

Natural Health Product–Drug Interactions: Evolving Responsibilities to Take Complementary and Alternative Medicine Into Account

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KEY WORDS

complementary therapies, herb-drug interactions, legal liability, pediatrics

ABBREVIATIONS

NHP—natural health product

CAM—complementary and alternative medicine

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abstract

Natural health products (NHPs) (known as dietary supplements in the United States) are a popular form of self-care, yet many patients do not disclose their use to clinicians. NHP-drug interactions are known to occur and can harm patients and affect the efficacy of conventional treatment. Using the example of an HIV-positive adolescent who had been responding well to antiretroviral therapy but then experienced a sudden unexplained deterioration in her condition, we review (1) clinicians' obligation to inquire about complementary and alternative medicine (CAM) use when assessing, treating, and monitoring patients, (2) how clinicians' duty to warn about risks associated with treatment has evolved and expanded, and (3) patients' and parents' responsibility to disclose CAM use. It also addresses the responsibility of hospitals and health facilities to ensure that the reality of widespread CAM/NHP use is taken into account in patient care to effectively protect patients from harm. *Pediatrics* 2011;128:S155–S160

Sixteen-year-old Jenny N., who has been HIV-positive for 1 year, has been taking the antiretroviral medications lamivudine, nevirapine, and indinavir and has had therapeutic success. Of concern, however, are results of her most recent blood tests, which reveal that her CD4⁺ T-cell counts are decreasing, her HIV-1 RNA levels are rising, and, after having reached a steady-state concentration for all her medications, her indinavir levels suddenly decreased by 40%. On questioning, Jenny asserts that she has complied with her doctors' instructions and denies use of other medications. The indinavir dosage is increased in an attempt to reach previous steady-state levels, but results of testing performed at her follow-up visit 1 month later indicate that the levels have continued to decrease, plateauing at 30% of the previous steady state.

Jenny's specialists are alarmed and puzzled by the dramatic decrease in her indinavir levels and fear that her condition may soon deteriorate. Jenny is asked to follow-up with her family doctor between specialist visits. The family doctor asks Jenny if she has been taking any new prescription, over-the-counter, or natural remedies. Only then does Jenny confide that she has been taking St John's wort (*Hypericum perforatum*) to combat depression. Her family doctor tells her that research suggests that St John's wort intake lowers levels of indinavir, so it is possible that a drug-herb interaction has led to her unstable indinavir levels and decreased CD4⁺ T-cell counts. He advises her that if she continues using St John's wort, it may further reduce the effectiveness of her anti-HIV regimen and possibly lead to drug resistance.

After hearing of this discovery, Jenny's parents are angry that her HIV specialists had not specifically questioned Jenny about her use of natural reme-

dies, especially after seeing the initial decrease in her drug levels. The specialists respond that adverse herb-drug interactions have only recently entered the medical literature and that asking about herbal remedies is not part of standard protocol in their institution.

In Canada, natural health products (NHPs) include herbs, vitamins, minerals, homeopathic remedies, traditional medicines, probiotics, and other substances used to prevent, diagnose, or treat disease, restore or correct function, or maintain or promote health.¹ Since 2004, NHPs have been governed under a separate federal regulatory regime aimed at ensuring their safety, quality, and efficacy.² In the United States, such products are termed "dietary supplements" and are defined and regulated differently.³

The use of NHPs has become widespread,^{4,5} and even greater use has been reported in populations that suffer chronic disease such as HIV/AIDS.⁶⁻⁹ NHPs are a popular form of self-care; people seldom consult any type of health care provider before using them.¹⁰ Many patients do not disclose NHP/complementary and alternative medicine (CAM) use to their physicians.^{9,11} Although NHP-drug interaction data are still scant, particularly from pediatric populations, interactions are known to occur and can affect efficacy and patient safety.^{7,8,12,13}

Of course, not all NHPs, or CAM therapies generally, are known to present risks. NHPs can be safe and effective when used as recommended.¹⁴⁻¹⁶ The case scenario we provide was deliberately framed to highlight the dangers of ignorance when there is a real risk of adverse NHP-drug interaction that could easily be mitigated by the routine procedures we suggest. In this article we review (1) clinician obligations when assessing, treating, and monitoring patients, (2) the evolving duty of

clinicians to warn about risks associated with treatment and, in particular, interactions between conventional treatment and NHPs/CAM, and (3) the responsibility of patients/parents to disclose CAM use.

ETHICS

History-Taking and Monitoring

A fundamental responsibility of physicians is to "[e]ngage in lifelong learning to maintain and improve... professional knowledge, skills and attitudes."¹⁷ Physicians, especially specialists who treat patients with chronic health conditions (a population known to make greater use of CAM⁷⁻⁹), should be aware of research regarding CAM use for those conditions to help prevent the potential harm of adverse interactions. They should make special efforts to explore CAM use with patients during history-taking.

It is now possible for adolescents who are HIV-positive to live a relatively normal life, but this possibility depends on adherence to a fairly rigid medication regimen. Indications, as in our scenario, that treatment is not or is no longer as effective as it might be warrant careful and thorough investigation, because significant harm may result if the problem is not identified and resolved.

There may be several reasons behind such results, including nonadherence to medical recommendations. Nonadherence in itself might have many causes including misunderstanding or lack of information, a deliberate decision to forgo medication that is not disclosed to the physician, and interaction with other agents. Physicians' obligations and intentions to benefit their patients require that they probe potential reasons in a competent, thorough, and respectful way.

Rebuilding Trust

Patients and families who have lost trust in their specialist physician may have limited options. There may simply be no one else to provide care to Jenny. The onus is on her physicians to take the steps needed to begin rebuilding trust and, more broadly, to alter their practice to take the increasing prevalence of various forms of CAM use into account.

LAW

There are 2 legal duties of care that health practitioners owe patients. The first duty is to exercise reasonable care, skill, and judgment in diagnosing, treating, and monitoring the patient. The second duty is for the practitioner to obtain informed consent before treating; that is, patients/parents must be given the information that a reasonable person in similar circumstances would want to know about the treatment and alternatives (including nontreatment) and the benefits and risks of each option so that they can make an informed decision about whether to proceed.^{18–22} The specialists' failure to inquire about the use of NHPs that might affect treatment could breach both their obligation to take reasonable care in treating the patient and the requirement to obtain informed consent.

History-Taking and Monitoring

To diagnose a patient's condition accurately and formulate an appropriate and effective treatment plan, clinicians must take a complete medical history. The physician's ability to plan treatment is compromised if he or she is unaware that the patient is taking NHPs that may diminish the efficacy of proposed treatment. Given the widespread use of NHPs and the risks associated with some of them, inquiring about use should be an expected part of history-taking, and the question

should be revisited as part of patient monitoring.

Whose responsibility is it to bring out information about NHP use: the physicians' or the patient's and parents'? Canadian courts have occasionally held patients responsible to inform doctors, but those cases dealt with special circumstances unique to the patient's life, such as a family member's poor response to similar surgery, not NHPs.^{18,23} In both the United States and Canada, a strong argument can be made that as part of taking a proper history, practitioners are legally obliged to inquire about use of NHPs just as they would about the use of other substances that can affect treatment. In addition, because many people do not consider NHPs to be medication, probing questions should be asked to elicit a complete picture of the substances and therapies a patient is using that may affect treatment. Especially when the patient is a minor, and the NHP-drug interaction is technical information reported in the medical literature, the responsibility to elicit this information should be on the physician rather than on the patient to volunteer it.

During treatment, the patient's health status should be monitored, and unanticipated significant changes in health status should be investigated appropriately. Changes in responsiveness to therapy should have alerted Jenny's treating physicians to carefully explore possible reasons for the development, including adverse herb-drug interactions.

Obtaining Informed Consent and Warning About Adverse Effects

Turning to the obligation to obtain informed consent, there have been no decided cases about legal liability for CAM-drug interactions in Canada. However, there has been a clear trend in judicial decisions to expand clinicians'

disclosure obligations in general.¹⁸ Given the prevalence of NHPs and the potential that some of them, such as St John's wort, could impair the patient's treatment regimen, it is likely that a reasonable patient/parent would want this information. In the United States and Canada, failure to warn of this risk could breach clinicians' obligation to obtain informed consent.²²

However, the legal analysis of whether physicians must warn patients about a risk differs if they were unaware of it.^{18,24–26} Health Canada estimates that there are more than 40 000 NHPs sold in Canada.²⁷ Physicians will not be expected to know about all or even most of them. In the case of St John's wort, since the interaction was first revealed by a National Institutes of Health clinical center study in February 2000,²⁸ there has been a relative abundance of information and wide reporting regarding the dangers of concomitant use of St John's wort and protease inhibitors.⁷ It would be reasonable to expect a specialist who works with this patient population to be aware of the risk of interaction. In the case of other NHPs or CAM therapies, the question of whether a physician should have known about the risk will depend on expert evidence of other specialists about the standard of care (ie, the knowledge that would be expected of one's peers in the same circumstances).^{21,22,24,25} If a court concludes that a reasonable specialist would have known about the risk, then the specialists' failure to warn the patient about it could be considered negligent.

CLINICAL RESPONSE

A large 2007 US survey revealed that in the general population, more than 1 in 9 children and teenagers used CAM; herbal remedies were the leading type of therapy chosen.²⁸ CAM use has been estimated at anywhere between 45%

and 62% by pediatric patients with chronic illness,^{30,31} and utilization rates have been reported to be between 27% and 100% among patients with HIV/AIDS.^{32–35} Although there have been limited studies regarding child/adolescent patients with HIV, their CAM use in 1 study³⁶ was noted at 22%. Despite these high utilization rates, physicians do not yet routinely question their patients about CAM usage.^{9,37,58}

Whether patients are concerned that their physician will disparage their choice of CAM therapies¹¹ or simply do not consider them to be “drugs” or “medications,” patients rarely disclose CAM use unless specifically asked.^{9,39} Not only do few physicians ask their patients about CAM, even fewer consult references about NHPs that their patients use.^{11,37,40} Regardless of the physician’s personal views regarding CAM, it is essential that he or she explicitly includes questions about NHP/CAM use as part of routine history-taking and uses specific terms such as “alternative,” “natural,” and “herbal” to convey fully the meaning of the question.⁴¹

In this case, the specialists not only failed to incorporate questioning specific about CAM into the history but also did not recognize signs that could have alerted them to the increased possibility that the patient was concurrently using CAM therapies that might compromise the efficacy of conventional care. In addition, the presence of chronic disease might suggest screening for depression, an ailment for which there is increased CAM use,⁴² and discussion of treatment options for that condition.

After appropriate questioning, the next requirement for preventing avoidable NHP-drug interactions is knowing where to access information* regard-

ing such herbs.¹³ Acknowledging that physicians should educate themselves about CAM places another responsibility on the shoulders of already taxed physicians. However, it is a reality that would be too dangerous to ignore. Physicians need not become homeopaths and herbalists; they simply need to ensure familiarity with the NHPs (or in the United States, dietary supplements) and other CAM therapies that they most often encounter or anticipate encountering, both in general and with specific patient populations.

In our scenario, the decision-making framework described in the introduction to this *Pediatrics* supplement⁴³ can assist.⁴⁴ There is evidence that the NHPs could impair the effectiveness of drugs prescribed for this serious health condition, endangering the patient’s health, and indications that it may have done so in this case that require investigation. As the framework suggests, the patient should be actively discouraged from continuing to use the NHP, and treatment alternatives should be offered.

PATIENT/PARENT RESPONSIBILITIES

In addition to physician education about CAM, patients and parents need to become more aware of the potential impact of products they consume. This scenario is an all-too-common example of those using herbal supplements believing them to be entirely safe because they are “natural.”³⁰ If adolescents and parents recognized the risks associated with certain NHPs, they might become better informed about their choices and more forthcoming with their health care providers.

index-eng.php) Web sites. Also, Consumerlab.com, NaturalStandard.com, and naturaldatabase.therapeuticresearch.com are available fee-based databases.

RECOMMENDATIONS

Clinicians

- Review the medical literature to determine what is known about NHP-drug interactions in areas of practice.
- Ensure that while obtaining informed consent and assessing and monitoring the patient, NHP/CAM use is explored.

Medical knowledge is in a constant state of evolution, as are patients’ habits; as a result, what constitutes reasonable practice, even in taking a history, will change over time and become more expansive in response to new realities. Clinicians should learn what CAM/NHP therapies and products patients are using and what their plans are about continuation during treatment and discuss possible risks and benefits of such use, particularly in combination with (or, if appropriate, as an alternative to) conventional care. This discussion should be revisited from time to time during treatment to ensure that information remains current.

Patients, Parents, Public

Patient and public education campaigns should inform consumers of NHPs about (1) potential risks and adverse effects, especially adverse herb-drug interactions, and (2) the importance of discussing NHP/CAM use with health care providers.

In Cases of Suspected Interaction Between NHPs and Medication

Clinicians should take immediate action to determine the cause of changes observed and tell the patient/parents the results. If the changes were caused by NHPs, the clinician should counsel patients about NHP use, including risks and benefits, and offer treatment alternatives.

*For information, visit the US Office of Dietary Supplements (<http://ods.od.nih.gov>) and Health Canada’s NHP (www.hc-sc.gc.ca/dhp-mps/prodnatur/

Hospital/Health Facilities

Hospitals/health facilities should ensure that guidelines clarify for all clinical staff (including allied health professionals when appropriate) that the intake process, as well as informed-consent obligations, must include questioning to ascertain NHP/CAM use and discussion of potential adverse herb-drug interactions.^{45,46}

At the same time, institutions should guard against overbroad prohibitions and warnings, because some CAM therapies and products may improve the patient's condition or well-being, and patients' autonomous choices should not be unduly skewed by unfounded concerns.

Patient Safety

- Hospitals, health care institutions, and professional organizations can implement programs and policies to help avoid adverse events.⁴⁵ For instance, a targeted system of e-mail alerts within institutions to

particular departments when risks become known, or assistance with consolidating and disseminating existing online resources, could improve patient safety and enhance the quality of care.⁴⁷

- Adverse events from NHP use, although infrequent, are more common than reported.^{11,48} All involved in patient care should be encouraged to report adverse events regardless of whether they are from conventional care, NHP/CAM use, or interaction of the two. Institutions should implement systems to prevent recurrence.

Education

- Institutions should develop resources and policies that provide more accurate and timely information about NHPs/CAM to physicians and other health care providers (eg, as part of orientation for new staff and/or continuing education).^{47,49–51}
- Regulatory authorities and professional associations should develop

effective educational materials and resources, including risk profiles for NHPs, to better support informed decision-making by health care providers and by patients, parents, and the public.⁵²

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