

FINAL REPORT

TITLE

Establishing Herbal Counseling Center in a Community
Pharmacy on Patients' Outcome

PRINCIPAL INVESTIGATOR:

Bisrat Hailemeskel, Pharm.D., M.S. Assistant Professor,
School of Pharmacy, Howard University

FUNDING AGENCY:

The NCPA Foundation Research Grant Program
(October 1999)

REPORT DATE:

April 19, 2001

FINAL REPORT

There were two phases of this study. Phase I of this project includes conducting and analysis of survey questionnaires to determine knowledge and attitude of pharmacists towards herbal products and Phase II of the study was to determine the impact of establishing an herbal center in a community pharmacy on patients' outcome.

PHASE I:

The primary focus of phase I of this project was to determine the knowledge and attitude of pharmacists towards herbal products through conducting a survey. A booth was set up at the 1999 NCPA Annual Meeting and prospective pharmacists were asked to complete a questionnaire. A 1999 pocket-sized pharmacopoeia was given to each participant to compensate him or her for his or her time and participation in the study. The questionnaire was separated into 3 sections: demographics, training and knowledge. In the demographics sections, participants were asked to provide information regarding their gender, age, race, academic background, years in practice as a pharmacist, and practice type. The training section was measured by asking respondents if they had any specific courses or training in herbal products and whether such exposure was helpful in dealing with issues pertaining to herbal products. The attitude portion asked pharmacists their opinions and perceived value of herbal therapies. The choices followed a 5-point Likert scale ranging from "strongly agree" to "strongly disagree".

ACCOMPLISHMENTS UNDER PHASE I.

- ◆ A total of 124 community pharmacists completed the survey at the 1999 NCPA National Meeting.
- ◆ The initial goal of the project was to study the opinion and knowledge of the community pharmacists regarding herbal products. However, once the data was collected it was necessary to compare the data obtained from the community pharmacists with other fellow pharmacists or at least other health care professionals. Therefore, two more surveys were conducted.
- ◆ In a second survey, a total of 151 hospital pharmacists completed a similar questionnaire.
- ◆ In a third survey conducted in a community hospital, a total of 100 nurses completed the survey questionnaire.

PUBLICATIONS:

- ◆ Data analysis is completed and a journal article entitled "A survey of knowledge and attitude of COMMUNITY versus HOSPITAL pharmacists towards herbal products" is under preparation to be submitted to *America's Pharmacist* for publication.
- ◆ An ABSTRACT entitled "A survey of knowledge and attitude of community vs hospital pharmacists towards herbal products" was presented at the ASHP to be presented at Midyear Clinical Meeting, December 2000.
- ◆ Data analysis was completed to determine the difference in opinion or/and knowledge of NURSES versus PHARMACISTS towards herbal products" and submitted to *America's Pharmacist* for publication.

PHASE II:

The focus of this phase was to determine the impact of establishing a pilot herbal-counseling centre in community pharmacy on patients' outcome. Three abstracts in the form of posters (Microsoft PowerPoint files) are attached along with this report. However, the results of the study are summarized below.

An Institutional Review Board (IRB) document was approved by the Howard University IRB (#IRB-00-PNAH-07). This pilot project was conducted by School of Pharmacy, Howard University in collaboration with Grubb's Care Pharmacy. Grubb's Pharmacy is an independent pharmacy servicing the Washington, DC area community for over 100 years and provides a wide range of services and products.

A senior doctor pharmacy student who had previous training on herbals and has shown interest in the area of herbal medicine was recruited for the project. An advertisement was displayed throughout the pharmacy regarding the availability of the services. Patients who came to the pharmacy to fill their prescription were informed about the service. Those who showed

interest in the program were asked to complete herbal product use history while waiting for their prescription. A pharmacist (or a senior pharmacy student) reviewed the information provided by patients. The computer software program published by the JAG Group, PDR for Herbal Medicine, and Review of Natural Products by Facts and Comparison were used as references.

The pharmacist or the senior pharmacy student screened for potential herb-drug or herb-disease interactions, potential adverse reactions and provided complete counselling to the patient on their herbal use in integration with their prescription.

RESEARCH COMPLETED UNDER PHASE II:

- ◆ Patient enrolment for the study started on February 2001 and ended at the end of March 2001.
- ◆ A total of 40 patients enrolled in the study (57.5% males and 42.5% females).
- ◆ Level of education of the participants was directly related to the consumption of herbal products. Participants with less than 12th grade education said they were taking significantly lower number of herbals compared to their counterparts (5.9% vs 94.1%; $p=0.000$).
- ◆ Fifty-five percent were taking three or less herbal products and 47.5% were taking some type of vitamin supplement. Over half of the participants (57.5%) were taking herbals along with prescription medications ($p=0.001$). All of those who take 3 or more herbal products were also on vitamin supplement.
- ◆ The patients were also on a varied class of drugs: 50% of them were on drugs for cardiovascular system, 37% were on drugs for central nervous system, 35.0% were on antibiotics and/or antiretrovirals, and 22.5% were on GI drugs.
- ◆ Many of the patients (77.5%) had a previous counseling experience while only 22.5% had never received counseling before.
- ◆ Those who said they had previous counseling tend to take more herbals than those said they did not. Forty percent of those with previous counseling said that they were on 4 or more herbal products versus 5% of those without ($p=0.04$). However, no effort was done in this study to determine the type or the level of counseling the patients received.

Three outcome measurements were identified to determine the value of this project. The outcome variables and the results are summarized below.

I. Patient Satisfaction with Herbal Counseling Services at A Community Pharmacy

- ◆ At the end of counseling session, the participants were asked to complete to evaluate the counseling session. A significant percentage of patients (97.5%) said they were satisfied with the counseling and the interaction they had with the pharmacist. Only 2.5% of them were not sure and none of the patients disagreed with it.
- ◆ An interesting finding; however, was that there was a direct relationship between the number of herbals one is taking and whether the patient is to be on a prescription drug for the management of gastrointestinal (GI) related diseases (such as antacids, H₂ antagonists, and or/and proton pump inhibitor). All of those who were taking 4 or more herbal products were also taking at least one prescription medication for GI-related diseases versus only 5.9% of those who were not taking any herbal product ($p=0.002$).

II. Impact of Herbal Counseling Services at A Community Pharmacy on Patient Knowledge

- ◆ Patients were tested on their knowledge of herbal products both before and after counseling. A list of six commonly used herbs was given and patients were asked to write at least one indication for each herb. The same test was repeated after counseling. Forty-seven percent scored 50% or less correctly prior to counseling. This number was significantly increased after counseling to almost 100% on the post-test.
- ◆ Pre and posttest questions were also administered to determine the overall knowledge of the participants on safety of the herbals and proper use of herbs. The scores were graded out of 10. Patient counseling significantly improved their overall knowledge. Fifty-five percent scored at least 5 questions correctly on the pretest whereas the percentage increased to 90% when the same test was repeated after counseling ($p=0.000$).
- ◆ The patients were also asked about the overall safety of herbals. Prior to counseling only 10% of patients said that herbals are not safe. However, almost two-thirds (65%) said that herbs are not safe after the counseling.

III. Patient Willingness to Pay for Herbal Counseling Services at A Community Pharmacy

- ◆ Participants were asked if they are willing to pay for similar future counseling session with a pharmacist on herbal products. Seventy percent of the patients were willing to pay up to \$30 for future counseling sessions of similar nature and 15% said they are willing to pay over \$60.
- ◆ A significantly higher number of those who had previous experience were willing to pay for future counseling sessions. About one-third (38.7%) of those with previous counseling experience said they will pay at least \$30 or more while none of the patients with no previous counseling were willing to pay over \$30 ($p=0.018$).

The National Community Pharmacy Association Foundation through the Research Grant Program funded this pilot project. For any questions or comment, please do not hesitate to call the principal investigator, Dr. Bisrat Hailemeskel at (202) 806-4214; e-mail :
bhailemeskel@howard.edu.

Principal Investigator: Dr. Bisrat Hailemeskel, Assistant Professor, School of Pharmacy, Howard University.
Impact of Establishing Herbal Counseling Center in a Community Pharmacy on Patients' outcome.
Funded by the National Community Pharmacy Association Foundation

April 19, 2001

B. Douglas Hoey, R.Ph., M.B.A.
NCPA Foundation
205 Daingerfield Road
Alexander, VA 22314-2885

Dear Mr. Douglas Hoey,

Please find the enclosed interim report on the project funded by NCPA Foundation entitled "Establishing Herbal Center in a Community Pharmacy". A summary of the findings of the study with three posters presentations was attached.

I would like to thank you and the members of the NCPA Foundation to allow me to conduct this project by providing me the funding needed through the Research Grant Program. I am looking forward to continue to work with you on future projects.

For any questions or comment, please do not hesitate to call me at (202) 806-4214 or e-mail me at: bhailemeskel@howard.edu.

Thank you,

Bisrat Hailemeskel, Pharm.D., M.S.
Assistant Professor

Principal Investigator: Dr. Bisrat Hailemeskel, Assistant Professor, School of Pharmacy, Howard University.
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Funded by the National Community Pharmacy Association Foundation

INTERIM REPORT

TITLE

Establishing Herbal Counseling Center in a Community Pharmacy: Its
Impact on Patient Care and Sales.

PRINCIPLE INVESTIGATOR:

Bisrat Hailemeskel, Pharm.D., M.S. Assistant Professor,
Howard University

FUNDING AGENCY:

The NCPA Foundation Research Grant Program
(October 1999)

REPORT DATE:

July 19, 2000

ACCOMPLISHMENTS

PHASE I:

Phase I of this project includes conducting and analysis of survey questionnaires to determine knowledge and attitude of pharmacists towards herbal products. A booth was set up at 1999 NCPA Annual Meeting and prospective pharmacists were asked to complete a questionnaire. A 1999 pocket-sized pharmacopoeia was given to each participant in order to compensate him or her for their time and participation in the study. The questionnaire was separated into 3 sections: demographics, training and knowledge. In the demographics sections, participants were asked to provide information regarding their gender, age, race, academic background, years in practice as a pharmacist, and practice type. The training section was measured by asking respondents if they had any specific courses or training in herbal medicine and whether such exposure was helpful in dealing with issues pertaining to herbal medicine. The attitude portion asked pharmacists their opinions and perceived value of herbal therapies. The choices followed a 5-point Likert scale ranging from "strongly agree" to "strongly disagree".

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- ◆ An ABSTRACT entitled "A survey of knowledge and attitude of community vs hospital pharmacists towards herbal products" was sent to ASHP to be presented at Midyear Clinical Meeting in December 2000.
- ◆ Data analysis is underway to determine if there is any difference in opinion or/and knowledge of NURSES versus PHARMACISTS towards herbal products." When the data analysis is completed, it will be submitted to *America's Pharmacist*.

PHASE II:

Phase II was designed to determine the impact of establishing a centre on the overall sales of the store particularly on herbal sales and the number of new and refill prescriptions. Because this phase of the project involves human subjects, an Institutional Review Board approval was necessary.

RESEARCH COMPLETED UNDER PHASE II:

- ◆ An Institutional Review Board (IRB) document was prepared and submitted to Howard University IRB (#IRB-00-PNAH-07) for their approval on March 17, 2000. A reply from the IRB dated June 8, 2000 was just received. I am in the process of resubmitting the proposal with the recommended changes hopefully for a final consideration. Depending on the response from the IRB, phase II project might be initiated in September or October of 2000.
- ◆ An independent pharmacy is identified, contacted, and agreed to work with us on the project.

I would like to thank the NCPA Foundation again to allow me to conduct this project by providing me the funding needed through the Research Grant Program. I am looking forward to continue to work with the Foundation on this project and a final report will be submitted as soon as the research is completed. For any questions or comment, please do not hesitate to call me at (202) 806-4214; e-mail me at: bhailemeskel@howard.edu.

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July 19, 2000

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I would like to thank you and the members of the NCPA Foundation to allow me to conduct this project by providing me the funding needed through the Research Grant Program. I am looking forward to continue to work with you on this project or future projects. A final report will be submitted as soon as the project is completed.

For any questions or comment, please do not hesitate to call me at (202) 806-4214 or e-mail me at: bhailemeskel@howard.edu.

Thank you,

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Herbs and phytomedicinals are one of the top growth categories in drug stores. Analysts predict sales of such products could surpass \$12.5 billion by the start of the next century. Almost 70% of Americans now turn to alternative forms of medicine or therapy to cure various illnesses when regular medicine has failed. Patients who take herbal medicine do so because of the belief that herbs are natural and safe, whereas synthetic substances are harmful. The main sources of supply of herbal products in the United States are health food stores where there are no qualified personnel to advise on health problems on the potential problems with the use of these products, and this could lead to negative health consequences. Health store personnel who work in herbal drug stores are not trained as a herbalists.

The objective of this project is three-fold. First, to study the impact of providing pharmaceutical care service through establishing a pilot herbal center in a community pharmacy on patient knowledge and satisfaction. Second, to determine the impact of an establishment of such center on the overall pharmacy sales particularly on the sales of herbal medications and on the number of new and refill prescriptions. Third, to determine the level of interest of the pharmacists and pharmacy students who participated in the counseling session towards future similar activities. Patients with 5 or more medications and at least 18 years of age will be recruited from a community pharmacy for the study and provided with individualized counseling on drug-nutrient, drug-herb, and herb-disease interactions. The project will provide a pilot data on the impact of pharmaceutical care on patient care and satisfaction.

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<TI> Survey of pharmacists' attitude towards herbal medicine

<AU> Edirisinghe, T.K.

<AA> School of Pharmacy, College of Pharmacy, Nursing and Allied Health Sciences, Howard University, 2300 4th Street, NW, Washington, D.C. 20059, USA Internet: bhailemeskel@howard.edu

<AU> Hailemeskel, B.

<DT> Abstract of Meeting Presentation

<JA> ASHP Midyear Clinical Meeting

<JV> 34

<JP>

<JI> Dec

<PY> 1999

<LA> English

<AB> The increasing use of herbal supplements by the public place pharmacists in an excellent position to offer advice and discuss the risks and benefits pertaining to herbal products. Since herbal remedies present problems in terms of their quality, safety and efficacy, drug interactions and adverse reactions, it is imperative that pharmacists have the necessary knowledge to properly address these issues. A national survey will be conducted at an ASHP hosted annual meeting in order to assess the level of training of pharmacists on herbal therapies as well as their perceptions toward it. The results of this survey will be used to ascertain the need for more education and training for pharmacists in the area of herbal medicine.

Rationale:

Use of herbal treatments by the public is increasing yearly¹. An increased health consciousness accounts for the increased public interest in herbal therapy. Although conventional medications have been extremely successful in treating many disorders, they have not cured all diseases, especially cancer, cardiovascular and neurodegenerative diseases². Also, emphasis has shifted more toward disease prevention than treatment². For these and other reasons, more Americans are turning towards herbal remedies. Patients who take herbal medicine do so because of the belief that herbs, because they are natural, are safe, whereas synthetic substances are harmful³.

Due to the lack of regulation of herbal products by the FDA, many concerns arise regarding their quality, safety and efficacy. The dosages and purity level can vary widely among manufacturers⁴. In addition, many herbal products are mislabeled and/or contain different plants than those indicated on the label². This leads to a lack of standardization such that consumers can't be certain that sufficient active ingredients are present in a product to be therapeutically useful². Because herbal remedies have been used for centuries, the view is often expressed that they must be safe and efficacious³. However, for the majority of herbal medicines, there is no evidence for this belief. Herbal medicine can only be evaluated from subjective assessments whereas conventional medicine requires objective research before they can be manufactured, sold and supplied to the public³. Also, a number of herbs are capable of causing adverse reactions or drug interactions.

Thus, herbal remedies can present many problems in terms of their quality, safety and efficacy, drug interactions and adverse reactions. The vast majority of people are not familiar enough with herbs to be developing their own care regimen⁴. The effectiveness of a given herbal preparation strongly depends on its proper usage and the correct diagnosis of the patient². A potential danger arises from self-diagnosis and treatment since herbal preparations are easily available and many patients are restricted only by cost rather than the need for professional opinion². In addition, most of these herbal products are sold in health food shops where there are no qualified personnel to advise

patients on the potential problems with the use of these products, and this could lead to negative health consequences³.

Since plant products are medicines, pharmacists have an opportunity to assume a high-profile role in the delivery of herbs to consumers, and they are in a position to advise patients on the use of herbal medicines³. Consumers need a pharmacist's knowledge in helping them select the best quality products and counsel in how to use them². Unfortunately, there is a lack of training in the area of herbal medicine in pharmacy schools². A situation has developed where consumer interest in alternative herbal therapy is expanding rapidly and today's newly trained pharmacists lack the knowledge to be able to effectively advise the public². Educating consumers is the greatest and most immediate challenge to pharmacists to ensure that people use herbs properly and engage in successful therapies⁴. Therefore, it is imperative that pharmacists have the necessary education to provide adequate advice to consumers of herbal medications. This is a health care responsibility that the profession cannot and must not ignore.

Objective:

Due to the increasing use of herbal remedies in the US, a survey will be conducted at an ASHP hosted annual meeting to assess the extent of the level of training and attitude towards herbal medicine by pharmacists.

Methods:

The survey sample will be taken from participants at an ASHP annual meeting. A booth will be set up on each of 3 days and prospective pharmacists will be asked to complete a questionnaire. We will attempt to collect a minimum of 100 volunteers to fill out the survey. A 1999 pocket-sized pharmacopoeia will be given to each participant in order to compensate them for their time and participation in the study.

The questionnaire will be separated into 3 sections: demographics, training and knowledge. In the demographics sections, participants will be asked to provide information regarding their gender, age, race, academic background, years in practice as a pharmacist, and practice type. The training section will be measured by asking respondents if they had any specific courses or training in herbal medicine and whether such exposure was helpful in dealing with issues pertaining to herbal medicine. The attitude portion will ask pharmacists their opinions and perceived value of herbal therapies. The choices will follow a 5-point Likert scale ranging from "strongly agree" to "strongly disagree".

The results of the questionnaire will be tabulated and evaluated using statistical software package SPSS/PC. Frequency analysis, cross-tabulations, and Chi-square analyses will be conducted.

Implications:

The increasing use of herbal therapies in the US has necessitated the need for pharmacists to prepare themselves with knowledge on the uses and adverse effects of herbal remedies. Questions regarding herbal medicine must be included when asking customers about their drug-taking history. Assessing pharmacists' attitudes toward herbal therapies will give insight into the areas that will require more instruction or teaching. The results of this study will be used to ascertain the need for more research and education on

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herbal medicine so that pharmacists can become more knowledgeable and thus be able to give guidance about how patients' choices may affect their healthcare.

References:

1. Cirigliano M, Sun A. Advising patients about herbal therapies. *J Am Med Assoc.* 1998; 280: 1565-1566. Letter.
2. Combest WL, Nemezc G. Herbal remedies in the pharmacy. *US Pharm.* 1997; 22: 50, 52, 55-56, 59.
3. Anderson LA, Phillipson JD, Herbal medicine, education and the pharmacist. *Pharm J.* 1986; 236: 303-305, 311.
4. Heller A. Herbs & pharmacy: natural alliance. *Pharm Times.* 1996; 62: 75-76, 79.

SURVEY OF PHARMACISTS' ATTITUDE TOWARDS HERBAL MEDICINE

Abstract:

The increasing use of herbal supplements by the public place pharmacists in an excellent position to offer advice and discuss the risks and benefits pertaining to herbal products. Since herbal remedies present problems in terms of their quality, safety and efficacy, drug interactions and adverse reactions, it is imperative that pharmacists have the necessary knowledge to properly address these issues. A national survey will be conducted at an ASHP hosted annual meeting in order to assess the level of training of pharmacists on herbal therapies as well as their perceptions toward it. The results of this survey will be used to ascertain the need for more education and training for pharmacists in the area of herbal medicine.

Rationale:

Use of herbal treatments by the public is increasing yearly¹. An increased health consciousness accounts for the increased public interest in herbal therapy. Although conventional medications have been extremely successful in treating many disorders, they have not cured all diseases, especially cancer, cardiovascular and neurodegenerative diseases². Also, emphasis has shifted more toward disease prevention than treatment². For these and other reasons, more Americans are turning towards herbal remedies. Patients who take herbal medicine do so because of the belief that herbs, because they are natural, are safe, whereas synthetic substances are harmful³.

Due to the lack of regulation of herbal products by the FDA, many concerns arise regarding their quality, safety and efficacy. The dosages and purity level can vary widely among manufacturers⁴. In addition, many herbal products are mislabeled and/or contain different plants than those indicated on the label². This leads to a lack of standardization such that consumers can't be certain that sufficient active ingredients are present in a product to be therapeutically useful². Because herbal remedies have been used for centuries, the view is often expressed that they must be safe and efficacious³. However, for the majority of herbal medicines, there is no evidence for this belief. Herbal medicine can only be evaluated from subjective assessments whereas conventional medicine requires objective research before they can be manufactured, sold and supplied to the public³. Also, a number of herbs are capable of causing adverse reactions or drug interactions.

Thus, herbal remedies can present many problems in terms of their quality, safety and efficacy, drug interactions and adverse reactions. The vast majority of people are not familiar enough with herbs to be developing their own care regimen⁴. The effectiveness of a given herbal preparation strongly depends on its proper usage and the correct diagnosis of the patient². A potential danger arises from self-diagnosis and treatment since herbal preparations are easily available and many patients are restricted only by cost rather than the need for professional opinion². In addition, most of these herbal products are sold in health food shops where there are no qualified personnel to advise patients on the potential problems with the use of these products, and this could lead to negative health consequences³.

Since plant products are medicines, pharmacists have an opportunity to assume a high-profile role in the delivery of herbs to consumers, and they are in a position to advise patients on the use of herbal medicines³. Consumers need a pharmacist's knowledge in helping them select the best quality products and counsel in how to use them². Unfortunately, there is a lack of training in the area of herbal medicine in pharmacy schools². A situation has developed where consumer interest in alternative herbal therapy is expanding rapidly and today's newly trained pharmacists lack the knowledge to be able to effectively advise the public². Educating consumers is the greatest and most immediate challenge to pharmacists to ensure that people use herbs properly and engage in successful therapies⁴. Therefore, it is imperative that pharmacists

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Implications:

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