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TITLE: Effects of Alternative Decision Support Technologies on Breast Cancer Patients' Knowledge of Options and Satisfaction with Treatment Decisions

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13. Abstract (Maximum 200 Words) (abstract should contain no proprietary or confidential information)
The objectives of the research are to (1) develop an innovative computer-based decision support (CDSS) that will enable women with breast cancer to integrate the information available to them, understand diagnoses, treatment options and risks associated with treatment options, construct and structure their preferences, and make important health decisions; and (2) assess the impact of the new CDSS by making it available to women newly diagnosed with breast cancer and comparing it with two other existing technologies and a control group in a carefully designed experiment. The assessment of the impact will be made in terms of understanding of diagnoses, treatment options and risks associated with treatment options, satisfaction with decision made, amount of involvement in decision, compliance with decision, change in health status, and change in quality of life.

This report describes the progress made to further enhance and update the CHES system. The study design and protocol are described as well as the survey data collection process, and the recruitment process. Preliminary survey data results and use data results are reported.

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(5) Introduction:

The objectives of the proposed research are to (1) develop an innovative CDSS that will enable women to integrate the information available to them, understand diagnoses, treatment options, and risks associated with treatment options, construct and structure their preferences, and make important health decisions; and (2) assess the impact of the new CDSS by making it available to women newly diagnosed with breast cancer and comparing it with two other existing technologies and a control group in a carefully designed experiment. The assessment of the impact will be made in terms of understanding of diagnoses, treatment options, and risks associated with treatment options, satisfaction with decisions made, amount of involvement in decision, compliance with decision, change in health status and change in quality of life.

Specifically, we will compare three types of decision support technologies to a control group:

1. CHES: a new CDSS designed specifically to meet breast cancer patients' needs;
2. Internet: the rapidly proliferating Internet technology;
3. Audio Tapes: an audiotape series produced by the National Coalition for Cancer Survivorship called Cancer Survivor Toolbox. This self-learning audio program is designed to assist patients diagnosed with breast cancer from the time of diagnosis through the rest of their life.
4. Control: standard patient education and any of the following books: Dr. Susan Love's Breast Book, Celebrate Life (a book on breast cancer aimed specifically at an African American population), and Breast Cancer? Let Me Check My Schedule.

(6) Body:

- Statement of Work Task 1
Development and testing of CHES enhancements (Months 1-15)
Develop and test new decision aid and demonstration program.

Accomplished in Year 1 (see previous report)

- Statement of Work Task 2
Acquire and Prepare Equipment (Months 9-12)

Accomplished in Year 1 (see previous report)

- Statement of Work Task 3

Refine research materials (Months 8-10)

Modify CHES user manual to reflect the CHES enhancements.

Develop user manuals for the Internet technology.

Develop and pilot test data collection forms.

Accomplished in Year 1 (see previous report)

- Statement of Work Task 4

Train staff from sites (Months 13-15)

Train site coordinators in study goals and rationale, subject identification and accrual, data collection, Internet installation and operation, and support for the video. Sites are previously trained in CHES installation and operation but will be updated for CHES enhancements.

Deliver materials to sites describing the project and conduct field tests of recruitment and study operation

The sites involved in this grant include University of Wisconsin Comprehensive Cancer Center (Madison, Wisconsin), Mayo Cancer Center (Rochester, Minnesota), University of Wisconsin – Milwaukee School of Nursing (Milwaukee, Wisconsin). One of the goals of the study is to recruit 100 African American participants. We did not get the number of African American participants that we expected from the University of Wisconsin - Milwaukee School of Nursing and therefore have added Wayne State University in Detroit Michigan as a recruitment site.

All of the sites have had site visitations from Dr. Gustafson and/or Dr. Sainfort. Ms. McTavish (the Project Director) followed up the visits by Dr. Gustafson and Dr. Sainfort with training sessions with each site coordinator. This included step by step review of the protocol (see Year 2 Annual Report Appendix #1) from recruiting study participants, the randomization process, installing computers (or other interventions), in home training of study participants in use of the Internet and CHES, setting up Internet Service Providers, documentation necessary for each study participant, removing computers, use data collection, as well as general study protocol.

- Statement of Work Task 5

Recruit subjects, pre-test, assign and install (Months 16-30)

15 months after funding we will begin recruiting subjects, pre-testing, randomizing for the 4 groups, and installing software and Web TVs (note: As described in Year 1 annual report – Laptop computers were used instead of Web TVs.

To date there are 314 participants on study. We had projected that we would have 400 subjects in study by this time. The major reason for our deficit in recruitment is due to the difficulty of recruiting African American women. Our initial site, UW – Milwaukee School of Nursing found it much more difficult to reach African American women than they expected. As a result we added Wayne State University in Detroit, Michigan as a recruitment site. Recruitment at this site is exclusively African American women.

- Statement of Work Task 6
Operate CHESS (Months 16-34)

Our first study participants were using CHESS beginning in July 1999. All study participants who are randomized to the CHESS group, or the Internet receive a laptop computer, basic Internet training as well as how to search the Internet. For those in the CHESS arm of the study they also are trained on navigating within the CHESS site. A toll free number for technical assistance as well as a toll free line for inquiries for all arms of the study have been supported since July 1999. As described in the grant, a trained facilitator oversees the CHESS discussion group to make sure that erroneous information is not transmitted. In addition all questions submitted to the Ask an Expert service of CHESS have been answered within two business days.

Along with the daily operational tasks to keep CHESS running smoothly, continual development and updating of the material in CHESS was and continues to be a focus of our work. An extensive review and update of all the CHESS informational services in the breast cancer module was completed within the last 2 months. This review and updating included the following CHESS services: Questions and Answers, Instant Library, Consumer Guide, Resource Directory, WebLinks, and Decision Notebook, Learning from Others, and Video Gallery. Over 3,000 pages of content was reviewed and updated.

As a result of focus groups and user feedback we also redesigned CHESS to make it more user friendly and easier to access information. Navigation of CHESS is now topic oriented (e.g. Surgery, Chemotherapy, Radiation,) as opposed to services oriented (e.g. Questions and Answers, Instant Library). In addition to the redesign we developed an online tutorial of how to most effectively use CHESS. Again user feedback suggested that additional training would be valuable especially for those who have little or no computer experience. The online tutorial allows users to quickly and easily receive help specific to where they are in the CHESS system.

- Statement of Work Task 7
Collect Post-test data (Months 16-39)

Short form (1 page) decision surveys will be sent at weeks 2,4,6,8,and 10. Longer form surveys will be sent to study participants at months 4 and 9. All surveys will be returned to the Madison Project Office.

Returns will be closely monitored to be sure the surveys are promptly returned and complete. Follow-up contacts (including interviews, if needed) will collect surveys not returned and fill in incomplete or illegible data.

We have continued to send out surveys, receive completed surveys, monitor survey return rates, and make telephone follow-up contact as necessary. Three days after a survey is sent out the study participant is called to make sure she received the survey and encourage her to fill it out as soon as possible. To date our survey return rate is at 92%. If the survey does not come back within one week from the date it is sent out, a follow up phone call is made to remind the participant that we are waiting for their survey. If the survey does not arrive within 2 weeks of

the date it is sent we call one last time and attempt to fill out the survey over the phone with the participant. If the study participant is unwilling to do this, or we are not able to reach the study participant we send a duplicate survey along with a letter explaining that their survey data is critical to the research. If they do not return that survey no further follow up attempts are made. Our success rate of completed surveys is extremely high (92%) and we will continue to follow the protocol outlined above throughout the study.

- Statement of Work Task 8

Remove computers (Months 20-34)

Computers will be collected from users after four months in the home.

Each study participant who is randomized into the CHESS or the Internet arm of the study is given a computer with Internet access for five months. The original proposal recommended access for four months. However after having focus groups and reviewing our past research access was increased by one month in order to allow women access to the Internet and/or CHESS throughout the majority of their treatment for breast cancer. The computers are collected at the five-month mark and Internet access is canceled at that time. The computers are cleaned, tested and put back in the file for use by other study participants.

- Statement of Work Task 9

Prepare the data for analysis (Months 17-40)

Survey data is prepared for analysis upon receipt of the survey. The project director (Ms. McTavish) reviews each survey within two days of receiving the survey to make sure all questions are answered and to determine if any answers need clarification. If there are questions or clarification is necessary a project assistant calls the study participant and clarifies the answer in question. If a portion of the survey has been skipped, that section of the survey will be duplicated and sent back to the study participant with a note asking them to fill out the marked portions.

The majority of surveys completed by study participants do not need further clarification and are added directly to our SPSS survey database by a student. Once the student has entered the data it is double-checked by a research assistant.

- Statement of Work Task 10

Conduct Secondary Analyses (Months 20-36)

Begin baseline and secondary analyses.

Describe the study population and examine similarities and differences of the 4 groups.

Exploratory analyses will begin with this initial data set.

Baseline and secondary analysis has been ongoing through out this period, both in terms of survey data analysis and computer use analysis. We will begin this section by describing the study population of 262 study participants who have completed the two-month survey. We will then discuss the exploratory analyses we have done to date.

Study Population:

The age range for the 262 participants who have completed the two-month survey at the time of this analysis is 26 to 80 years old with the mean age being 52 years old. The mean age range for the four interventions differ by 4 years; CHESS; 50 years old (range: 26-79), Internet Only; 52 years old (range: 27-80), Books; 52 years old (range: 28-77), and Audio-tapes; 54 years old (range: 26-76).

A total of 3% of study participants reported do not have any health insurance (2% from the CHESS group, 1% from the Internet Only group). In the CHESS intervention 23% of the women live alone compared to 21% in Audio, 19% in Internet Only, and 14% in the Books arm of the study. CHESS has the highest percentage of study participants with less than a high school education (7%), while 4% of Internet Only, 3% of Audio, and 0% of the Books arm of the study have less than a high school education. However, the CHESS intervention has the highest number of participants with a 4-year degree (CHESS 26%, Internet Only 21%, Audio 23%, and Books 11%). While the Books group has the least amount of formal education, they have the highest percentage of study participants making over \$40,000 per year (Books 70%, CHESS 64%, Audio 61%, and Internet Only 57%).

The book group appears to be the most knowledgeable about the stage of their cancer. Only 6% of the study participants in the Books intervention did not know the stage of their cancer at the time they filled out the two-month survey. 26% of the Audio participants did not know the stage of their cancer, compared to 17% of the Internet Only group and 12% of the CHESS group. 83% of the Audio group reported having early stage breast cancer, compared to 78% of CHESS, 71% of Internet Only, and 70% of the study participants in the Books intervention.

CHESS and Internet UseData:

The browser that we designed for this study allows us to track in detail a study participant's use of the Internet as well as use of the CHESS system (if they are randomized into that condition). We have looked at the use data of 145 users randomized into either of the computer interventions, CHESS or Internet Only. CHESS participants averaged 49 logins (approximately 2 logins per week over the five-month period). The Internet Only group averaged 34 logins (approximately 1.36 logins per week over the five-month period). The mean total minutes of uses for the CHESS group is 1114 minutes while the mean minutes of use for the Internet is 944 minutes. There is no significant difference in mean minutes of use between CHESS and the Internet group. However there is a significant difference in the type of use ($\alpha > .001$). CHESS users have a mean of 718 minutes of total health related use; the Internet Only group has a mean

of 149 minutes of use. In essence for every minute of health use of the Internet Only group, the CHES group has 4.8 minutes of health use.

We have also done some preliminary data analysis on how those who are randomized to the CHES arm of the study are using CHES. We are analyzing this use data in several ways. Traditionally we have looked at use data by the CHES service (e.g. Discussion Group, Questions and Answers, Instant Library). It is important however to understand the type of information a study participant is looking at, so we have analyzed the use data by topic also.

As seen in Figure 1, Questions and Answers was used by 64% of the CHES study participants, followed by Personal Stories (63%), Discussion Group and Ask an Expert (59% each), Decision Notebook and Video Gallery (49% each). We also analyzed the total amount of time spent in the various CHES services (see Figure 2). Discussion Group is the most frequently used service in terms of time with over 527 hours of use over a 5-month period. Discussion group by its nature encourages people to come back and follow the conversations over time. Almost all other CHES services use drops over time. We would expect this, as once someone finds the information they are searching for, they do not need to return to that information. For instance once a person learns about what a mastectomy is, they aren't likely to go back to that information. Ask an Expert is the second most frequently used service with a total of 36 hours of use over 5 months. This is followed by Personal Stories (32 hours), Journaling (24 hours) Questions and Answers (15 hours), and Instant Library (12 hours).

Discussion Group is the most frequently accessed service in CHES. It was accessed 39,616 times in a 5 month period. Figure 3 shows number of accesses of the rest of the CHES services (excluding Discussion Group). As one can see, Ask an Expert is the most highly accessed service (after Discussion Group) with 3,079 accesses over a 5 month period. This is followed by Questions and Answers (1,663), Personal Stories (1250 times), Instant Library (899 times), Decision Notebook (812), and Video Gallery (638). Figure 4 looks at percentage of users that accessed categories of information (e.g. Skills Building Services, Information Services and Support Services). Figures 6 and 7 look at the number of topics accessed and how that changes over time. As these data indicate, the analysis of use data is a complex process.

In addition to looking simply at the amount of time, number of accesses to a service or topic, and the percentage of participants using a service, we have done some case studies to see if use patterns are centered around critical incidents (e.g. having surgery, beginning chemotherapy treatment). It is too early to draw any conclusions at this point, but we will continue to investigate this line of research to get a clearer understanding of how women use CHES throughout their treatment for breast cancer.

Survey Data:

Summary of Decision Making Findings To Date:

Consistent with our preliminary findings last year, the number of treatment decisions considered by women with breast cancer decreased significantly from the 2-week post-intervention point to 2 months post-intervention from a mean of 3.5 (sd. 3.0) to a mean of 1.2 (sd 1.6). This decrease was not significantly different across the intervention groups. At 2-weeks post-intervention, over 80% of the subjects reported having at least one treatment decision under consideration whereas by 2-months post intervention, this percentage had dropped to 49%. This highlights the need for providing timely decision support. 14% of the women on study received the intervention prior to surgery. Our recruitment staff worked diligently to recruit participants to study prior to initial treatment; however the short time period between initial diagnosis date and surgical intervention has remained a barrier to earlier intervention. The remaining 86% of the study participants were evenly distributed between women who had had at least one surgery but had not started chemotherapy or radiation and those who had had surgery and/or started either chemotherapy or radiation.

Similar to treatment decisions, the number of women indicating that they were considering non-treatment decisions decreased from 77% at 2 weeks post-intervention to 51% at 2 months. Two of the three most frequently cited non-treatment decisions also changed over time:

Most Frequently Cited Non-Treatment Decisions:

2-weeks post intervention: Who/what to tell family, friends, coworkers (26%)
 Whether to quit work or go back to work (18%)
 Whether to seek a second opinion (15%)

2-months post intervention: Whether to go to a support group (20%)
 Whether to quit work or go back to work (17%)
 Who to be around (16%)

After eliciting the various treatment decisions under consideration, the next question that study participants were asked about decision-making addressed their desire for participation in treatment decisions. Over the course of 2 months, the majority (75%) of women's desire for participation remained constant with approximately 40% preferring to make treatment decisions themselves while 60% preferred to make decisions with their doctor or for their doctors to make treatment decisions for them. Of the women whose desire for participation changed over time, switch from all four groups is away from making their own decisions toward desiring physician involvement .

Initial desire for participation in decisions (at 2 weeks post-intervention) appears to be a good indicator of satisfaction with decisions: women who indicated a preference for making decisions themselves appear to be more satisfied with their treatment choices at 2 weeks, 4 weeks and 6 weeks post-intervention. By 2 months, this relationship no longer exists, perhaps due to the changes over time that study participants exhibited in their desire for participation in decisions.

The importance of timing the intervention with respect to a woman's treatment also appears again when we examine preliminary data on decision satisfaction at different points post-intervention. Women who received an intervention prior to surgery were most satisfied with their treatment decisions at 2 weeks post-intervention whereas women who received the intervention later in their treatment process were more satisfied at 4-weeks post intervention. No significant findings have been found yet regarding the relationship between the type of intervention and decision satisfaction. These preliminary findings, however, highlight the importance of taking into account the timing of the intervention and data collection points with respect to the course of treatment. Since data collection is still underway, no multivariate analyses have been conducted. These analyses will allow us to take into account some differences between the subjects within the different intervention groups at pretest and will allow us to examine changes within the groups over time.

Other Findings:

Those who have access to CHES have better outcomes in 5 of 8 scales than the other interventions (Internet Only, Audio Tapes, or Books). The scales where CHES patients have the greatest improvements include Emotional Well Being, Self Efficacy, Functional Well Being, Negative Emotions, Breast Cancer Concerns, and Participation in Health Care. These trends have held since our last report and we expect that some of these differences will be significant once all of the data collection is completed.

- Statement of Work Task 11
Conduct Primary Analyses (Months 40-45)

The work for this task will take place after this annual report.

- Statement of Work Task 12
Prepare Final Report and Other Publications (Months 22-45)

As mentioned under Work Task 10, we have been completing our initial stages of survey data analysis and computer use analysis. This work is the foundation for all of our analysis for the Final Report as well as publications that will result. We are currently working on a descriptive paper on Internet Use in general. We hope to get this publication out for review by October 2001. The majority of the work for other submissions as well as the Final Report will take place after this annual report.

(7) Key Research Accomplishments

- Added Wayne State University in Detroit, Michigan as a recruitment site
- Updated all information material in CHES
- Redesigned the CHES site to improve ease of information access
- Recruited 314 study participants
- Operated CHES
- Collected and cleaned survey data
- Began preliminary computer use-data analysis and survey data analysis:
 - There is no difference in amount of computer use between CHES and the Internet only group.
 - There is a significant difference in type of material accessed by CHES and Internet only users. CHES users accesses health information almost 5 times as much as Internet Only users.
- Began preliminary survey data analysis
 - Most frequent non-treatment decision concerns 2-weeks post intervention:
 1. Who/what to tell family, friends, coworkers (26%)
 2. Whether to quit work or go back to work (18%)
 3. Whether to seek a second opinion (15%)
 - Most frequent non-treatment decision concerns 2-months post intervention:
 1. Whether to go to a support group (20%)
 2. Whether to quit work or go back to work (17%)
 3. Who to be around (16%)
- 75% of women's desire for participation remained constant over two months, and most women prefer to have some involvement from their physicians.
- Shifts in desire for participation are in the direction of including the doctor.

(8) Reportable Outcomes:

We submitted a proposal and received funding from the National Cancer Institute for a project targeting underserved women newly diagnosed with breast cancer in inner-city Detroit and rural Wisconsin. The purpose of the feasibility study is to help overcome the "Digital Divide." The initial data analysis from last year's annual report on CHES and Internet use as well as some of the outcome measures (reported in previous year's annual report) were the foundation of this proposal. In addition, the Markle Foundation awarded a grant to extend the time period of the original funding by NCI. The additional funding by the Markle Foundation increases the recruitment period from 6 months to 24 months. Both of these grants are a result of initial work supported by the Department of Defense.

(9) Conclusions:

Women randomized to our four conditions differ slightly but not significantly in demographic characteristics. Initial results indicate that the two conditions who received computer

intervention (CHESS and Internet only) used the computers differently. Those receiving CHESS used health information almost 5 times as often as those who with Internet access only. There appears to be substantial differences in most outcomes (functional health status, negative emotions, and participation in health care, self-efficacy, and breast cancer related concerns). Those who have access to CHESS have better outcomes than those who get the Internet only. It is too early to examine statistical significance at this time; however the trends suggest that they will be there. In addition, women appear to increasingly value the participation of their doctor in the decision making.

(10) References:

Not applicable at this time

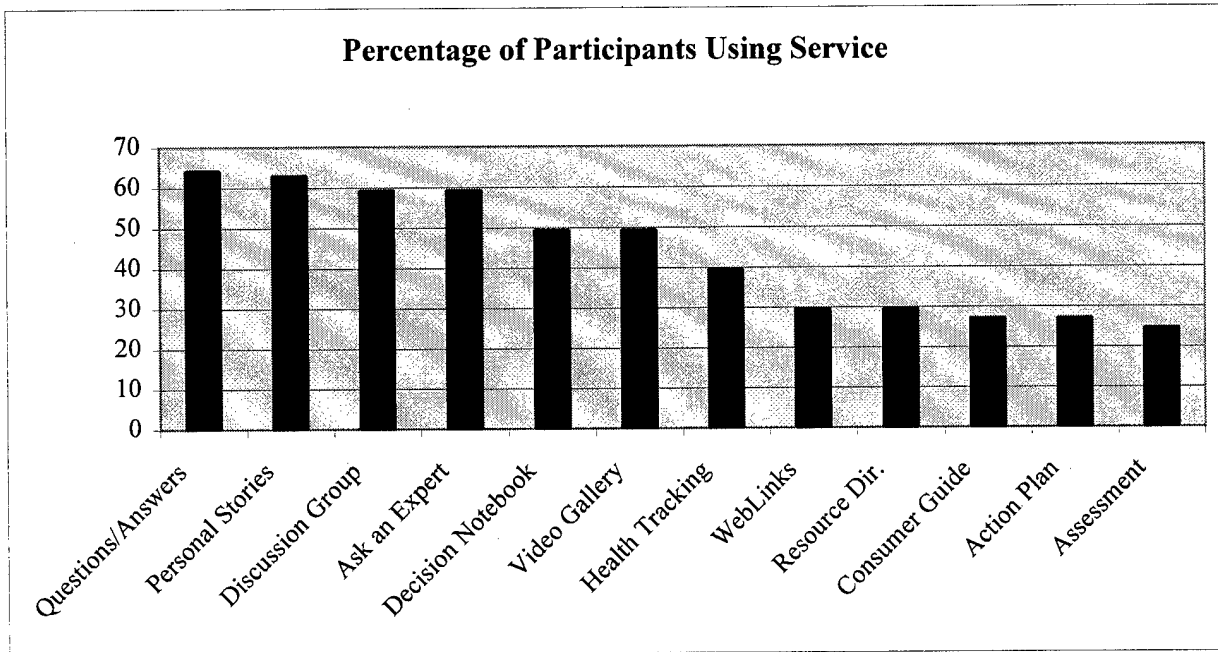


Figure 1: Percentage of Users Using CHES Services over a 5 Month Period

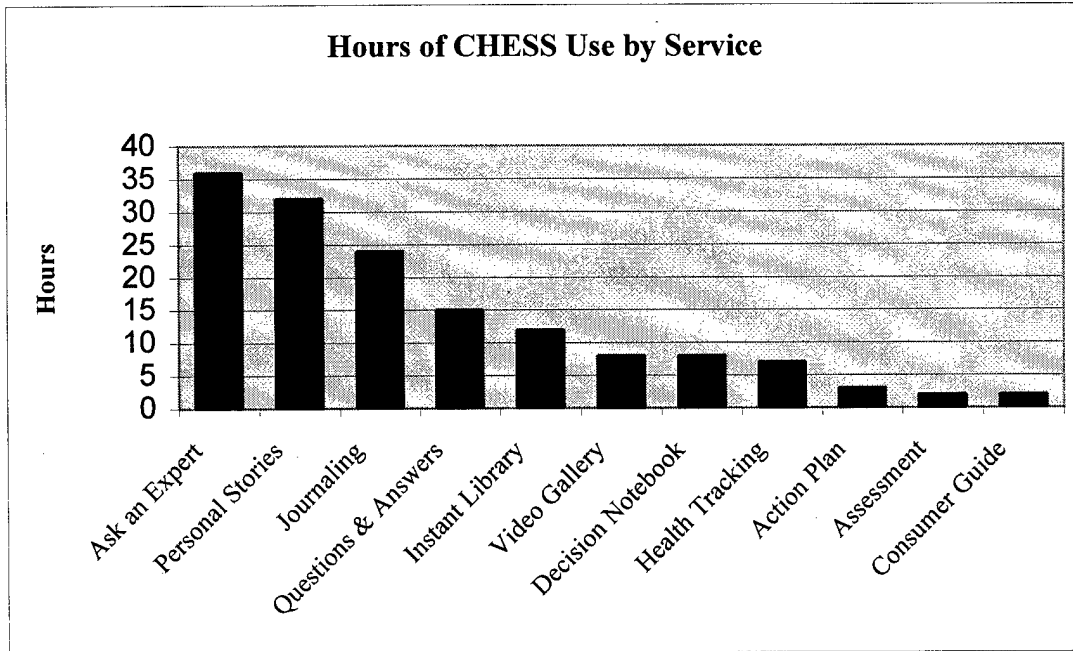


Figure 2: Hours of CHES Service Use (excluding Discussion Group)

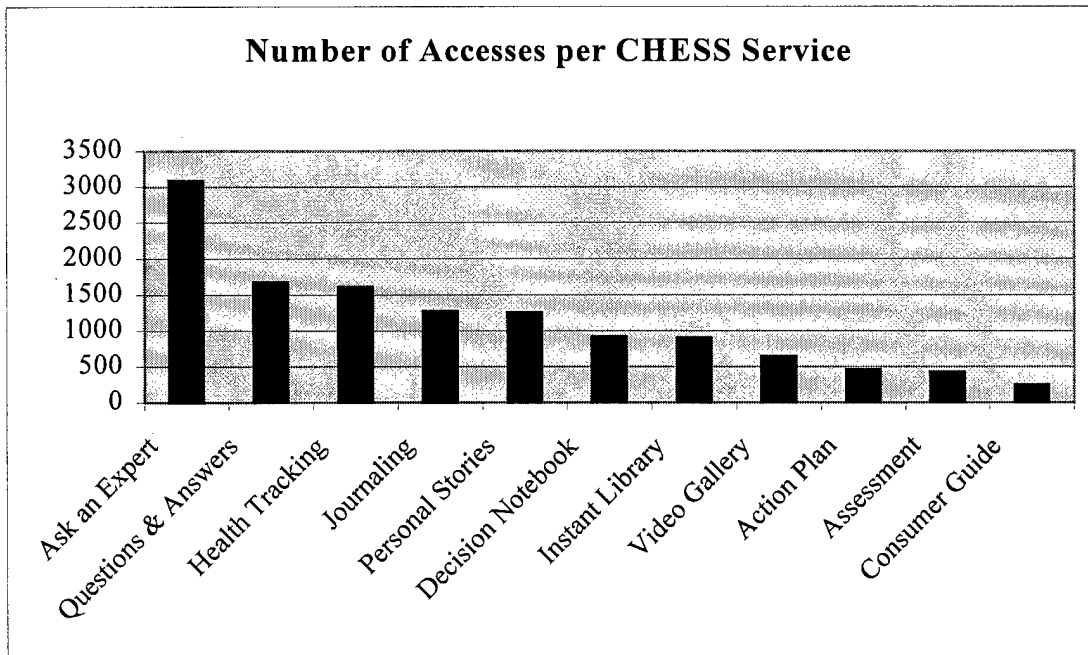


Figure 3: Number of Accesses per CHESS Service (excluding Discussion Group)

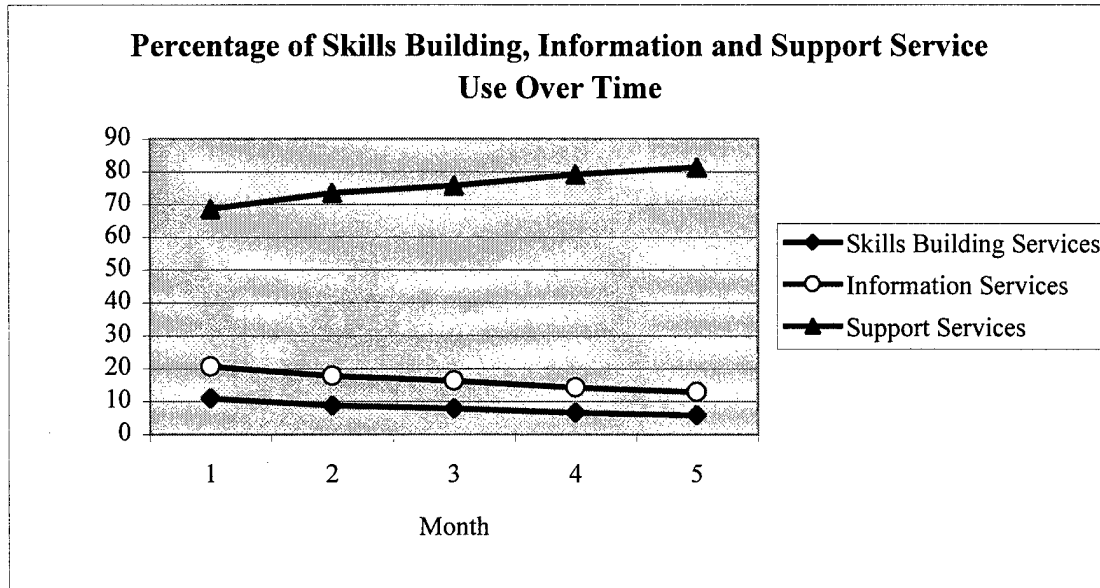


Figure 4: Percentage of Skills Building, Information and Support Service Use Over Time

Skills Building Services: Decision Notebook, Learning from Others, Action Plan, Health Tracking

Informational Services: Questions and Answers, Instant Library, Ask an Expert, Consumer Guide, Resource Directory, Weblinks

Support Services: Discussion Group, Chat, Personal Stories, Video Gallery

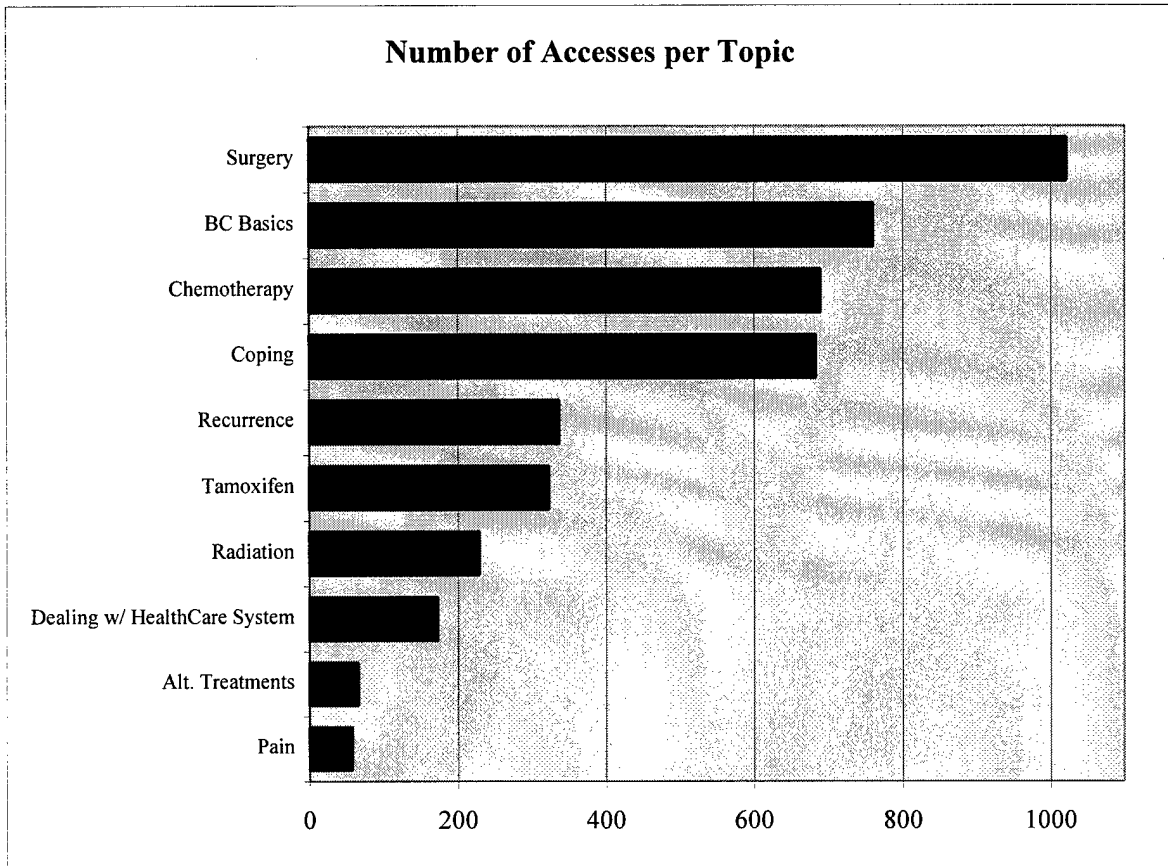


Figure 5: Accesses per Topic

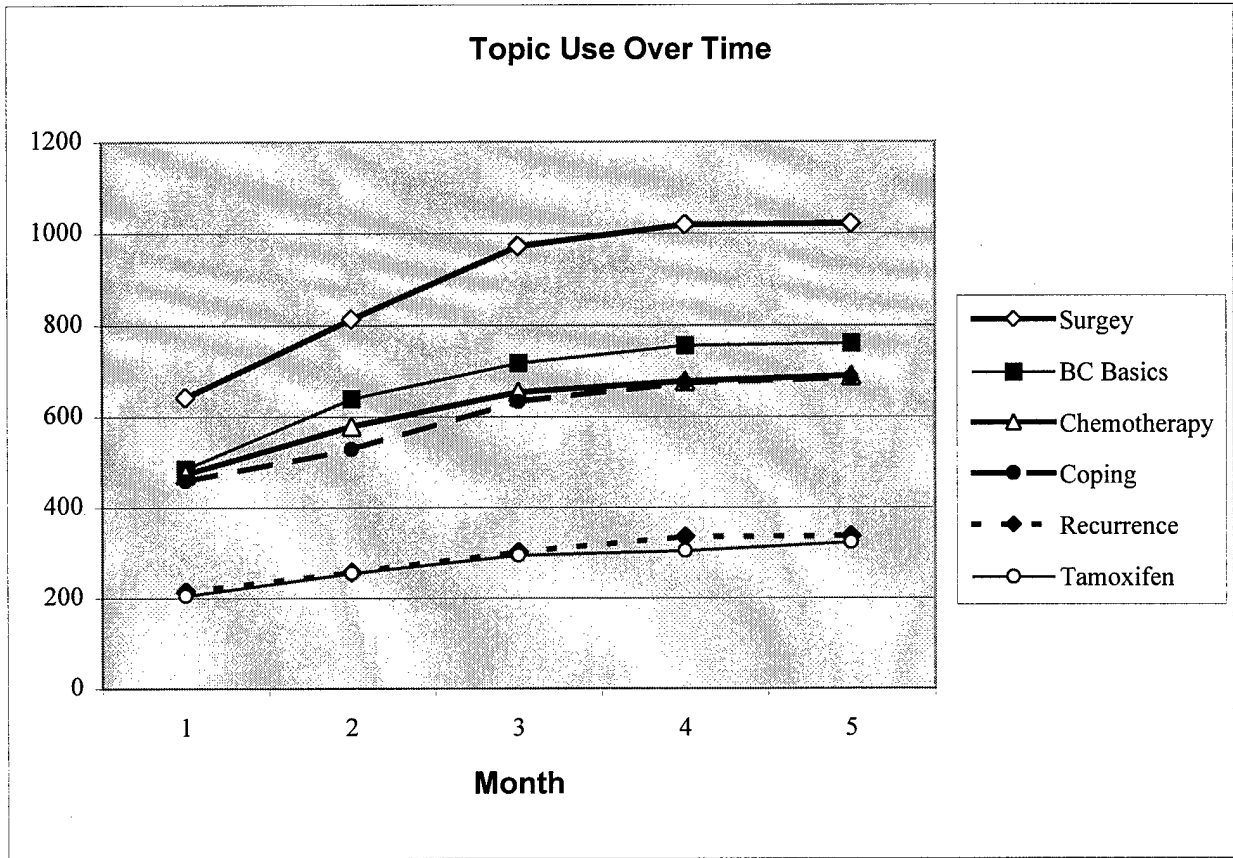


Figure 6: Topic Use over Time