attitudes, avoiding toxins and pollution, ensuring proper elimination, getting good social support, and encouraging spiritual growth. Healthy lifestyle promotion treats the whole person and helps prevent disease.
- **Stimulate the *vis medicatrix naturae*.** If the physician determines that the patient's vital force can benefit from support and augmentation in ways other than simply removing obstacles to cure, treatments that gently stimulate the *vis medicatrix naturae* (the vital force), such as acupuncture, should be prescribed.

The following treatment criteria components apply to all treatments for all conditions:

- **Individualization of treatment.** This can be done by incorporating patient preference (after patients are properly informed) and/or by "sub-diagnosis" (eg, not all patients with the same diagnosis have the same underlying causes for their illness, and different causes will indicate different treatments).<sup>1</sup>

- **Use least-force interventions and avoid symptom suppression.** The operationalization of this component likely will require a significant amount of debate in the profession, but for the illustrative purposes of this paper, the following criteria are offered as a starting point. Prescription drugs (other than antibiotics) and referral for surgery are used only after less invasive/suppressive interventions have failed (or have failed in comparable situations), and where unavoidable, are accompanied by therapies to minimize side effects. Judicious use of antibiotics is accompanied by therapeutic support to avoid/minimize side effects. Herbs and other supplements are used at dosages well below toxicity, and any known negative interactions are avoided.

- **Patient education.** The process, timing, risks, expected outcomes, and place in the overall healing strategy of all therapies prescribed should be explained to patients to the level of their understanding and interest.

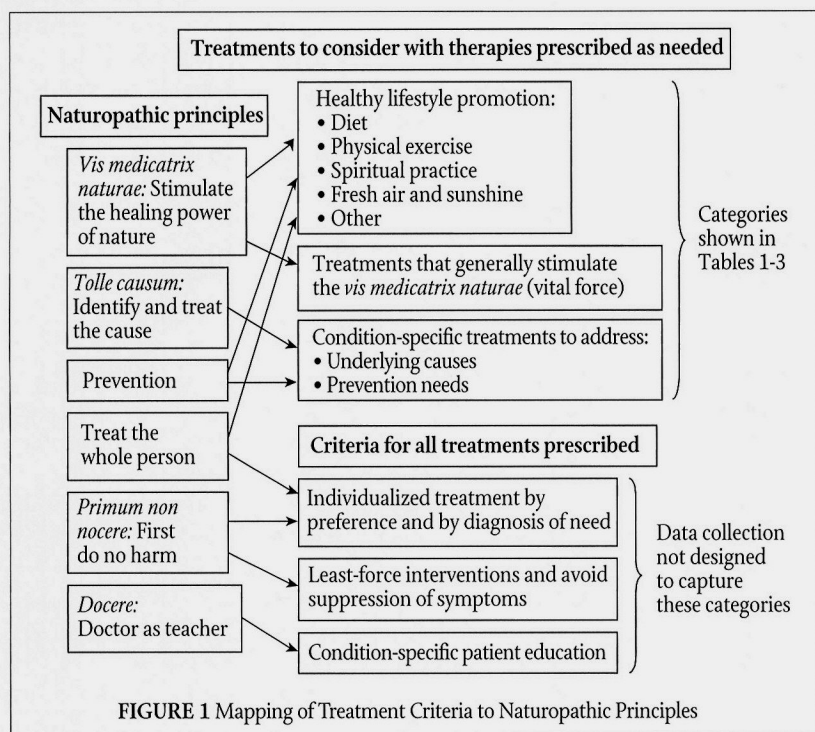


FIGURE 1 Mapping of Treatment Criteria to Naturopathic Principles

### Treatment Criteria Components That Apply Only to Patient Visits for Specific Conditions

The treatment criteria components specific to each condition were based on a review of the literature relevant to naturopathic medicine and each condition and address the possible underlying causes of each condition or preventive measures appropriate for that condition. The treatment criteria specific to each condition can be seen as the row headings in the lower portion of Tables 1-3. References are given in the tables for many of these components and for the examples of treatments included under each component. For any one patient with a specific ICD-9 diagnosis code, treatments are prescribed only for the causal mechanisms and prevention needs appropriate for that patient's individual situation and needs.

### Variation in Therapies Prescribed

Table 4 shows the tabulation of the treatments prescribed

**TABLE 1** Illustration of How Treatments Used in Visits for Menopausal Symptoms Might Be Assigned to Treatment Criteria Components (n=66)

|                                                                                                                                                                                                         | No. of visits where<br>prescribed | No. of<br>prescriptions |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|-------------------------|
| <b>Components Applying to All Conditions</b>                                                                                                                                                            |                                   |                         |
| Healthy lifestyle promotion*                                                                                                                                                                            | 39                                | 102                     |
| Stimulate the <i>Vis</i> †                                                                                                                                                                              | 15                                | 16                      |
| <b>Components Applicable Only to Menopausal Symptoms (with examples of specific treatments)</b>                                                                                                         |                                   |                         |
| Hormonal imbalance<br>(eg, DHEA, <sup>31</sup> exercise, <sup>32</sup> HRT, soy, <sup>33</sup> ginseng, <sup>34</sup><br>Black cohosh, <sup>35</sup> St John's wort <sup>36</sup> )                     | 50                                | 131                     |
| Heart disease prevention<br>(eg, exercise, <sup>37</sup> folate and vitamin B6, <sup>38</sup> vitamin<br>E, <sup>39</sup> fiber, <sup>40</sup> essential fatty acids, <sup>41</sup> soy <sup>42</sup> ) | 46                                | 136                     |
| Osteoporosis prevention<br>(eg, exercise, <sup>43</sup> calcium and trace minerals, <sup>44</sup><br>magnesium, <sup>45</sup> vitamin D, <sup>46</sup> HRT)                                             | 42                                | 125                     |
| Breast cancer prevention<br>(eg, phytoestrogens and lignans, <sup>47</sup> liver<br>support diet <sup>48</sup> )                                                                                        | 38                                | 67                      |
| Cumulative Totals Across All Visits and<br>Components                                                                                                                                                   | 59                                | 354                     |
| Median no. of prescriptions per visit<br>(25th–75th percentile)                                                                                                                                         |                                   | 4<br>(2-8)              |
| Total Treatments Prescribed (from Table 4)                                                                                                                                                              |                                   | 432                     |
| % of Treatments Addressed by the Treatment<br>Criteria                                                                                                                                                  |                                   | 82%                     |

DHEA = dehydroepiandrosterone; HRT = hormone replacement therapy

\* Includes diet, exercise, meditation, music therapy, and the following education and counseling categories: growth/development, mental health, psychotherapy, self-care education, tobacco use/exposure, and prenatal care.

† Includes constitutional homeopathy, hydrotherapy, massage, and acupuncture.

by NDs in visits for each condition. A large number and wide variety of treatments are prescribed.

### Evaluation of How Well Treatments Prescribed Reflected Treatment Criteria

As illustrated in Tables 1-3, the treatment criteria developed generally "fit" (could have generated) 82% (354 of the 432) of the total treatments prescribed for menopausal symptoms, 93% (698 of 752) of the total treatments prescribed for bowel dysfunction,

**TABLE 2** Illustration of How Treatments Used in Visits for Bowel Dysfunction Might Be Assigned to Treatment Criteria Components (n=121)

|                                                                                                                                                                               | No. of visits where<br>prescribed | No. of<br>prescriptions |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|-------------------------|
| <b>Components Applying to All Conditions</b>                                                                                                                                  |                                   |                         |
| Healthy lifestyle promotion*                                                                                                                                                  | 84                                | 268                     |
| Stimulate the <i>Vis</i> †                                                                                                                                                    | 33                                | 37                      |
| <b>Components Applicable Only to Bowel Dysfunction (with examples of specific treatments)</b>                                                                                 |                                   |                         |
| Nutrient deficiencies <sup>49</sup><br>(eg, essential fatty acids, <sup>50</sup> folate, <sup>51</sup> other nutrients)                                                       | 57                                | 147                     |
| Food sensitivities <sup>52</sup> (eg, hypoallergenic diet <sup>53</sup> )                                                                                                     | 53                                | 79                      |
| Gut lining abnormalities <sup>54,56</sup><br>(eg, probiotics, <sup>57</sup> fructooligosaccharides, <sup>58</sup><br>demulcent herbs, <sup>59</sup> glutamine <sup>60</sup> ) | 50                                | 95                      |
| Infectious processes <sup>61</sup><br>(eg, berberine, <sup>62</sup> probiotics <sup>57</sup> )                                                                                | 45                                | 75                      |
| Lifestyle causes of bowel dysmotility<br>(eg, fiber, <sup>63</sup> exercise)                                                                                                  | 40                                | 66                      |
| Liver/biliary tract dysfunction <sup>64,65</sup><br>(eg, methionine derivatives, <sup>66</sup> milk thistle, <sup>67</sup><br>choline, <sup>68</sup> fiber)                   | 30                                | 39                      |
| Oxidative stress <sup>69</sup> (eg, antioxidants)                                                                                                                             | 23                                | 54                      |
| Psycho/neural dysfunctions <sup>70-72</sup><br>(eg, peppermint oil, <sup>73</sup> stress management <sup>74</sup> )                                                           | 22                                | 26                      |
| Pancreatic insufficiency <sup>75</sup><br>(eg, digestive enzymes)                                                                                                             | 22                                | 23                      |
| Adrenal dysfunction <sup>76,77</sup> (eg, DHEA, Siberian<br>ginseng, licorice <sup>78</sup> )                                                                                 | 15                                | 16                      |
| Cumulative Totals Across All Visits and<br>Components                                                                                                                         | 112                               | 700                     |
| Median no. of prescriptions per visit<br>(25th–75th percentile)                                                                                                               |                                   | 5<br>(2-8)              |
| Total Treatments Prescribed (from Table 4)                                                                                                                                    |                                   | 752                     |
| % of Treatments Addressed by the Treatment<br>Criteria                                                                                                                        |                                   | 93%                     |

DHEA = dehydroepiandrosterone

\* Includes diet, exercise, meditation, music therapy, and the following education and counseling categories: growth/development, mental health, psychotherapy, self-care education, tobacco use/exposure, and prenatal care.

† Includes constitutional homeopathy, hydrotherapy, massage, and acupuncture.

and 87% (472 of 542) of the total treatments prescribed for fatigue/fibromyalgia.

DISCUSSION

Naturopathic medicine is a medical system that is based on its practice principles and the medical philosophy of vitalism. This study gives an example of how these components of theory

can be transformed into a set of quantifiable treatment criteria for use in future trials and observational studies of naturopathic medicine. Although a plethora of treatments are prescribed for the conditions studied here, the criteria developed could have generated the majority (82% to 93%) of the specific treatment prescriptions. Therefore, there is evidence that a naturopathic theory-based set of treatment criteria may work to provide meaningful measures by which to ensure treatment fidelity and “unpack” the “black box” for future studies of the naturopathic medical system.

If the treatment criteria had been used to generate the prescriptions in the database, 100% of the treatments prescribed should have matched the treatment criteria. However, the treatment criteria were developed for certain conditions, and the patient visit records for those conditions were selected based on the first of up to 5 diagnosis codes. The patient may have had more than 1 condition under treatment during the same visit. In those cases, prescriptions intended for the non-primary diagnoses would not necessarily match the treatment criteria.

Because the patient visit data in the original study’s database were not designed to test these treatment criteria, it was not possible to test certain components. Whereas there was a great variety in the treatments prescribed, it can only be assumed that this reflected “individualization” of treatment; however, it could also reflect provider preferences. When evaluating the criteria of “least-force interventions,” prescription drugs could be used as a proxy for more forceful therapies. Unfortunately, a number of known non-prescription items were included in the category labeled “prescriptions” in the database. Therefore, the prevalence of prescription drugs is likely to overestimate the use of

| TABLE 3 Illustration of How Treatments Used in Visits for Fatigue/Fibromyalgia Might be Assigned to Treatment Criteria Components (n=95)                                                                                     |                                |                      |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|----------------------|
|                                                                                                                                                                                                                              | No. of visits where prescribed | No. of prescriptions |
| <b>Components Applying to All Conditions</b>                                                                                                                                                                                 |                                |                      |
| Healthy lifestyle promotion*                                                                                                                                                                                                 | 57                             | 152                  |
| Stimulate the Visc†                                                                                                                                                                                                          | 42                             | 48                   |
| <b>Components Applicable Only to Fatigue/Fibromyalgia (with examples of specific treatments)</b>                                                                                                                             |                                |                      |
| Nutritional deficiencies <sup>79-81</sup><br>(eg, essential fatty acids, <sup>82</sup> B vitamins, <sup>83</sup> magnesium and malic acid, <sup>84</sup> other nutrients)                                                    | 50                             | 117                  |
| Unknown physiological pain mechanism<br>(eg, hydrotherapy/balneotherapy, <sup>85</sup> osteopathic manipulation, <sup>86</sup> acupuncture <sup>87</sup> )                                                                   | 31                             | 38                   |
| Liver dysfunction <sup>88</sup><br>(eg, choline, <sup>88</sup> liver support diet, <sup>89</sup> milk thistle, <sup>67</sup> fiber)                                                                                          | 28                             | 37                   |
| Oxidative stress <sup>90</sup><br>(eg, vitamin C, <sup>91</sup> other anti-oxidants)                                                                                                                                         | 24                             | 39                   |
| Psycho/neural dysfunctions <sup>92,93</sup><br>(eg, 5-hydroxytryptophan, <sup>94</sup> valerian, <sup>95</sup> counseling and cognitive behavioral therapy <sup>96</sup> )                                                   | 23                             | 27                   |
| Food sensitivities <sup>96</sup><br>(eg, hypoallergenic diet)                                                                                                                                                                | 22                             | 28                   |
| Adrenal dysfunction <sup>97,98</sup><br>(eg, licorice <sup>78</sup> , DHEA, Siberian ginseng <sup>99</sup> )                                                                                                                 | 19                             | 21                   |
| Immune dysfunction/infectious process <sup>100</sup><br>(eg, berberine, probiotics <sup>101</sup> )                                                                                                                          | 13                             | 21                   |
| Muscular disuse dysfunction (eg, exercise <sup>102</sup> )                                                                                                                                                                   | 10                             | 10                   |
| <hr/>                                                                                                                                                                                                                        |                                |                      |
| Cumulative Totals Across All Visits and Components                                                                                                                                                                           | 94                             | 473                  |
| Median no. of prescriptions per visit (25th – 75th percentile)                                                                                                                                                               |                                | 4<br>(2-7)           |
| <hr/>                                                                                                                                                                                                                        |                                |                      |
| Total Treatments Prescribed (from Table 4)                                                                                                                                                                                   |                                | 542                  |
| <hr/>                                                                                                                                                                                                                        |                                |                      |
| % of Treatments Addressed by the Treatment Criteria                                                                                                                                                                          |                                | 87%                  |
| <hr/>                                                                                                                                                                                                                        |                                |                      |
| DHEA = dehydroepiandrosterone                                                                                                                                                                                                |                                |                      |
| * Includes diet, exercise, meditation, music therapy, and the following education and counseling categories: growth/development, mental health, psychotherapy, self-care education, tobacco use/exposure, and prenatal care. |                                |                      |
| † Includes constitutional homeopathy, hydrotherapy, massage, and acupuncture.                                                                                                                                                |                                |                      |

| TABLE 4 Number of Treatments and Variety of Treatment Types Prescribed at Naturopathic Physician (ND) Visits for Each Condition |                    |                   |                      |
|---------------------------------------------------------------------------------------------------------------------------------|--------------------|-------------------|----------------------|
|                                                                                                                                 | Menopause symptoms | Bowel dysfunction | Fatigue/fibromyalgia |
| Number of visits                                                                                                                | 66                 | 121               | 95                   |
| Number of visits with prescriptions                                                                                             | 63                 | 115               | 95                   |
| Number of different types of treatments prescribed                                                                              | 158                | 225               | 175                  |
| Total number of individual treatments prescribed                                                                                | 432                | 752               | 542                  |
| Median number of prescriptions per visit                                                                                        | 5.5                | 6                 | 5                    |
| (25th-75th percentile)                                                                                                          | (3-9.75)           | (2-8)             | (2-8)                |

more forceful therapies. It also was impossible to use these data to test the notion that "symptom suppression" was avoided. Finally, patient education can take a variety of forms, including descriptions of the usual etiology, risks, and usual course of conditions and the alternatives available for treatment. This information was not captured in the database.

Many studies of CAM in general and naturopathic medicine in particular have categorized treatments by modality.<sup>16,18,19</sup> Such studies, however, give only a superficial description of the CAM system under study. Regarding this study, the use of modalities to categorize treatments says little about how NDs actually practice naturopathic medicine. For example, even though botanical medicine treatments were prescribed during about half of visits for each condition, the targeted underlying causes and the actual herbs prescribed varied greatly. Botanical medicines for hormonal rebalance (eg, black cohosh) were prescribed most often for menopausal symptoms, botanicals to soothe and heal the gut lining (eg, marshmallow root) and to aid digestion (eg, gentian) were used most often for bowel dysfunction, and botanical medicines for adrenal support (eg, Siberian ginseng) or depression (eg, St John's wort) were used most often for fatigue/fibromyalgia. It is the delineation of treatment criteria rather than modality that creates a meaningful categorization of specific treatments for use in whole systems research.

Although this study relied exclusively on published documents, to properly apply this concept of treatment criteria to whole systems of medicine, researchers must initiate discussions with practitioners of the medical system under study early on. This collaboration is required to first define the underlying theory that drives practice in that system and then to translate that theory into a set of operationalizable treatment criteria for each diagnosis/condition of interest. Ideally, the treatment criteria will outline for the medical system those elements of practice that are essential and unique, those that are essential but not unique to that system, those that are not essential but allowed, and those that are prohibited.<sup>8</sup> This study did not go beyond defining what was essential because no prohibitions were found (other than that of initial use of high-force interventions without just cause), and the designation of uniqueness requires a comparison to another medical system. For intervention studies involving a specific condition, practitioners and researchers might choose to develop a list of specific treatments that would address each component of the treatment criteria and ask practitioners to choose from this list during the trial. However, if the purpose of the criteria is its use in observational studies of the medical system in situ rather than in studies of particular protocols, care must be taken that these lists are clarifying and not restrictive.

Data collection for any study would then include not only the specific treatments prescribed but also their relation to the treatment criteria. In addition to mapping the specific treatments prescribed to the criteria, data collection would include treatment criteria components evaluated but not deemed appropriate for this patient (eg, the patient may have a healthy lifestyle other than lack of exercise and not need additional healthy

lifestyle promotion prescriptions, or the patient may be of low risk for breast cancer and not need specific breast cancer prevention treatments). Data collection also would include whether specific treatments were or were not prescribed due to patient preference (individualization) and whether patient education was offered for that visit's treatment plan.

Given the progression of treatments appropriate for many conditions and the limit of the time available at any one patient visit, it is likely that any treatment criteria developed should be assumed to be implemented and measured over a series of visits. At any one visit, practitioners may prescribe treatments for only certain components, likely addressing the most pressing issues at that time. However, the other components could be addressed in a long-term treatment plan.

In addition to the obvious benefit of ensuring that the "black box" actually contains the medical system under study, there are a number of other benefits to defining treatment criteria and measuring treatment fidelity:

- Measurement of treatment fidelity allows researchers to begin to determine which elements of the system had the most influence on patient outcomes.
- Replication studies are difficult if there is no assurance of what was done before.
- In CAM, more than 1 medical system can use the same treatments, and philosophies often overlap. Without a clear understanding about what is essential, unique, and prohibited in treatment under each system, effect sizes will suffer. (See Waltz et al<sup>8</sup> for a description of components needed to ensure treatment distinctiveness, which is related to treatment fidelity.)
- Treatment criteria can be used to communicate best treatment under each medical system and provide a way to document differences between CAM systems.
- Higher fidelity interventions may have higher retention rates and better outcomes through providing better quality of care. Fidelity measures allow for comparison of practitioners across locations and over various types and levels of education.

There were several limitations to this study. First, these treatment criteria were developed using only written sources and the consensus of the 2 authors who are NDs. Although reasonable, the criteria developed may not be truly representative of the practice of naturopathic medicine and are offered only as an example. Actual treatment criteria for future research must be developed with ample input from practicing NDs. In addition, this study presents a measure of treatment fidelity focused on treatments prescribed. It may be that a better measure would also include diagnosis methods, the character of the patient-provider interaction, and other elements. Next, treatment information used to evaluate the criteria were available only for 1 visit for each patient, allowing only a cross-sectional "snapshot" of 1 point in time during that patient's treatment history. Also, as

noted above, patients were grouped into conditions based on their primary diagnosis (based on ICD-9) but could have up to 4 additional diagnoses. No information was available to link treatment to specific diagnoses, and no information was available as to the context of each treatment within the practice of naturopathic medicine. Finally, we acknowledge that a rigorous test of treatment criteria must be prospective and would involve their application in practice.

This study presents an example of the development of treatment criteria as a measure of treatment fidelity for studies of the whole medical system of naturopathic medicine as practiced by licensed naturopathic physicians. The treatment criteria developed could have generated the majority (82%-93%) of treatments prescribed by a sample of NDs providing some evidence that the method is viable. In addition to ensuring model validity, treatment criteria also can be used to identify the critical components of each system with respect to outcomes, are critical to the replication of studies, ensure that the best form of each system is represented in comparison studies, and are a measure of quality of care. The development of treatment criteria is 1 step toward allowing CAM to be studied as it is generally practiced—as distinct systems of medicine.

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