KNOWLEDGE OF SAFETY AND HERB-DRUG INTERACTIONS AMONGST HIV+ INDIVIDUALS: A FOCUS GROUP STUDY

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ABSTRACT

Objective
To determine how HIV+ individuals access safety and knowledge of drug interactions related to complementary and alternative medicine (CAM).

Methods
We conducted two separate focus group sessions with HIV+ users of complementary therapies. A total of 8 men participated at an urban health centre. Focus group sessions were audio taped and transcribed verbatim. Analysis was conducted independently and in duplicate, using thematic analysis.

Results
All focus group participants described their use of CAM as very important for their health maintenance, giving them a feeling of empowerment in their health care. Potential side effects and safety issues were indicated as major concerns for treatment decisions, but the participant's knowledge of safety issues involved in CAM care for HIV+ patients was limited. The sources used by the participants to gather information regarding safety and interactions with medications were varied but included: their CAM providers, their physicians, books, resources from AIDS Service Organizations, the internet and health food stores. Participants acknowledged that appraising the quality of such information is difficult.

Conclusions
The participants in this study had a strong trust in CAM and used a wide variety of sources to gather information on CAM safety, though their knowledge base was poor. As the use of CAM grows, further research on how to disseminate reliable information on safety and efficacy to this potentially vulnerable population is required.

Key Words: HIV, complementary medicine, herb-drug interactions

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A recent nationwide survey of HIV+ individuals in the USA found that up to 68% of participants admitted to using Complementary and Alternative Medicine (CAM) therapy within the previous 12 months.[1]

Approximately 12% of the surveyed group acknowledged use of an herbal natural health product (NHP). In addition, many reports have suggested that HIV patients do not tell their physicians about their use of CAM.[2,3.] Reasons for CAM use include managing symptoms, medications and emotions; self experimenting to evaluate disease progression; gaining freedom from medical regimens; and managing AIDS stigma.[4, 5] While patient values and belief systems have to be respected, the potential for important adverse effects and drug interactions exists and needs to be conveyed to patients. The evidence for the potential interactions between NHPs and protease inhibitors is low level, but indicates garlic, St. Johns Wort and Vitamin C may reduce HIV drug concentrations.[6,7,8,9] It has been suggested that these interactions could lead to drug failure. Sources of information for safety

include physicians, CAM providers, books and the internet.[10] However, there is little information about how the HIV+ population might access or appraise this important information.

We attempted to investigate this through a qualitative study of HIV+ users of CAM, to determine how they access information on safety and drug interactions of natural health products. A focus group approach was used, because this can encourage participation from people who would be reluctant to contribute on their own,[11] is perceived as less condescending,[12] and minimizes the expression of investigator perspective in the results.[13] These are all important issues in a population such as this.

METHODS

Focus groups were conducted with HIV+ individuals at an urban health centre offering free complementary therapies. Clinic services available to participants included acupuncture, nutritional advice, homeopathy, herbal medicine, massage and chiropractic care. A study team member actively recruited participants at the health center. Eligibility criteria included HIV+ status, ability to participate orally and ability to provide oral and written informed consent. Two focus groups were held in Toronto during March 2003. Twenty participants expressed interest and were eligible. A semi-structured interview guide was used to ensure that the issues of importance were discussed.

Focus group questions

We conducted a systematic review of studies of NHP-drug interactions to develop questions, which could be addressed at the focus groups. During the focus groups we asked about current and past CAM use, perceptions of how their CAM practitioner and physicians interact or judge CAM use, and the sources of information drawn on relevant to the safety and potential drug interactions of CAM. Questions were open-ended. Focused questions were also used to determine levels of knowledge about drug interactions.

Two trained moderators conducted each 2-hour session. Each focus group was audio taped and field notes were also taken. We used constant comparison to ensure the validity of responses. Audiotapes were transcribed verbatim. Two study team members analyzed each transcription independently, in duplicate. Decisions of thematic structure were determined through consensus.

Themes were categorized into: communication of CAM use with healthcare providers, knowledge of safety and drug interactions of natural health products in HIV, and sources of information utilized regarding safety and drug interactions of natural health products.

Ethics and Consent

All participants provided written informed consent and had the option to discontinue participation at any time. The Institutional Review Board of University of Toronto and the Institutional Review Board at the Canadian College of Naturopathic Medicine approved this project.

RESULTS

A total of 8 men attended and participated in the 2 focus groups, 4 at each session. All participants were white, with duration of HIV+ status ranging from 2- 21 years.

Communication between healthcare providers

All participants reported discussing their CAM use and natural product regimen with their primary care physicians, HIV specialists and CAM practitioners. This health care team also acted as the primary source of information regarding safety and efficacy of natural health products, though at least one participant indicated: "I'm about on a sort of fifty-fifty basis between the clinic and just reading. My biggest problem I guess is I don't know how to evaluate the opinions of the authors..."

Knowledge of efficacy and safety of natural health products in HIV

Focus group participants expected to be informed by their health care team of any safety issues or dangerous side effects. All participants knew that St. John's Wort has been shown to reduce the effectiveness of HIV medications.[6]

Participants reported receiving this information from a variety of sources, including physicians, naturopathic doctors, AIDS Service Organizations (ASO) and newspapers. When asked if anyone knew of other natural products

that could interact with HIV medications, no participants were able to identify correctly any other natural products that had been clinically tested. One participant incorrectly mentioned products that have not been tested to determine interactions. Importantly, when discussing CAM therapies in comparison to western medicine, participants consistently noted a lack of fear concerning safety issues. As one participant put it: "I've read enough about a lot of natural products and herbal products and things like that and they just don't seem to be toxic or carry a lot of side effects…"

Sources of information on safety and efficacy of natural health products

The majority of participants relied upon their health care team for information on safety and efficacy of natural health products. Other sources of information include AIDS service organizations, which participants described as "very trustworthy", books on natural health available from the library, and the Internet was also a major source of information for all participants.

However, all participants expressed concern that the latter could not be trusted, and that information available on some web sites was potentially harmful and misleading. Participants reported using various methods to appraise the quality of information from the Internet, including how well referenced the web site was, the reputation of the sponsoring organization and how many other web sites displayed the same information.

A further source of information was health food stores.[14] Participants suggested that the naturopathic clinic and their physician clinics should make information clearly available about herb-drug interactions for ease of access.

DISCUSSION

The results of this study should be of interest to clinicians working with HIV+ patients. The increasing use of CAM therapies by the HIV community indicates the need for patients to be aware of the potential for serious adverse events and drug interactions, and the need to ensure that this information reaches the patient population in a timely and effective manner.

Most of the participants described CAM clinicians and the patient's physicians as the primary sources of information regarding the safety and side effects of natural products, though at least one participant relied just as heavily on self-research using books and the internet. However, apart from the highly publicized St. John's Wort/ indinavir study, the participants were unable to identify commonly used NHPs that have been shown to be capable of affecting HIV drug metabolism.[6-9] Viewed in this context, it is a concerning finding that participants viewed NHPs in general as non-toxic due to their "natural" status, as this is clearly not the case.[15, 16]

Physicians and CAM therapists need to be aware that their opinions on safety and side effects are highly valued and thus, they have a responsibility to ensure that these opinions need to be up-to-date and evidence-based. Clinical practitioners also need to ensure that this information reaches the target population, especially given the prevailing dogma equating "natural" with "safe." The focus group participants were concerned about their own lack of information on safety and side effects, and suggested this information be made as readily available as possible, in a clear and concise manner. This responsibility may also extend to ASOs who may consider providing evidence-based compendia and workshops on NHP safety as well as skills such as critical appraisal.

A further important finding of our study was the variety of sources that the participant's access for safety information related to CAM. Though CAM providers and physicians were considered important, participants mentioned other sources of information including books, magazines, the Internet and health food stores. The participants indicated their concern with the quality of Internet information and were aware of the potential problems with this information. The use of health food stores as a source of information was particularly concerning, as we have previously shown that health food stores are a potential source of harmful information.[14]

There were several limitations to our study. We sampled a small, male-only population at an urban clinic in Toronto. As well, our sample was a self selected and potentially biased group, because they chose to attend our focus group sessions, it is possible that the participants have views that are

different in important ways from those of other patients at the clinic who chose not to attend. It is possible that women and children hold different views than the male views reported in this study. Further research is needed to confirm the consistency of these findings.

The topic of NHP-drug interactions has garnered substantial attention in the media as well as medical journals. However, despite this attention, clinical trials in this area are limited to 8 studies[6-8,17-21] and one population-pharmacokinetics study.[9] Of these studies, only 3 NHPs have been shown to interact: St. John's Wort,[6, 9] garlic,[7] and Vitamin C.[8] Further research in this area is required so that clinicians and patients may be adequately informed.

To our knowledge, this is the first study to identify where HIV+ individuals access and how they appraise information on the safety and potential for drug interactions of CAM. Our results indicate that further research is required to best disseminate reliable information about safety and drug interactions. The participants in our study had a strong belief and trust in CAM, but were not well informed about the safety and drug interactions of the products they were using. Effective strategies to deliver this information must be implemented to avoid potentially serious drug interactions in this vulnerable patient population.

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