

EDITORIAL

Call to Action: Announcing the Traditional, Complementary and Integrative Health and Medicine COVID-19 Support Registry

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In collaboration with numerous global organizations, we have moved forward with a clinical registry aiming to capture key case, treatment/supportive care, and outcome variables related to the use of traditional, complementary, and integrative health and medicine products and practices in response to the COVID-19 crisis.

—Ryan Bradley, ND, MPH, Director, Helfgott Research Institute; TCIHM COVID-19 Registry Principal Investigator

The Need

THE VARIABILITY IN GUIDANCE by national governments on potential value relative to COVID-19 through traditional, complementary, and integrative products, practices, and practitioners is nothing short of astounding. The Chinese government credits its swift turnaround to an “integrative” method through which patients received Traditional Chinese Medicine plus biomedicine.^{1,2} The Indian government issued a memorandum that was a composite of practices viewed as potentially useful by the various branches of its AYUSH ministry (Ayurveda, yoga, Unani, Siddha, homeopathy, and naturopathy).³

On the contrary, North American and European governments are typically silent on these practices,⁴ unless to warn of possible harm and overselling.⁵ The guidance from these federal bodies is typically limited to what may be called “healthy waiting”—social distancing, mild exercise, stress reduction, no smoking, and limiting alcohol.⁶ The view is that if there is no hard evidence that product *x* reverses COVID-19, it is not worth mentioning. This position is, of course, a double standard: no practices have definitive evidence for benefit against COVID-19, yet providers with other stripes are using experimental practices and off-label drugs every day in their desperate to ease patient suffering and elicit hope.

In these Europeans and North American countries, practitioners of integrative, nutritional, naturopathic, Chinese, and other traditional medicine tend to practice philosophically more closely to the Chinese and Indian government perspective. Multiple organizations—the University of Arizona Andrew Weil Center for Integrative Medicine,^{7,8} the American Nutrition Association (ANA),⁹ and the American Association of Naturopathic Physicians (AANP)¹⁰ among

them—responded to COVID-19 by developing resource sites with respectful caveats and then linked professionals and members of the public to potentially useful supportive practices and natural agents cited by the existing suggestive science. These methods might have value in preventing, supporting, complementing, or rehabilitating. While there is no direct evidence at this time, other than some uncontrolled studies on Traditional Chinese Medicine out of China,¹¹ some of these approaches may also have the potential to be effective treatments directly against the virus’ activity.

The Integrative Medicine COVID-19 Support Registry

In this context, the Traditional, Complementary and Integrative Health and Medicine Support Registry¹² is a critically important tool for the community of professionals and patients using these natural agents and supportive practices. The origins and intent of the Registry are captured at the top of this editorial in the explanatory note from Ryan Bradley, ND, MPH, the director of the Helfgott Research Institute, based in Portland, Oregon.

The registry is housed on a secure server at the Helfgott Research Institute. Institutional Review Board approval (as “exempt”) was secured through the National University of Natural Medicine. Bradley, the project’s principal investigator, is an experienced clinical researcher and epidemiologist with a portfolio of peer-reviewed papers in natural products, mind–body therapies, diabetes, heart disease, and whole-practice research. He is also a *JACM* Associate Editor who has been a recipient of multiple National Institutes of Health grants.

Less than a week after creating the registry, a multidisciplinary set of organizations and institutions endorsed the

registry. They have begun recruiting their members to participate (a partial list is given in Table 1). In some cases, Memoranda of Understanding have been developed. Examples are the AANP and the ANA, each of which link directly to the registry from their resource sites.

The fields in the registry include basic demographic information such as location and professional training, followed by basic information about goals and therapeutic agents used via quick response lists:

- Patient symptoms
- COVID-19 status
- Comorbidities
- Therapeutic goals (“prevention, treatment, health promotion, recovery/convalescence, rehabilitation, other”)
- Immune support (12 agents, plus “other”)
- Antiviral agents (13 noted, plus “other”)
- Respiratory health (15 noted, plus “other”)
- Inflammation (18 noted, plus “other”)
- Pharmaceutical drugs (17 categories)
- Other contributions to health (8 noted, plus “other”)
- Case outcome.

The registry collects longitudinal data so that practitioners can return to the registry via a survey access code and update information, such as outcomes, while patients/clients remain under their care. Practitioners can also download their own case information to augment their records, or organize case reports. Note that the drop-down choices on therapies may require users of Traditional Chinese Medicine, Ayurvedic, or other products and practices from other traditional medicine systems to use the “other” box.

Intended Use

Where is the value? A FAQ provided by Helfgott (see Table 2) describes initial plans for intended use. The first is simply to determine characteristics of care. The second is to

TABLE 1. INITIAL SUPPORTING ORGANIZATIONS

Webpage:
<https://redcap.nunm.edu/redcap/surveys/?s=PE3EHAYDT3>

Lead agency
 Helfgott Research Institute/National University of Natural Medicine

Some initial supporting organizations
 Academic Collaborative for Integrative Health
 Academy of Integrative Health and Medicine
 American Association of Naturopathic Physicians
 American Nutrition Association
 Association of Accredited Naturopathic Medical Colleges
 Canadian College of Naturopathic Medicine
 Integrative Complementary and Traditional Health Practices
 Section-American Public Health Association
 Integrative Health Policy Consortium
 Maryland University of Integrative Health
 National Ayurvedic Medical Association
 Oregon Association of Naturopathic Physicians
 Southern California University of Health Sciences
 Traditional, Complementary, and Integrative Medicine
 (TCIM) Network of the Americas
 University of Sydney
 University of Technology, Sydney
 World Naturopathic Federation

TABLE 2. FAQs REGARDING THE INTEGRATIVE MEDICINE COVID-19 SUPPORT REGISTRY

1. *Will my entry be linked back to me or my practice?*
 The registry provides the option of including your contact information so that the investigators can contact you for more information about the case, including its outcome. However, this entry is completely voluntary.

2. *Will the registry collect any Protected Health Information (PHI)?*
 No. No PHI is included, and the data collection platform is completely HIPAA compliant.

3. *Can I enter more than one patient/client per record?*
 In order to record accurate outcomes for each case, ideally each case would be entered in an individual record. However, if *identical* care and *identical* outcomes are observed for multiple patients, it allows for the number of cases to be entered.

4. *Can I return to my registry entries?*
 Yes. Upon submission of a record, a survey access code is provided. We strongly recommend you store this code in your patient/client record so you can return to the registry and update content as needed.

5. *Can I print or otherwise access my entries?*
 Yes. Upon submission of a record, you can generate a PDF that includes your entries for your records.

6. *I'm hesitant to report adverse treatment experiences or observations. Why should I do so?*
 It is very important for the community to learn about potentially adverse treatment outcomes. This is as critical as learning about favorable treatment outcomes. Your entry will not be linked to you or your practice unless you provide your contact information.

7. *I'm hesitant to describe my practice because I practice in an unregistered jurisdiction. Why should I do so?*
 The registry only collects practice data at the country level. Therefore, it is impossible to determine the licensure status unless when regulated at the country level. As above, your entry will not be linked to you or your practice unless you provide your contact information.

8. *How will this information be used?*
 The information will be used to: (1) determine characteristics of care, (2) report contributions of integrative practitioners to COVID-19 management and risk reduction, and (3) provide data for the generation of hypotheses regarding both promising and potentially harmful treatments and protocols. These goals can only be accomplished with broad participation. These data may be published and may be used in advocacy work to promote the contributions of integrative practices globally.

report contributions of integrative practitioners to COVID-19 management and risk reduction. The third is particularly useful for moving governments toward greater proactivity on integrative practices, if warranted: “Provide data for the generation of hypotheses regarding both promising and potentially harmful treatments and protocols.” Not mentioned is the learning that will come to any practitioner through the process of entering a subject in the registry, and the added value in recognizing patterns for those who choose to submit multiple entries. The Helfgott team anticipates that the data may be published in various forms. The potential mid-range uses include education and research, as well as advocacy work “to promote the contributions of integrative practices globally.”

What You Can Do: A Call to Action in the Time of COVID-19

These values of the registry will be more significant the greater the participation. If each practitioner entered a single case example, the result would be tens of thousands of entries from around the world. If you are an integrative practitioner who is working with COVID-19 patients, or individuals concerned that they might have the virus, register the case! If you are a researcher, administrator, or organizational leader who works with complementary, functional, integrative, naturopathic, and traditional medicine professionals, alert them to the registry! Send a brief article and a link in your e-newsletter. Host information and a link on your organization's Web site. Then, do all of this again and again to catch those who need to be told twice or a third time or be reminded.

N of 1

As a human being on planet Earth, I have a chance of contracting COVID-19. As a 68-year-old who has the damaging sequelae of a successful radiation and Cisplatin treatment 11 years ago, my chances of dying are higher. As a citizen of the United States, the most knowledgeable agency related to these approaches, the National Institutes of Health National Center for Complementary and Integrative Health, warns me that "there is no scientific evidence that any of these alternative remedies can prevent or cure the illness caused by this virus. In fact, some of them may not be safe to consume."⁶ Yet, as a long-time participant in the movement for more evidence-informed health and medicine, I am familiar with the research that suggests there may be multiple tools that may be valuable to anyone who breaks out of the binary perspective that such choices are not worth considering if they haven't been proven against COVID-19 itself.

This Traditional, Complementary and Integrative Health and Medicine COVID-19 Support Registry can be a critical tool for breaking down this polarization. The power of the registry to support greater understanding and integration will depend on interested professionals in the global traditional, complementary, and integrative communities powering it up by contributing. Please do, and let others know. This registry could prove lifesaving, if not for COVID-19 in this pass through, perhaps for its second, or for the next challenging virus that follows SARS-CoV-2.

The registry is located here: <https://redcap.nunm.edu/redcap/surveys/?s=PE3EHAYDT3>

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