Folk Medicine Beliefs And Practices In Hispanics Attending Aim Clinics In Columbia Presbyterian Hospital

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A. Statement of study and purpose rationale

Folk medicine has been defined as those illnesses and beliefs that are commonly recognized within a cultural group, and whose explanatory model often conflict with that of the biomedical paradigm (Pachter, 1993). In Hispanic Americans, folk medicine incorporates religious belief system, including those of Catholicism, Native American herbal lore, medieval Spanish medicine, witchcraft, modern spiritualism, psychic phenomena, and scientific medicine.

According to the 1991 Council on Scientific Affairs-Hispanic Health in the United States, Hispanic patients may be more likely to perceive their illnesses according to folk practices and to describe their illnesses according to their cultural understanding providing another barrier for appropriate health care.

In Hispanics, the relative frequency of folk medicine practices varies according to the studied group. A prevalence study of folk medical beliefs in a Hispanic patient community in Hartford, Connecticut (Pesky, 1979), revealed that 81% of respondents reported using folk medical remedies during illness, while 72% of respondents indicated use of these remedies prior to presenting to the physician for treatment. Use of folk remedies was strongly related to belief in folk medicine, age of respondent, family unit, education level, immigration, and delay in presenting to the physician for treatment.

Suarez, et al, (1996) recently explored the use of folk healing practices by HIV infected Hispanics in a clinic serving indigent populations in northern New Jersey. Results from the study revealed that 66% of respondents engaged in folk healing (espiritismo, and/or santeria). The main desired outcomes of folk healing included physical relief (44%), spiritual relief (40%), and protection from evil (26%). Additionally, 48% of respondents stated that the spirits had a causal role in their infection (either alone or in conjunction with the virus). The most commonly reported practices included praying (52%). Use of herbs was reported in 18%. However, the study did not include identification of these herbs or inquire about the use of other remedies.

Zaldivar A. & Smolowitz (1994) from the Division of Primary Care of St. Luke's Roosevelt Hospital Center; studied perceptions of the importance placed on religion and folk medicine by non-Mexican American Hispanic adults with diabetes. The group studied was similar to the population served by our clinics (inner-city, primarily minority and Medicaid-insured). Their results revealed that 78% of patients believed they had diabetes because it was God's will: 34% of respondents believed they had an imbalance of "hot" and "cold" elements; and 17% of patients reported using herbs to treat their diabetes. But, once again, the instrument used in this study only included one item regarding folk medicine practices with no identification of the herbs used or inquiring about the use of other remedies.

In summary, controversy still exists regarding the relative frequency of folk medicine practices of Hispanic patients in the general medicine practice. There is no good description regarding the specific practices used; herbs, over the counter preparations and other folk remedies. This is important for future evaluation of their safety and possible interactions with the prescribed medications.

Effect of folk medicine practices in patient's compliance or adherence to the conventional medical treatment is not known. Pachter and Weller (1993) studied acculturation and compliance in mainland Puerto Rican families having a child with asthma. The study showed that degree of acculturation was related to compliance with medical treatment in this population. In the past, less acculturation has been correlated with stronger folk medicine beliefs (Suchman, 1964; Andersen, 1981). Nevertheless, how the use of folk medicine practices may correlate with compliance has not been assessed.
As physicians that serve mostly Hispanic patients, it is important for us to know the community served by this hospital, and learn about their health-belief system.

The goals of this study are to:
(1) Identify folk medicine beliefs and practices of Hispanic patients attending AIM clinics.
(2) Characterize patients involved in these practices.
(3) Investigate possible effects in compliance with prescribed medications.

Long term goals are to better understand the community served by our clinics, identify possible harmful practices, study interactions of most commonly used remedies with the prescribed medication, and obtain physician's perception regarding practices used by their patients.

B. Study Design and Statistical Analysis.

a. Study design: Cross-sectional; Descriptive
A survey conducted in the hospital outpatient population attending Associates in Internal Medicine (AIM) Clinics. This clinic serves an inner-city, primarily minority and medically indigent population. Data will be collected using a questionnaire written in English and Spanish.

b. Subject selection
The questionnaire will be administered to patients attending AIM clinics between September and October 1997. The sample will be selected by limiting eligibility to Hispanic patients, in whom cognitive or physical impairment does not prevent the completion of the questionnaire. In this study, Hispanic will be defined as those patients born in Spanish-speaking countries or whose parent(s) were born in these countries.

According to the reviewed literature the prevalence of mainland Hispanics that practice folk medicine varies from 17-80% (Suarez et al, 1996, Zaldivar & Smolowitz, 1994, Pasky, 1979). In this study, using an estimated prevalence of 40% with a power of 80% and a p-value <0.05, the number of patients necessary for obtaining a representative sample of this population is 80 (n=80). However, it was decided to double the sample to facilitate the process of data analysis (post-stratification).

c. Cross over
None.

d. Randomization
None.

e. Duration of the entire study
The data will be collected during a period of approximately 2 months. The patients' participation, which will include the obtaining of consent and the administration of the questionnaires, has been estimated to be approximately 15 minutes. Additional time will be required to review the patients' hospital and pharmacy records.

f. Repeated measurements
None.

g. Statistical analysis
Data analysis will be carried out using the statistical software: SPSSx (13). Frequency of responses to questionnaire items will be analyzed. Socio-demographic, self-health perception, folk medicine beliefs and practices, and patient's compliance with medical treatment variables will be analyzed by means of cross-tabulations. The choice of a test of significance or measure of association (i.e., chi-square test, Fisher's exact or t-test) will depend in the level at which the two variables employed in the cross-tabulation are measured and the number of cases (Nie N et al, 1975).

C. Description of Study Procedures:

The subjects will be randomly selected from the clinics' daily registration list. The AIM clinics consist of a total of four general medicine clinics run by internal medicine residents and attendings. Each
The clinic has morning and afternoon sessions where patients are seen by appointment. There is also a daily walk-in clinic where patients are seen without appointment in either the morning or afternoon sessions.

We intend to interview ten to fifteen patients per session in different weekdays, alternating morning/afternoon sessions and days per week. For each selected session, we will use the clinics' computerized registration list, from which the first fifteen patients listed as odd number (i.e. patient #1, #3, #5, etc.) will be selected. Of note, the registration list does not identify patients' clinic number, Hispanic descent or if they have a scheduled appointment. To approach these patients, we will go through each clinic looking for the ones selected. An example of the study design for data collection is as follows:

- Week 1: Monday p.m., Wednesday am and p.m.: Total of patients approached: 30.
- Week 2: Tuesday am and p.m., Thursday am: Total of patients approached: 30.
- Week 3: Monday am, Friday am and p.m.: Total of patients approached: 30.
- Week 4: Thursday am and p.m., Friday p.m.: Total of patients approached: 30.
- Week 5: Monday am and p.m., Wednesday p.m.: Total of patients approached: 30.
- Week 6: Wednesday am, Friday am and p.m. Total of patients approached: 30.

The physicians will be first approached by the co-investigator Dr. Maria M. Pesquera who will inform them about the survey and the selection of their patient(s) as possible subject(s). If they agree with their participation, an assigned bilingual interviewer (public health graduate student) will proceed to approach the patient while they are seated in the waiting room. The selected patients will be informed about the survey, and asked about their Hispanic origin. If the patients are Hispanic, according to this study's definition, and agree to participate, they will be asked to sign informed consent. Finally, a questionnaire will be administered in a confidential manner in one of the clinic's rooms.

Hospital records also will be reviewed to look for information regarding the patients' medical problems, medications and insurance status. Pharmacy records from a subset of subjects will also be used to calculate a compliance rate. These will be used after obtaining proper consent.

D. The Questionnaire

A review of the literature failed to provide a previously-tested evaluation tool that addressed every topic of this study. Therefore, a 45 item questionnaire was developed that focuses on the following information:

1. Sociodemographic information including variables indicative of more or less acculturation as previously used by Pachter, (1994).
2. Self-health perception to establish how these patients perceive their health status and degree of concern about their health. Items used will be adapted from the Medical Outcomes Study (MOS) Short-form General Health Survey (Stewart et al, 1988).
3. Compliance with medical treatment. This section will include a series of items focused on self-reported medication-taking. Items will be used from a structured four-item self-reported adherence scale developed and tested by Morisky et al (1986) in hypertensive patients. According to these authors, the positive predictive value of this scale is 0.75, the sensitivity is 0.81 and the specificity is 0.44. The items are questions with Yes or No answers. Scoring will be "High" if the patient answers "Yes" to 0 items; "Medium" if the patient answer "Yes" to 1 or 2 items; and will be "Low" if the patient answers "Yes" to 3 or 4 items.

Validation of this scale in our study group will be done by selecting a subset of subjects who score "High" on the four-item scale versus a subset of subjects who score "Low" and compare these results with the calculated compliance rate obtained by the pharmacy records. For this purposes, we will select patients whose medical record and pharmacy file prescription data indicate that one or more drugs are to be taken on a regular schedule (each day) for at least six months after the original prescription is written (i.e. prescriptions with five refills). A patient's compliance rate for a maximum of three drugs (randomly selected) will be estimated in the following manner:
% of compliance =

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\frac{\text{refills obtained "on time" after date of original prescription}}{5 \text{ possible refills}} \times 100
\]

We will calculate an average from the number of selected drugs. This measure of compliance can assume per cent values depending on the number (0-5) of possible refills a patient obtained during the specified time interval for a single prescription. For validation purposes, 100% compliance will be compared to the self-reported scale high compliance, and less than 60% will be compared to low compliance.

4. Religious, spiritual and folk medicine beliefs. This section will consist in a series of 7 statements. For each one of them, patients will select a response that most accurately reflect their feelings regarding the statement. Answer choices were "yes", "no", or "I don't understand the question". These statements will be adapted from the evaluation tool used in the study "Perceptions of Importance on Religion and Folk Medicine by Non-Mexican-American Hispanic Adults with Diabetes" by Zaldivar and Smolowitz, 1994. Of note, this instrument's content validity was established using the index of content validity (CVI), which was derived from the rating of the content relevance of each item by a panel of experts (Catholic priests trained in Latin American countries, Hispanic certified diabetes educators and a Hispanic physician).

5. Folk Medicine practices. This section will include multiple choice and open-ended questions to identify and describe these practices and reasons for their use.

The instrument was reviewed by CPMC Division of General Medicine's anthropologist, Dr. Linda Weiss. Reliability of this tool will be determined using a pretest period with 20 patients. During this period, we will evaluate time required for completion of the questionnaire and its degree of difficulty. The translation of the questionnaire will be done with the help of members of the community to identify the dialect most commonly used in the region. Moreover, as recommended in the literature (Hendricson et al, 1989), a bilingual individual will be recruited to "back-translate" the instrument from Spanish into English.

E. Study drugs

None.

F. Medical devices.

None.

G. Study questionnaires

See attached copy

H. Study Subjects and Methods of Recruitment.

a. Eligibility criteria

See Section B

b. Exclusion criteria

The focus of this study is to know about folk medicine beliefs/practices of the Hispanic patient population. Thus, all non-Hispanic patients will be excluded from the study.

c. Subject identification and approach

• See section B and C.
• Consistent with CPMC policy, the patient's primary care physician will be first contacted for agreement that the patient is suitable for the study.

d. Subject recruitment
• See Section B.
• The patients will be asked to participate in the clinics, giving them the opportunity to ask questions and to refuse participation. Two written informed consents will be obtained before the interview; the first will indicate that the patient agrees to participate and the second will give permission to review their records (Hospital and Pharmacy).

e. Gender or race restrictions
See Section G2.

I. Confidentiality of Study Data

No names, hospital medical record numbers or other identifying information will be kept in the data set or study forms. Identifying information keyed to the study numbers will be kept by the Principal Investigator in a separate locked file. No subject will be individually identified by name or in any other way in any reports of this research.

J. Location of the Study

The study will be conducted in the Associates in Medicine Clinics located in the second floor of the Vanderbilt building at Columbia Presbyterian Medical Center. The statistical analysis and writing of reports will be done in the Co-investigator's home computer and in the Irving Center of Clinical Research administrative offices located in the 10th floor of Harkness building.

K. Risks and benefits

Physicians will benefit to know about the folk medicine practices used by their patients; By identifying handful practices, subsequent discouragement and replacement can be made; By understanding non-harmful ethologically-based beliefs and practices, physicians may be able to improve compliance with the conventional therapies. By improving compliance, both patient and physician can benefit from a better quality of health care and may control costs.

The risks of the study are minimal in that the study requires only to complete a questionnaire. Since the risks of the study are negligible, we believe the benefits outweigh the risks and possible inconveniences to participants enrolled in this investigation.

L. Alternative Therapies

None.

M. Compensation and Costs to Subjects

None.

N. Minors and Research Subjects

No minors.

O. Radiation or Radioactive Substances

None.
P. References