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Probiotics Are Food; Herbs Are Plants; What's the Risk? Informed Consent for Complementary and Integrative Therapies

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Complementary and alternative medicine (CAM) is a group of products and services that are not considered part of conventional western healthcare practice. Complementary and alternative medicine includes hypnosis, acupuncture, aromatherapy, chiropractic care, and the use of herbs and supplements. The National Institutes of Health includes a subarea devoted to CAM: the National Center for Complementary and Alternative Medicine, which monitors the use of CAM therapies and promotes research on their safety and effectiveness. The goal is evidence-based information that can be shared with consumers to assist them in making informed decisions.¹ According to National Center for Complementary and Alternative Medicine, in 2007, Americans spent nearly 11.2% of their total out-of-pocket expenditures,¹ with 38% of adults and 17% of children using some form of CAM.

COMPLEMENTARY AND INTEGRATIVE THERAPIES

Another term used to describe the same group of CAM modalities is *complementary and integrative therapies* (CIT), which is more inclusive of health professions and alternatives beyond or in addition to medicine. Complementary and integrative therapies will be the term used for the remainder of this column and examples will be drawn from therapies where evidences of safety and efficacy exist.

Use of CIT during pregnancy

It is unclear how consumers get information about CIT during the perinatal period. On the basis of a recent survey, it would appear that television and trusted lay persons are major sources of health information during pregnancy.² Despite barriers due to poverty, approximately 70% of Americans have Internet access, and nearly half of all Internet searches are related to health information.³ However, most of these searches are never discussed with a healthcare professional.^{4,5} The National Center for Complementary and Alternative Medicine Web site includes tips for consumers about talking to healthcare professionals about CIT.¹ These tips include suggestions that consumers give their healthcare professionals a comprehensive picture of how they manage their health, including proactively discussing any CIT approaches that they may be using.

The prevalence of the use of prenatal CIT is unknown, but based on a review of 24 publications on complementary therapies during pregnancy, it may be as high as 87%.⁶ Complementary and integrative therapies used in the studies reviewed included herbs (ginger, raspberry leaf tea, Echinacea) and “acupuncture, acupressure, aromatherapy, massage, yoga, homeopathy, and chiropractic care.”^{6(p238)} The authors of the review found that older, more affluent, and educated pregnant women, with more gestational discomforts, were more likely to use CIT. Although women regarded these alternative therapies as more safe and natural and having at least the same efficacy as pharmacologic treatments during pregnancy, only a small portion of the women had much knowledge of the therapy that they used. For example, in one of the studies reviewed,⁷ 39% of Norwegian women studied used herbal preparations that had unknown safety for use during pregnancy or were considered harmful.⁶

Concerns about CIT

Sanderson and colleagues⁸ described the characteristics of alternative therapies likely to magnify consumer risk. These include ones for which the promoters (*a*) claim the therapy is a panacea; (*b*) deny responsibility for safety and/or discourage standard medical care, discounting the medical model; (*c*) foster psychological dependence in users; and (*d*) manifest no concern for the need to demonstrate therapeutic outcomes scientifically.⁸ Other authors argue that although there are unscrupulous, self-serving producers and practitioners of unproven alternative therapies, the real question is whether the healthcare community is willing to follow where research findings about CIT lead.⁹

Legal considerations

The mostly noninvasive nature of CIT has led to the observation that CIT malpractice claims have been reported to represent less than 5% of all law suits.^{10,11} Nurses have the duty to stay current with the scientific literature on alternative therapies as well as include questions about CIT that their clients may be using. This preparation will help prevent accusations of fraud and/or recklessness on the part of the nurse recommending unproven therapies.¹¹ If a professional nurse is planning to provide CIT, it is important to consult the state licensing statutes.¹¹ This is recommended because if treatments with CIT are not considered a part of professional nursing practice in a particular state, a nurse who practices CIT could be disciplined for failing to conform to standards of acceptable practice, even without an adverse event. Fortunately, more than half of all state boards of nursing have explicit CIT guidelines.¹¹

As perinatal nurses provide health information to clients, it is imperative to think holistically. Nurses can gather important data that may otherwise be missed, and open further discussions by taking histories that include questions about which specific modalities of CIT a patient may be using. Upon discharge, it would be critical for nurses to address the CIT options that a client may be considering for future use. Most important, this information can help prevent potentially dangerous interactions between CIT compounds and/or supplements and pharmacologic therapies.¹² Furthermore, if the nurse fails to react and provide accurate information when a patient discloses CIT use, the patient may interpret that the nurse approved the therapy. If harm occurs later, there could be a claim for failure to warn.¹¹

INFORMED CONSENT CONCERNS WITH CIT

Sakala and Corry¹³ recently identified barriers to evidence-based maternity care. One such barrier was inadequate informed consent. Inadequacies exist in both the informed consent process and the woman's preparation to make decisions on the basis of sound information. Jordan and Murphy¹⁴ described informed consent as a "process of exchange between woman and healthcare provider to foster her ability to make the best decision about what to allow to be done to her."^{14(p198)} The general principles of informed consent can be applied to any perinatal procedure, test, or intervention including CIT. These authors also outlined the steps in the process of informed consent that will be used to shape the discussion that follows, including risk management, with examples pertinent to perinatal nursing.

Health concern requiring treatment

The diagnosis or health concern that requires treatment¹⁴ should be clearly discussed with the client. Often the exact diagnosis is unclear and CIT may be used while waiting for diagnostic testing to lessen symptoms. Alternatively, physiologic states and transitions, such as pregnancy symptom management, may be the primary goal of CIT. As previously noted, Adams and colleagues⁶ identified a variety of studies in which an array of CIT was used during pregnancy.

Purpose of CIT approach

The purpose of the CIT treatment¹⁴ approach should also be discussed with the client. It is crucial to distinguish how the CIT approach will be positioned within the entire plan of care. For example, clarification concerning how the therapy will complement or be integrated with the other approaches that are planned is essential. When a modality is being used to complement another, any interaction effect should be carefully considered. For example, probiotics can be used to successfully treat bacterial vaginosis in both pregnant and nonpregnant women.¹⁵ Since it is known that 10% to 15% of women do not achieve resolution to bacterial vaginosis following one course of antimicrobial treatment and that the recurrence rate is up to 80% for bacterial vaginosis,¹⁶ antibiotics alone do not appear to be the best or only option. These facts raise questions about the efficacy of current antibiotic therapy and the best approach to treatment and prevention. Furthermore, probiotics can reduce antibiotic-associated diarrhea and restore and/or maintain the normal gut flora during antibiotic treatment; therefore, they are often suggested as a complement to antibiotic therapies for a variety of infections. However, if probiotics and antibiotics are taken at the same time, the antibiotic may interfere with the efficacy of the probiotic. Therefore it is recommended that probiotic and antibiotic dosing be separated by at least 2 hours.¹⁷

Interactive discussion of benefits and risks of CIT

The benefits and risks of the CAM treatment approach¹⁴ should be outlined with the client. This is an area that may be the most challenging for perinatal nurses. The discussion needs to take place in a manner that allows for an interactive exchange where the woman is viewed as an essential partner who ultimately makes the decision.¹⁸ This approach is congruent with the American Nurses Association Code of Ethics. Philosophically, the

code protects patient autonomy as the foundation for informed consent.¹⁹ Pregnant women reported wanting providers who were good listeners and collaborators in decision making.^{20, 21}

Potential adverse effects specific to pregnancy

Potential adverse effects and risks¹⁴ of any CIT approach should be discussed in detail. Concerns about adverse effects for the fetus were found to be the most common reason that women stopped CIT during pregnancy.⁶ It is tempting to assume that the use of over-the-counter therapies is benign, but it is well known that herbal therapies and supplements can have adverse effects.²² Similarly, acupuncture is widely recommended to treat and prevent a variety of health issues, but it is not completely risk-free. In a prospective observational study using a sample of 229 230 patients who received an average of 10 acupuncture treatments from German physicians, 8.6% reported at least 1 adverse event, most of which were minor.²³ The most common of these were bleeding, hematoma, and pain.²³ The authors developed and proposed an informational handout with a consent portion to facilitate the informed consent process for acupuncture patients in the future. Borup and colleagues²⁴ conducted a controlled trial of 607 healthy laboring women at full term who were randomized to acupuncture, transcutaneous electrical nerve stimulation (TENS), or labor analgesics. No adverse effects were reported. Women in the acupuncture group used significantly fewer pharmacologic and invasive pain-relief measures than those in the TENS or standard analgesic groups. The authors identified that the acupuncturists' education and experience were associated with the most optimal results and suggested that the best results might be achieved by a professional acupuncturist.

Likelihood of success of CIT

The likelihood that the CIT treatment will be successful¹⁴ should be discussed, including realistic goals and expectations of the time required to achieve the desired effects. Using a herbal CIT as an example, a recent Cochrane review²⁵ found that St John's wort was equally effective for the treatment of major depression as standard antidepressants and had fewer adverse effects. In addition, St John's wort costs about one-fourth of the price of antidepressants.²⁶ The duration of the studies in the Cochrane review ranged from 4 to 12 weeks and the efficacy was noted within that time.²⁵ However, the time range to achieve therapeutic effect was not clearly stipulated in this review. This may be due to the poor study designs and lack of standardization among the 29 studies included. Furthermore, it is known that it can take as much as 8 to 12 weeks before the maximal therapeutic effects of antidepressants are experienced.²⁷ Therefore, recommendations for St John's wort need to be tempered by the reality of the limitations in current research. It is also important to consider that the list of potential adverse effects and possible interactions for both the herbal and pharmacologic preparations are extensive.²⁷

Comprehensive explanation of varied approaches

The range of treatment alternatives that are reasonably available, including benefits and risks, should also be shared with the patient.¹⁴ For example, if discussing the option of St John's wort for the treatment of major depression, the options of counseling and/or antidepressant therapies should be thoroughly discussed as well. Providing all the information provides a solid basis from which the woman can make an informed decision.

Documentation of CIT discussion

Documentation of informed consent is essential, including the patient's response to the suggestions made. When a client discloses the use of any CIT that does not have a solid scientific evidence base, it is important that the nurse alerts the patient to that fact and documents the conversation in the record.¹¹ Jonas²⁶ advised healthcare providers to follow 4 Ps when providing informed consent for CIT. They are (1) *protect* by promoting safety through the identification of any potentially harmful or toxic aspects; (2) *permit* by opening discussion of safety, efficacy, and costs of various therapies; (3) *promote proven practices* by making scientific evidence

readily available to clients to increase their access; and (4) achieve *partnership* by actively cooperating with the client and CIT providers as part of the healthcare team. Following this approach could facilitate documentation.

CONCLUSION

Radzyski¹¹ stated that several CITs are recognized components of general nursing care and have been used for centuries (eg, nutrition, exercise, and massage). However, until the specifics of CITs are fully tested, it is inadvisable for nurses to recommend them to clients as if all aspects are evidence-based. More high-quality research on CIT approaches is needed to better inform these discussions. If nurses do not take the opportunity to be informed, other professional groups may take legal control of the therapies that had their origins in nursing practices. Remaining current with the ever-increasing evidence that exists about CIT may be the nurses' best risk-management strategy of all.

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