DNP Portfolio Executive Summary

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The Doctor of Nursing Practice portfolio is comprised of a number of papers, projects and various curriculum competencies. It showcases my professional growth over the last two years. That growth is also evident through the progress toward publication of papers. At the beginning of this program I submitted an ethics case study for publication (case 1). Not only did it get rejected, the reviewer's comments were harsh and embarrassing, making me wonder how I got this paper past my instructor. Almost a year later I had summoned the courage to submit again, this time a case study on chronic beryllium disease (case 5). It was accepted with major revisions; a success compared with the previous experience. Finally, the last paper I submitted for publication on the history and future of free clinics (publishable manuscript) was accepted with only minor revisions. The progression from rejection to acceptance speaks to the professional growth achieved throughout this program.

Throughout the last two years in this program my focus has been on individuals with diabetes mellitus. More specifically, on those low income and uninsured individuals with type 2 diabetes. Just before this program commenced I had joined a diabetic management team at a free clinic where I was volunteering. We were in the initial stages of development, discussing what we hoped to accomplish and how we wanted to accomplish it. My growth and change is evident when I reflect on my participation in this management team.

I started in the team as an attendee with a background voice, contributing to meetings when asked but not volunteer many thoughts or ideas. Through the work of my CIP that voice and the way I saw myself interact with the team changed dramatically. I wasn't a background voice or a meeting attendee; I was a crucial member of that team. I provided expert clinical care to the individual patients during the day and then afterhours helped develop and implement interventions which would change the care to the population of people affected with diabetes. Arguably the most useful skill I learned through the completion of this project was team development, and how to work within a group to achieve results that far outreach any individual efforts possible. The personal and professional growth I attained in these short two years encompasses what the doctor of nursing practice is about.

I was, and still am, an expert clinician, caring for individual patients in an evidence based, holistic manner. Through my role in the multidisciplinary diabetes management team, it is evident that I am also influencing the health outcomes of populations of people with chronic disease. I also address system level issues of raising rates of people without health insurance and improve access and quality of care for this population.

Running head: MULTIDISCIPLINARY DISEASE MANAGEMENT

Program Evaluation: Multidisciplinary Disease Management and Diabetes Care in a Free Medical Clinic

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Program Evaluation: Multidisciplinary Disease Management and Diabetes Care in a Free Medical Clinic

Type 2 diabetes is a prevalent condition affecting approximately 17.5 million people nationally (ADA, 2008), including more than 340,000 in Washington State (Washington State Department of Health, 2008), and 8,800 people in Benton and Franklin counties (Washington State Department of Health, 2007). The rate of diabetes has been increasing at alarming rates in the last decade (Cowie, Rust, Byrd-Holt, Eberhardt, Flegal, & Engelgau, et al., 2006). The Center for Disease Control lists diabetes as the fifth leading cause of death by disease in the United States (National Center for Health Statistics, 2006).

A growing number of people with type 2 diabetes are without health insurance, leaving the burden of chronic illness management to safety net clinics and free clinics which traditionally have been designed to treat acute illnesses. The uninsured are disproportionately more likely to develop diabetes (Cowie et al, 2006; Rabi, Edwards, Southern, Svenseon, Sargious, & Norton et al., 2006). Nationwide the prevalence of uninsured patients with diabetes is estimated at over 1.4 million (Wilper, Woolhandler, Lasser, McCormick, Bor, & Himmelstein, 2008).

The free clinic serving Benton and Franklin County has been in existence since 2002 and has been growing significantly since. According to unpublished clinic documentation, the first year just over 300 patient visits were recorded; in 2007 there were over 3,400 patient visits. The population demographics for 2007 showed users of the clinic were 65% female. Ethnicity was fairly evenly divided between Hispanic and Non-Hispanic populations; 35% of the patients seen did not speak English. In the last couple of years the free clinic has grown significantly and has had to move into a large new building which has increased the public knowledge of the services provided and opened the clinic to professional scrutiny. There are groups of health care providers

in the community who have expressed concerns that the chronic needs of diabetic patients are not being addressed sufficiently. These concerns prompted the development of a diabetic management team in the fall of 2007 to better address the clinic's patients' chronic needs. The multidisciplinary diabetic management team has implemented many interventions to improve quality of diabetes care including implementation of a flow chart to improve continuity of care, diabetic education, diabetes insulin clinic and nutrition counseling. We have initiated and standardized diabetic education sessions and nutrition counseling with a dietitian in addition to providing food from our food cupboard designed for the diabetic patient's dietary needs.

The purpose of this project is to evaluate a multidisciplinary diabetes management team implemented in a free clinic serving low income, uninsured, type 2 diabetics in two bordering Washington State counties. The diabetic management team (DMT) has intervened in a number of ways including initiating a standardized flowchart for data recording diabetic education by an advanced practice nurse and retired internal medicine physician, nutrition counseling with a registered dietician, and a clinic for insulin dependent diabetics with a certified diabetes specialist. The aim of the project will be to respond to the following questions: does participation in the services provided by a diabetes management team improve blood glucose levels, blood pressure, lipids and weight among patients with diabetes in a free clinic? And second, what is the feasibility of starting a diabetic management team in a free clinic setting?

Conceptual Framework: The Chronic Care Model

This practice improvement project will be guided with an adapted chronic care model (CCM) (Figure 1). The CCM was initially conceptualized by the MacColl Institute for Healthcare Innovation and has gone through a number of refinements over subsequent years. The Robert Wood Johnson Foundation funded research to test the model nationally across varied

health care settings, creating the national program, Improving Chronic Illness Care (ICIC). The most recent changes occurred in 2003 when ICIC and a small panel of experts modified the CCM to reflect evidence based research and more specifically define the models concepts (Wagner, 2004).

The CCM identifies essential elements of a health care system that encourage high-quality chronic disease care. The complete model elements include the community, the health system, self-management support, delivery system design, decision support and clinical information systems (ICIC, 2008; Wagner, 1998; Wagner, 2004). For the particular setting and population focus of this clinical project, the model will be adapted to include three of these original elements; community, self-management systems and delivery system design.

The CCM has been tested in diabetes management and has been found to be effective in improving outcomes in primary care settings (Nutting, Dickinson, Nelson, King, Crabtree, & Glasgow, 2007) as well as in free clinic settings with uninsured populations (Stroebel, Gloor, Freytag, Riegert-Johnson, Smith, & Huschka et al., 2005).

The CCM will provide the foundation for practice improvement in this medically underserved population of type 2 diabetics. Key concepts include the community, delivery system design, self-management systems and diabetes outcomes. Community resources are one element of the health care system that focuses on finding and organizing local resources in order to meet patients' needs. The community resources pertaining to this clinical phenomenon are the free clinic system, laboratory services and pharmacy services.

The goal of self-management systems is to prepare patients to manage their health and health care through educational interventions. This is meant to emphasize the patient's role in the care of their chronic disease and improve their self-management techniques. It includes the use

of programs that provide basic information, emotional support, and strategies for living with chronic illness (ICIC, 2008). Specifically with the working population and setting, this was be provided through information support of ongoing diabetes education classes and nutritional classes taught by a registered dietitian, in addition to regular follow up care with a primary care provider. The classes are free and open to diabetic patients and their families. The patients were be provided with information to improve knowledge and will be active in goal setting and treatment plan development.

Delivery system design aims to provide effective, and efficient clinical care through a team member approach, using evidence based care and ensuring regular follow up by the care team. The formation of a diabetic management team led by the clinic's medical director, include a nurse practitioner certified in advanced diabetes management, a retired internal medicine physician, a registered dietitian, a masters prepared nurse and a registered nurse. This team was formed to design and implement programs to improve the efficiency of care.

The three central concepts chosen to help guide and direct the proposed clinical inquiry are interrelated and woven together providing improvement in diabetic outcomes. The community resources of the free clinic provides basic access to health care for this medically underserved population, while providing additional resources and tangible aid such as medications and food from the food cupboard. The goal is not only to provide informational support but to provide a balance and mixture of informational, tangible and emotional support. The delivery design system includes a dynamic diabetes team which has incorporated evidence based interventions and treatment algorithms in addition to nutrition and diabetic education classes which will enable and prepare the patients for self-management of their chronic disease.

Literature Review

There are more than 47 million people without health insurance in the United States according to 2006 data. This represents an increase of more than 2 million from the previous year. The percentage of the population without health coverage has increased from 15.2% in 2005 to 15.6% in 2006 (U.S. Census Bureau, 2007). The decreasing access to primary care services presents a challenge at the local level as well. Information from the 2006 Washington State Population Survey shows that13% of the state's population is uninsured, totaling more than 787,000 people (Kaiser Family Foundation, 2006).

To combat the problem of the growing number of uninsured, communities have established clinics aimed to help the underserved population. Free clinics are non-profit, community based organizations that provide a variety of medical care, primary care, mental health counseling, pharmaceutical and dental services at little or no cost to low-income, uninsured people (National Association of Free Clinics, 2007). Since their emergence in the 1960's relatively little has been published about them. A small body of evidence suggests free clinics have made significant impact in quality of care and access to medical care in the uninsured, showing a decrease in emergency room and hospital use (Hadley & Cunningham, 2004) and improvement in morbidity and mortality (Nadkarni & Philbrick, 2005). Results from the Charlottesville free clinic study showed that the proportion of patients seen for chronic illness steadily increased each year of the clinic's existence. Diabetes was one of the principle diagnoses among patients utilizing this free clinic (Nadkarni & Philbrick, 2003).

The CCM has been found to be useful in improving chronic illness outcomes, including type 2 diabetes. Many of studies have been done implementing components of the CCM into primary care settings and have shown success in diabetes outcomes (Nutting et al., 2007; Parchman, Pugh, Wang, & Romero, 2007; Piatt et al., 2006; Solberg, Crane, Sperl-Hillen,

Hroscikoski, Engebretson, & O'Conner, 2006; Vargas et al., 2007). A meta-analysis of chronic care interventions containing components of the CCM supports the use of this framework to guide chronic disease management. Although statistical analysis did not dictate which elements of the CCM were most responsible for the improvements in outcomes, delivery system design and self-management support were more strongly associated with improvements (Tsai, Morton, Mangione, & Keeler, 2005). Other data has shown that clinical information systems and decision support were two of the CCM elements most significantly correlated with improve diabetes measures (Solberg et al., 2006).

Piatt et al (2006) randomized primary care patients into three groups, CCM intervention, provider education only or usual care group. The results demonstrated improvement in physiologic parameters including glycosylated hemoglobin levels and HDL cholesterol in the CCM group compared to the other two groups. The CCM group also showed improvements in diabetes knowledge test scores and empowerment scores when compared to the usual care and provider education groups.

There is much less literature on the use of the CCM in free clinic settings with low income and uninsured populations. Stroebel et al (2005) conducted a pilot study to determine the feasibility and effectiveness of an adapted chronic care model applied to uninsured patients in a free medical clinic setting. The authors studied 149 patients, 62% (n=91) of which were diagnosed with diabetes. Intervention included case management by two registered nurses providing disease management using evidence based guidelines. More than 50% of the diabetic patients completing the study reduced their glycosylated hemoglobin values by at least 1%. The chronic care model was found to be useful template for the delivery of effective diabetes care to uninsured diabetic patients utilizing a free medical clinic.

Multidisciplinary management teams are one way to change deliver system design. Many studies have shown improved outcomes with management teams compared to individual patient/provider systems which have dominated health care to date (Baker et al, 1993; The California Medi-Cal Type 2 Diabetes Study Group, 2004; Trento et al, 2008; McLean et al, 2008). The California Medi-Cal Type 2 Diabetes Study Group (2004) was a multidisciplinary group comprised of physicians, nurses, public health professionals, and registered dieticians. The study randomized 362 patients to regular primary care or to the intervention group. The intervention consisted of case management along with primary care. The results were significantly greater improvement in glycosylated hemoglobin levels in the intervention group ($P<0.001$).

Accumulating evidence has demonstrated case management with registered nurses and physician provided treatment algorithms are successful in improving diabetes outcomes (Cramer, Sibley, Bartlett, Kahn & Loffredo, 2007; Davidson, Ansari & Karlan, 2007; Stroebel et al, 2005). There is less research about nurse practitioner led management teams. Recent research published in the Journal of the American Academy of Nurse Practitioners describes the roles of nurse practitioners in a management team to improve care to patients with chronic disease (Watts, Gee, O'Day, Schaub, Larrence, Aron & Kirsh, 2009). The study concluded that NPs have multiple roles in development, implementation and sustainability of quality improvement interventions.

Methods

Design

This is a single group, quasi- experimental, pretest-posttest designed study of uninsured diabetic patients utilizing a free clinic. The first research question is: does participation in the services provided by a multidisciplinary diabetes management team (DMT) improve

glycosylated hemoglobin levels, blood pressure, cholesterol levels and weight among patients with diabetes? The diabetic management team program has replaced usual care for all diabetic patients in the clinic; therefore it is not feasible or ethical to include a control group. The study will be retrospective starting January 2007 through January 2009.

The second research question is: what is the feasibility of starting a diabetic management team in a free clinic setting. This question will be addressed with a focus group made up of members of the DMT. It will use a qualitative, descriptive design. Focus groups are thoughtful, planned discussions among participants with similar experiences that allow the researcher to obtain the individuals' perceptions in a nonthreatening and relaxed environment (Wyatt, Krauskopf & Davidson, 2008).

Setting

The study will take place at a free medical clinic for the uninsured located in southeast Washington. As of December 2007, the clinic had served over 10,000 patients since opening in 2002. It is staffed with a paid clinic director, front office manager, mental health specialist, and dental coordinator. In addition to these paid positions, the clinic operates with help from many volunteers, including a medical director, primary and specialty care physicians, nurse practitioners, nutritionists, pharmacists, mental health counselors, nurses, translators and front office personnel. The organization and team members have been dedicated to this change effort and after months of preparation, planning, and discussion, the program was implemented on January 1, 2008. Diabetic education, a specialized insulin clinic for the insulin dependent diabetics, nutrition counseling, disease management, medication management, laboratory testing and focus group meetings will all occur on the premise of the free clinic. The study will not require any off premise work.

Sample

The population examined to address the first research question is the uninsured type 2 diabetic patients utilizing the clinic. Criteria for inclusion into the study include adults, aged 18 with a diagnosis of type 2 diabetes documented in the past medical history. In order to adequately compare group's pre and post intervention, the study will include only those patients with clinic visits in the 12 months prior to the DMT program and 12 months after the program initiation with documented blood pressure, weight, lipids and glycosylated hemoglobin (HgA1c). Exclusion criteria will include those people with a diagnosis of gestational diabetes and those with type 1 diabetes. There are approximately 200 active diabetic patients in the clinic, 60 of which fall within the criteria for this study.

The population examined for the second research question is the members of the diabetic management team. This includes two physicians, a registered nurse, two nurse practitioners, an advanced practice nurse, and a registered dietician. The program required substantial support and dedication by the team members. Focus group interviews will be used to explore the feasibility of the program, identifying the program's successes and struggles in order to improve future programs.

Intervention

The multidisciplinary diabetes management team started meeting in fall of 2007 to discuss ways to improve diabetes management in the clinic. In January 2008 the team implemented the first intervention, a standardized diabetic flow sheet (Appendix A) to be put in the patient charts. The use of flow sheets is associated with better adherence to national guidelines and better treatment of diabetes (Hahn, Ferrante, Crosson, Hudson, & Crabtree, 2008). The literature supports the use of flow sheets and the other interventions implemented into

practice, including a standardized diabetic education plan and check list (Appendix B), expanded insulin clinic, nutrition counseling program and modified food cupboard.

Measure

A list of the variables and measures for the study are summarized in Appendix C.

Blood pressure. Blood pressure measurements were collected from the year prior to intervention and from the year after the intervention. Pre-intervention blood pressure readings will be averaged and measured against the average of post-intervention blood pressure readings. Blood pressure will be measured as systolic and diastolic. A normal reading is less than 120 mmHg systolic over 80 mmHg diastolic. Goals set by the national diabetes association and adopted by the clinic are to have blood pressures below 130/80 mmHg (American Diabetes Association, 2005b). Blood pressures are taken by registered nurses at each visit. Some variation in blood pressure is expected due to variation in equipment used and technique of persons taking the measurements.

Weight. Weight will be collected in the year prior to intervention and in the year after the intervention. Pre-intervention weights will be averaged and compared to the last available weight in the post intervention record. Weight will be measured in pounds and will be extracted from the patient charts. Participants are weighed on the same scale at each visit and the nurses are trained not to accept patient reported weights. Some variability in weight is expected due to variation in equipment and technique of persons taking the measurements.

Laboratory data. Glycosylated hemoglobin levels (HgA1c) and cholesterol measures were obtained through a patient data set from a local licensed laboratory. The pre-program laboratory data was collected from January 2007 to December 31, 2007 and was averaged and measured against the post-intervention average laboratory data from January 2008 to December

31, 2008. All laboratory data was processed by the same laboratory reducing variability within reporting. The American Diabetes Association (2005b) target HgA1c and lipid levels for diabetics are summarized in table 1. The clinic goals for laboratory testing are to obtain HgA1c levels every three months on uncontrolled diabetic patients or when treatment has changed. In controlled patients, HgA1c levels will be obtained every six months. Lipid panels for lipid profile monitoring need to be ordered every three months on uncontrolled patients and then every six to 12 months in controlled patients. Patients are encouraged to come to the clinic fasting in order to maintain laboratory accuracy. The laboratory is open at times during the week and on the weekend if patients need to return for laboratory testing.

Table 1. American Diabetes Recommendations for Adults with Type 2 Diabetes

Summary of Recommendations for Adults with Diabetes	
HgA1C	<7.0%
Blood Pressure	<130/80 mmHg
LDL Cholesterol	<100 mg/dl
Triglycerides	<150 mg/dl
HDL Cholesterol	>40 mg/dl in men, >50mg/dl in women

Data Collection Procedures

Subject Recruitment. Subject recruitment is not applicable to this study as all diabetic patients in the clinic are enrolled in the management team program. The clinic will not recruit new diabetic patients. The patients will not be recruited for the specific interventions available for the patients, including diabetic education, insulin clinic, nutrition counseling and food cupboard but the primary care providers can make recommendations and referrals into these programs and information will be made available for the patients so they are aware of the

program. For the second research question, members of the diabetic team were given consent forms individually to obtain approval for participation in the focus groups.

Data collection and management. After IRB approval from the Oregon Health and Science University, baseline data included blood pressure and weight records will be extracted from the subjects' charts using a health record extraction form (Appendix D). Baseline data will be extracted from the chart for the time January 2007 through December 2007 and averaged for comparison to post-program data. Other baseline data, glycosylated hemoglobin levels and cholesterol levels will be available in a data set from a local laboratory. The post intervention data will be available from chart review and data set and will be done between January 2008 and January 2009. Data from the health record extraction form will be transcribed into an Excel file and SPSS software on a password protected personal laptop computer. Data extraction will occur on premises. All data extraction will be done by the principal investigator. Data from five randomly selected charts will be extracted a second time to assess intra-rater reliability which will be calculated based on the number of inconsistent items divided by the total number of items extracted.

For the second research question, the principal investigator will conduct focus group sessions of the consenting DMT members. The interviews will be audio recorded to verify accuracy of field notes. Consent forms, audio recordings and any notes will be maintained by the investigator in locked file cabinets for five years after the completion of the study at which time they will be destroyed.

Financial Analysis. The perspective that will be used for analysis of the financial aspects of the study is that of a free clinic administration or board of directors. The audience is geared for other free clinic change agents, boards, and administration. Other perspectives this study

could assume could be one of a larger, broader community based level with an audience to other community resources such as community clinics and emergency departments.

Analytical Methods

Analyses will be conducted using SPSS v.15.0 (SPSS, 2006) statistical software. Descriptive statistics (means and standard deviations) will be calculated when appropriate for continuous variables and categorical variables will be summarized with frequency counts and percentages. The first research question uses time (pre and post) as the predictor with continuous outcome variables. A repeated measures t-test will be used to compare the average glycosylated hemoglobin, lipid panels, blood pressure and weight of participants before and after the program intervention. Paired t-tests improve the power of the study (Munro, 2005).

The second research question will be evaluated using focus groups. The researcher, using investigator-developed open-ended questions, will meet with the DMT on one or two occasions for approximately 30 minutes to discuss and reflect on the programs successes and barriers. Themes and exemplar cases will be used to report data. Focus groups are considered particularly suited for intervention refinement and the group setting will provide rich data that could potentially be missed in individual interviews.

Protection of Human Subjects/Ethics

Oregon Health & Science University IRB approval was obtained (Appendix I), as well as permission from the Grace Clinic for this study to be conducted (Appendix E). The participants will be given an informational consent form (Appendix F) which includes information about the study. They will also be given a list of the focus group questions (Appendix G) and a frequently asked questions and answer information sheet (Appendix H). The Human Subjects Protection

Education for Research Teams has been reviewed by the investigator. Participants were made aware that they may withdraw from the study without penalty.

Plan for Dissemination to Key Stakeholders

Information obtained from this study will be used internally for program evaluation. It will also be used to provide progress report to funding organizations. The study is being completed with the intent to publish. Dissemination of information to other providers and health care workers interested in improving quality of care for uninsured populations will be completed through publication and through work with national associations.

Results

Sample

Research Question 1. There were 152 subjects with glycosylated hemoglobin levels recorded in the laboratory data bank. Seventy subjects fit the criteria, having labs done in both the pre and post intervention time periods. Seventeen were excluded because they did not have complete lipid level recordings. Of the remaining 53 subjects, three charts were not able to be located after four different attempts, and were not included in the analysis. The final analysis was completed with a sample of 50. Demographic characteristics of the sample subjects were not collected for data analysis.

Research Question 2. The diabetic management team (DMT) is comprised of a family practice physician, retired internal medicine physician, a diabetes specialist nurse practitioner, family nurse practitioner, masters prepared nurse, registered nurse with a masters in social work and a registered dietician. The masters prepared nurse was not present in the focus group as she was out on maternity leave at the initiation of this research. All other team members were present at the focus group interview.

Approval for the study was obtained from Oregon Health & Science University's Internal Review Board (Appendix I). The participating clinic also wrote a letter of endorsement for the research to be conducted at the facility (Appendix E). The Human Subjects Protection Education for Research Teams was reviewed by the investigator.

Findings

The first research question focused on the physiological parameters of diabetes, inquiring if the diabetes management team interventions improved glycosylated hemoglobin, blood pressure, lipids and weight among patients using the clinic facilities. Retrospective data were extracted from patient charts into the health record extraction form (Appendix D). It was transcribed into an Excel file then into SPSS version (15.0) for analysis. A paired t-test was used to analyze eight biophysical markers (Table 2).

Glycosylated hemoglobin levels improved significantly ($p=0.001$) at the second testing (mean = 7.6) compared to the first testing (mean = 8.5). The range of values recorded varied from 5.6 to a maximum value of 12.7 (Table 3). Both systolic ($p = 0.001$) and diastolic ($p = 0.005$) blood pressures also improved significantly. Systolic blood pressure reduced by an average of 10 points, bringing the mean systolic pressure into recommended goal range (Table 1). The average diastolic pressure decreased by just over five points, bringing the average to 76.4, also within the guideline's recommended goal.

Table 2. Changes in Biophysical Markers

Measure	Initial	Final	Change	p-value*	N
Mean HgA1c (sd)	8.47 (1.97)	7.62 (1.36)	-0.85 (1.43)	0.000	50
Mean Systolic Blood Pressure (sd)	132.1(18.55)	121.3 (20.72)	-10.8 (22.56)	0.001	50
Mean Diastolic Blood Pressure (sd)	82.0 (10.89)	76.4 (11.39)	-5.60 (13.43)	0.005	50
Mean Weight (sd)	202.5 (48.45)	201.2 (49.37)	-1.3 (9.39)	0.348	50
Mean Total Cholesterol (sd)	178.8 (31.41)	169.9 (35.08)	-8.9 (33.37)	0.065	50
Mean Triglycerides (sd)	178.8 (103.15)	150.6 (60.33)	-28.2 (92.86)	0.036	50
Mean LDL (sd)	101.6 (31.65)	94.8 (30.36)	-6.8 (22.93)	0.103	50
Mean HDL (sd)	41.0 (8.15)	42.3 (8.47)	1.3 (5.03)	0.093	50

*A paired *t*-test was used to calculate significance

Analysis of the triglyceride findings is more difficult. Type 1 errors are more common when performing multiple comparisons (Munro, 2005). In order to protect against this error, the level of significance is divided by the number of comparisons that are made, establishing the new level of significance. In this case 0.05/8 = 0.006. In order for a comparison to be considered significant, it must be at or below 0.006. Triglyceride levels (p = 0.036), although improved, are not statistically significant. The other lipid levels: total cholesterol, low density lipoprotein and

high density lipoprotein, along with average weight, did not result in changes that were significant.

Table 3 Variable Characteristics

Measure	Minimum Pre/post	Maximum Pre/post	Range Pre/post	Average Pre/post
HgA1c	5.6/5.6	12.7/11.4	7.1/5.8	8.47/7.62
Systolic Blood Pressure	87/86	193/157	106/71	132.1/123.3
Diastolic Blood Pressure	52/52	111/135	59/83	82/76.4
Weight	110/112	335/346	225/234	202.5/201.1
Total Cholesterol	107/99	258/288	151/189	178.8/169.9
Triglycerides	69/43	532/376	463/333	178.8/150.6
LDL	46/31	190/206	144/175	101.6/94.8
HDL	22/28	68/77	46/49	41.0/42.3

The second research question examined the feasibility of starting a diabetic management team (DMT) in a free clinic. This was accomplished through a focus group interview with the team members. Every team member except the masters prepared nurse was at the meeting, she was not available for the interview as she was away on maternity leave. The focus group was done prior to a scheduled team meeting and as a result, everyone was available to participate at the same time. The meeting lasted approximately 15 minutes. Two open-ended questions were asked of the participants.

1. What has gone well with implementation of the diabetes management team?
2. What were the struggles involved in starting a diabetes management team?

Notes were taken by the primary researcher as well as a member of the DMT. The notes were read back to the group for clarification and completeness. Reading of the two sets of notes led to the identification of concepts and central themes relevant to the feasibility of starting a diabetic management team in this setting. Review and content analysis of the responses resulted in the identification of three major themes: standardization of care, role of team members and the challenge of time.

Team members were quick to identify standardization of care with the development of the algorithm infused diabetic flow sheet (Appendix A) as a significant contribution of the DMT. The flow sheets made it easier to track and manage ongoing care and also served as treatment reminders for standards of care.

The participants identified other potential benefits from the development of the flow sheets. The flow sheet will help guide treatment and management of the disease, ensuring standardization among the large number of volunteer providers, not just those within the DMT. Volunteer medical providers vary greatly in background education and clinical experience. One of the focus group participants tells of a retired pulmonologist who has started seeing patients at the clinic but wanted to care for all health needs, not just respiratory concerns. His educational training included internal and family medicine but his clinical experience was in pulmonology and he did not feel comfortable managing diabetic patients. The participants see the flow sheet as a way to improve his comfort and summarize diabetes management, making it more manageable.

Participants cite the team members as a large reason for the success of the program. The inter-professional collaboration resulted in complete and comprehensive tool development and a large pool of ideas were generated. For example, diabetes fair was proposed by a team member

as a fun learning experience for a group of diabetic patients. The idea was discussed and many activities were planned that incorporated elements from all the members background experience.

Not every aspect of the team was positive. Although there is a lot of benefit from the formation of a large multidisciplinary group, the participants recognized at times there was too much discussion about certain topics and weeks would go by without progress.

Unanimously, the focus group felt that the largest challenge in forming the DMT was finding a time when everyone could meet. Meetings were usually held once a month and most times at least one of the group members was not able to make it due to other engagements. The participants consider finding a meeting time to be a challenge in any clinical setting but think that it is probably a larger variable in volunteer settings.

Financial Considerations

The cost to run a diabetic management team can vary widely depending on volunteer support and available services. The DMT described in this research functioned using resources already established. A DMT program would face many more economic challenges in a clinic without laboratory and pharmacy support. The costs of the current program will be categorized into administrative, patient supplies and staff.

Administrative costs. There were added administration costs to run the diabetic management team. The team used brightly colored paper to print the flow sheets and diabetic education sheets to make them more easily identified. Bright colored stickers were purchased and placed on the chart to make the diabetic patient more easily identified when being seen for acute visits. Increased paper copying and printing was required. The rent and building expense, telephone, fixed payroll salaries were not changed with the initiation of the team and there was not an added cost for the team to operate within the facility.

Patient Supplies. Medications were dealt with in a number of ways. The clinic has purchased medications that are reserved for patients with very low income and used at the discretion of the medical providers. The majority of medications are paid for by the patient through $4 prescription programs at a local pharmacy. Medication that is not available though the pharmacy programs are supplied through manufacturer prescription assistance programs (PAP). Glucometers and glucometer strips are also supplied to diabetic patients through the PAPs.

A local laboratory provides serum testing for all patients in the clinic. They contract with the facility and offer a dramatically reduced fee schedule. The clinic has a volunteer phlebotomist that works two days a week. The clinic spends a fair proportion of their budget of laboratory fees. The DMT program operated on treatment algorithms which defined when laboratory testing was needed. There were patients who needed testing more often, and those who needed it less often, the net result was not a significant increase in the cost.

Salaries. The program operated with a team of volunteer providers. Only one of the team members held a salaried position in the clinic, but her time with the DMT was voluntary. The team has discussed the idea of hiring a full time registered nurse to help manage the diabetic patients and paperwork, but to date, this has not been done.

In general, the diabetic management team operated within the confines of an already functioning system without dramatically increasing costs. In other free clinics with similar systems, such a team could operate if they had member support and volunteers. The costs for paid staff would be significant and one that most free clinics could not support, emphasizing the role of dedicated volunteers.

Situation analysis

Overall the project operations went smoothly and met expectations. The need for chronic disease management fueled the research, making it even more interesting and rewarding. From the initial conceptualization of the DMT to the current date, much has been learned about working with this transient and dynamic population involved in this study. Interventions were tried; some failed and some have been very successful, but regardless, the learning that accompanied this project was enormous. Over the last two years I further developed my clinical skills in diabetes management and gained knowledge about program development and analysis. Arguably the most useful skill I learned through the completion of this project was team development, and how to work within a group to achieve results that far outreach any individual efforts possible. It was made obvious that time is generally underestimated. If I were to do the project over again, I would allow for twice as much time for each step of the project.

Two important leadership skills enhanced and developed were my interpersonal skills and communication skills. Coming into the program I felt comfortable in most aspects of individual patient care. I could relate and communicate well with individual patients across the cultural and socioeconomic spectrum. However, I struggled in communication with colleagues and patient families. Through the completion of this program these two areas that have become well developed.

My role as a future Doctor of Nursing Practice provider was twofold. One aspect of this new role was to provide expert clinical care to the individual patients. A second part of my view of the DNP role was to improve the care to the population of low income, uninsured diabetic patients. I accomplished this through leadership and inter-professional collaboration within the diabetic management team. I view myself as a valuable member of the DMT. I helped foster

team development, generated new ideas and encourage application of those ideas into health care practice. I will also serve as a local and political advocate for this population over the years.

Outcomes

There were many changes in processes of care and patient outcomes that were associated with the DMT. Prior to the development of this program, no systematic approach to managing chronic disease existed within the clinic. The DMT, and application of current evidence based practice research, completely shifted the design of the delivery system from acute and problem focused care to systematic management of chronic disease. The team implemented flow sheets and tracking tools as well as algorithms to improve standardization of care. The short term patient outcomes were a decrease in average glycosylated hemoglobin and blood pressure scores, which could have important impact on the long term outcomes if the team and patients stay engaged.

Discussion

Executive Summary

Jessica Johnson, FNP-BC

Doctor of Nursing Practice Candidate

Oregon Health & Science University

May 4, 2009

This project was undertaken as a program analysis to evaluate a multidisciplinary diabetes management team in a free clinic serving low income, uninsured, type 2 diabetics. The purpose of this clinical inquiry project was to evaluate if the DMT was making a significant difference in chronic care management. To answer this, eight biophysical markers: glycosylated hemoglobin, systolic and diastolic blood pressure, weight, total cholesterol, triglycerides, low

density lipoprotein and high density lipoprotein, were compared in 50 individuals meeting study criteria.

The intervention period spanned from January 1, 2008 until December 31, 2008. The variable values were averaged and compared to the average value from the pre intervention period (January 1, 2007- December 31, 2007). The study used a paired *t*-test to analyze the comparisons and a Bonferroni correction was used to determine level of significance. Each of the variables showed improvement during the intervention period. Glycosylated hemoglobin, systolic and diastolic blood pressures improved statistically. Triglyceride levels, LDL and total cholesterol levels were decreased to goal of the American Diabetes Association recommendations. Two areas were identified that require ongoing intervention: weight and HDL. Although both improved marginally, the focus of future interventions should be weight reduction and HDL improvements.

A secondary aim of the study was to assess the feasibility of starting a diabetic management team in this challenging clinical setting. Focus group interviews were conducted of the members of the DMT. Through analysis of these interviews, two predominant themes were identified: the importance of team members and the challenge of time. The volunteer team members were crucial in the success of the DMT. Each member brought unique experiences and different educational backgrounds which resulted in comprehensive interventions.

The DMT was successfully implemented in a challenging clinical setting. Although randomized control trials are needed to demonstrate the relationship between the DMT and the clinical improvements, the success in reducing biophysical parameters is likely due, in part, to the DMT interventions.

Context

The project was completed with a group a busy volunteer providers in a clinic with limited hours of operation and limited resources. Additionally, the patient population was low income and culturally diverse. These contextual factors strongly influenced the project interventions and results. Even basic care instructions had to be modified for this patient population and setting. For example, glucometers were available to give to the patients for glucose monitoring, but the test strips that were needed are expensive and without insurance coverage they ran at least $1.00 per strip. The team had to find alternative ways to provide care, while still utilizing evidence based practices and adjusting for the financial and environmental challenges.

I expected to find an overall improvement in biophysical markers and did not know if the analysis results would be statistically significant. Given that this is just the first year of the program, the team would have been satisfied with showing a positive trend toward improvement. The results were comparable to what has been shown in the literature. Stroebel et al (2005) reported a 1% improvement in glycosylated hemoglobin levels in more than 50% of the diabetic patients in his study of free clinic patients in Minnesota.

Interpretation

The interventions developed by the DMT may have influenced the successful improvement in biophysical markers in this population. Without further studies to examine the relationship between the interventions and the outcomes specific conclusions cannot be drawn. The data suggests that there may be a relationship between the DMT and improvements in glycosylated hemoglobin levels, systolic and diastolic blood pressures. Other clinical markers improved, but not great enough to produce statistical significance.

Many of the markers which failed to produce clinical significance were in fair control at the initiation of the study. For example, the average total cholesterol pre-intervention was 178.8 and improved to 169.9 after the intervention time. The guidelines call for total cholesterol to be under 200 (Table 1), indicating that total cholesterol was in control prior to the DMT and limiting the effect the team interventions might have. The same is true for the LDL cholesterol. The pre-intervention average was just slightly above the evidence based recommendations at 101.6 and improved to 94.8 post intervention. Not a statistically significant difference but clinically this put the average into the controlled range. Average triglyceride levels improved from 178.8 to 150.6. The guidelines recommend triglyceride levels to be under 150. Getting cholesterol levels to goal is clinically significant even if not statistically so.

As the primary researcher in the clinical inquiry project, I contributed to the project completeness in many ways. As a future DNP and nursing leader I saw a need for the diabetic patients in the community and, along with my colleagues, decided to intervene. The clinical inquiry project was done concurrently with the formation of a multidisciplinary diabetes management team. Literature has shown multidisciplinary teams to improve chronic disease management in other settings and I wanted to see if this team was possibly making any difference in the care of our patients. I was involved with all aspects of the project, from conception of the project, literature review and pushing thought the IRB. I was solely responsible for data collection and worked through the statistical analysis and interpretation. The high level of involvement in the project helped me obtain a greater understanding of the data.

Limitations

The number of visits to the clinic varied greatly among our patients, confounding data analysis and raising questions about the validity and generalizability of the results. The large

range in clinic visits was found in both the pre and post intervention periods. The analysis did not take into context the strong cultural diversity in this population. Many of the patients served at the clinic are Hispanic and disease perception can vary greatly among different cultures (Shaw, Huebner, Armin, Orzech, & Vivian, 2005), causing potential variability in the data. Additionally, the data are averages and individual patients may not have had improvement in their personal values. The study may be limited in its generalizability to other free clinics or community health clinics due to these and other limitations.

In the future, repeating the study and analysis, taking into account each individual intervention would enhance the richness and significance of the data. Controlling data for influencing variables, such as number of patient visits, may produce more accurate results. Finally, randomized controlled trials are needed to identify the relationship between the DMT interventions and patient improvement.

Conclusion

The DMT was successfully implemented in this challenging clinical setting guided by aspects of the chronic care model (Figure 1). The study results show a significant improvement in glycosylated hemoglobin, systolic and diastolic blood pressures. The relationship between these results and the DMT cannot be established based on the research. The first phase of the DMT focused on the development of the diabetic flow sheet to improve disease monitoring and management, emphasizing blood sugar control and diabetic education. Algorithms were developed to improve diabetes care. Total cholesterol, triglycerides, LDL and HDL cholesterol along with weight, did not produce statistical change, indicating an area of needed improvement and focus. The development of treatment algorithms and cholesterol monitoring is already

occurring and will be implemented in the second year of the program. The study helped evaluate our current progress and identified areas where focus is needed.

The first year of the DMT was a major change in the fundamental operations of the clinic. Moving from a traditional acute and basic health care system to chronic disease management required a dynamic and flexible environment. The first year saw the implementation of the diabetic flow sheet, standardization of diabetes education and many other programs. The project has been very useful as a program evaluation tool. The focus groups findings resulted in positive feedback about the implementation of the team approach to chronic care and the team and identified challenges and struggles. Significant improvement in the biophysical markers has validated our current efforts and guided our future interventions. Although the research cannot demonstrate a cause and effect between the DMT and the improvements, it does reveal improvements in disease states, which is the ultimate ambition.

Further analysis is needed to see how the subsequent years of DMT interventions may improve patient care and patient outcomes. Interventions focused on improving the variables that did not produce significant results should be emphasized. Expanding the multidisciplinary team into managing other chronic illnesses should be explored. An important area of investigation will include the patients' perception and experience with the diabetic management team and analysis of which interventions were more useful.

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List of Appendices

Appendix A. Diabetic flow sheet

Page:____ of ____

GRACE CLINIC
DIABETIC FLOW SHEET

Name:_____ DOB: _____ _____ Height: _____
Allergies: _____ CHART #: _____

HGB-A-1C (Q 3 mos, uncontrolled; Q 6 mos, controlled (<7)						
BMI						
BP (<130/80) EVERY VISIT						
HDL (women >50, men>40)						
LDL (<100, if CV history<70)						
Triglycerides (annual) (<150, if A1C normal)						
Urine MicroAlbumin/ creatinine ratio, (annual <30)						
ACE (HTN, UAlb/ Creat >30)						
ARB (Fails or allergy ACE)						
STATIN						
ASA (81-325mg >21yo)						
CMP,CBC, TSH annual						
Foot exam, (annual)						
Retinal exam (annual)						
SMBG (Self Moniter blood glucose)						
Diabetic Education (once a year and prn)						
Life Coaching & counseling						
Dental Visit (annual)						

Examples:		
	AIC	6.8 12.12.07
	ACE	YES 12.12.07

Revised 9-25-08

Appendix B. Diabetic education sheet

GRACE CLINIC DIABETES EDUCATION FORM

PATIENT FIRST NAME: _____ LAST NAME: _____
(NOMBRE) (APELIDO) PATERNO/MATERNO

DATE OF BIRTH (FECHA DE NACIMIENTO): _____ AGE (EDAD): _____ PATIENT #_____

NURSING

BP:_____ HEIGHT:_____ WEIGHT:_____ WEIGHT Δ:_____ BMI:_____ A1C:_____ BS:_____

CURRENT MEDICATIONS:_____

_____

PROBLEMS OR QUESTIONS:_____

_____

SIGNATURE:_____

DIABETES EDUCATION

PATHOLOGY OF DIABETES	DC	NR	TR	NI
TYPE I / TYPE II	DC	NR	TR	NI
OBESITY & DIABETES	DC	NR	TR	NI
COMPLICATIONS OF DIABETES	DC	NR	TR	NI
MANAGEMENT GOALS	DC	NR	TR	NI
DM EDUCATOR & HCP ROLES	DC	NR	TR	NI

AADE 7 SELF-CARE BEHAVIORS

HEALTHY EATING DC NR TR NI
- KEEP FOOD LOG
- DAILY CALORIE GOAL:_____
- EAT REGULAR MEALS
- CARB COUNTING DC NR TR NI
- REDUCE FAT & CHOLESTEROL
- INCREASE WHOLE GRAINS, VEGETABLES, FRESH FRUIT

BEING ACTIVE DC NR TR NI
- AEROBIC EXERCISE
- EXERCISE GOALS:_____

MONITORING DC NR TR NI
- FREQUENCY:_____
- FASTING BS GOAL:_____
- 2 HR AFTER MEAL:_____

TAKING MEDICATION DC NR TR NI
- REFILL BEFORE OUT
- MEDICATION CHANGES:_____

PROBLEM SOLVING DC NR TR NI
- HYPOGLYCEMIA
- HYPERGLYCEMIA

REDUCING RISKS DC NR TR NI
- PREVENTIVE CHECK-UPS
- STOP SMOKING; LOSE WEIGHT; CHECK FEET

HEALTHY COPING DC NR TR NI

RESOURCES PROVIDED

NOVO-NORDISK
- DIABETES AND YOU
- CARB COUNTING
- EXERCISE
- INSULIN THERAPY
- OTHER:_____

MYPYRAMID.GOV
- PROTEINS GRAINS
- VEGETABLES FRUITS
- FOOD PYRAMID

SIDE BY SIDE "WHAT IS DIABETES"

OTHER RESOURCES:_____

_____

NOTES:_____

_____

_____

_____

INSTRUCTIONS/GOALS FOR NEXT VISIT:_____

_____

_____

_____

_____

_____

_____

_____

SIGNATURE:_____

DC = Demonstrates Competency NR = Needs Review
TR = Teaching Reinforced NI = Needs Instruction

DATE:_____

Appendix C. Variables and measures

Variable	Measure	Abbreviation
Glycosylated Hemoglobin	Chart review or data set from Laboratory. Measured as percentage. Interval level	HgA1c
Blood Pressure	Chart review, measured standard unites of measurements, millimeters of mercury. Ratio level.	BP
Lipid Panel	Specifically measuring low density lipoproteins, high density lipoproteins, and triglycerides. Data obtained as data set from Laboratory. Interval level.	LDL HDL
Weight	Chart Review, measured in pounds. Ratio measure.	

Appendix D. Health Record Extraction

Health Record Abstraction Form
Patient Identification Number……
Biophysical Data include date with each measure Blood pressure……... Weight……

Appendix E. Grace Clinic Support

Bringing Christ's love and healing to those in need

November 2, 2008

Jessica Johnson, RN, MSN, ARNP
Three Rivers Family Medicine
945 Goethals Dr.
Richland, WA 99352

Re: Research Project

Dear Jessica:

Thank you for the copy of your CI Manuscript outlining the research project that you are undertaking at Grace Clinic. The Clinic is pleased to participate with you in this effort. Thank you for your continued interest in the work of Grace Clinic.

Very Truly Yours,

Mark C Brault
President

509-735-2300 - fax 509-735-2323
email: GraceClinic@GraceClinicOnline.org – www.GraceClinicOnline.org
P.O. Box 6794 – 3180 West Clearwater Avenue, Suite A – Kennewick, Washington 99336 – USA
A United Way Partner Agency

Appendix F: Informed Consent

INFORMED CONSENT COVER SHEET

Jessica Johnson, FNP-BS, MN, DNP candidate Oregon Health and Science University
509-432-9641

RESEARCHERS STATEMENT. You are being asked to participate in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to participate in the study or not. Please read the form carefully. This process is called 'informed consent.' You may keep a copy of this form for your records. This study has been reviewed and approved for human subject participation by Oregon Health and Science University Institutional Review Board.

PURPOSE AND BENEFITS

The purpose of this focus group is to obtain information about the feasibility of starting a diabetes management team in the free clinic setting, including what aspects of the program were successful and which were not. As a participant you will not directly benefit from participating in this study. There will be no compensation paid to you for your participation.

PROCEDURES

The interview consists of 2 open-ended questions. It is estimated to take approximately thirty minutes. The interview will be audio recorded to verify accuracy of field notes.

RISKS, STRESS, OR DISCOMFORT

There are no known emotional or physical risks associated with your participation in this study. You may experience some minor discomfort in answering the interview questions.

CONFIDENTIALITY

Recorded information will be kept confidential and available only to the investigator and the faculty committee. Any publications resulting from this study will report group data and will not identify you specifically.

SUBJECT RIGHTS

You may contact the investigators at 509-432-9641 if you have any questions about your participation in this study. Should you have any questions regarding your rights as a study participant you may contact the OHSU Institutional Review Board at ___.

OTHER INFORMATION

The audiotapes from the interviews will be stored separately from the completed demographic questionnaires and signed consent form. Only the investigator and her faculty thesis committee will have access to your audio-tape. The tape will be incinerated when it is no longer needed.

VOLUNTARY PARTICIPATION/WITHDRAWAL

Participation in this study is voluntary and you may withdraw at any time.

Appendix G. Interview Guide

NURSE PRACTITIONER INTERVIEW GUIDE

OPEN-ENDED QUESTONS

Start Tape Recorder

Investigator's Statement: I am going to ask you a few questions about the feasibility of starting a diabetes management team in your practice setting. There is no right or wrong answer to the questions. Anything you tell me will help me to understand better this important clinical issue. Please feel free to elaborate as much as needed on your answers. Are there any questions?

1. What has gone well with implementation of the diabetes management team?
2. What were the struggles involved in starting a diabetes management team?

Appendix H Frequently Asked Questions

QUESTIONS AND ANSWERS

Q. How long will the focus group take?

A. The interview will include two open ended questions, with prompts to be used if needed. It is estimated that the focus group will take approximately 30 minutes.

Q. How did I get chosen to participate?

A. You are part of the diabetes management team at the clinic, every member of the team is being asked to participate.

Q. How will information from the study be used?

A. You are participating in a research study, investigated by a Oregon Health and Science University, Doctor of Nursing Practice student, in partial fulfillment of the program requirements. Information obtained will be analyzed and presented for publication upon acceptance by the University's research committee.

Q. Will my name appear on any documents?

A. No, you will not state your name on the audio tape, and your the tapes will not be transcribed. Furthermore you will give verbal agreement for participation in this study, so you will not sign a written consent sheet. Your name will not appear on any documents. The audio tape containing your voice answers will be sealed in a confidential envelope and locked in a file cabinet until the completion of the study, at which time it will be destroyed.

Q. Why should I participate?

A. Your participation is important to further nursing research and to provide insight into the feasibility of starting multidisciplinary diabetes management teams in free clinics.

You will have an opportunity to ask additional questions before the interview.

Appendix I. IRB Approval Letter

OREGON HEALTH & SCIENCE UNIVERSITY
Research Integrity Office, L106-RI
2525 SW First Avenue, Portland, OR 97201
Phone: (503) 494-7887

MEMO

Date: December 22, 2008

To: Gary Laustsen, PHD, MS

From: Susan B. Bankowski, M.S., J.D., Chair, Institutional Review Board, L106-RI
Gary T. Chiodo, D.M.D., F.A.C.D., Director, OHSU Research Integrity Office, L106-RI
Charlotte Shupert, Ph.D., Associate Director, Research Integrity Office, L106-RI
Kara Manning Drolet, Ph.D., IRB Co-Chair, Institutional Review Board, L106-RI
Susan Hickman, Ph.D., IRB Co-Chair, Institutional Review Board, L106-RI
Elizabeth Steiner, M.D., F.A.A.F.P., IRB Co-Chair, Institutional Review Board, L106-RI

Subject: IRB00004847, Program Evaluation: Multidisciplinary Disease Management and Diabetes Care in a Free Medical Clinic

Initial Study Review
Protocol/Consent Form Approval

This memo also serves as confirmation that the OHSU IRB (FWA00000161) is in compliance with ICH-GCP codes 3.1-3.4 which outline: Responsibilities, Composition, Functions, and Operations, Procedures, and Records of the IRB.

This study is approved for 50 records, 30 subjects.

Your protocol is approved for one year effective _12/22/2008_.

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OHSU

Jessica Johnson
Doctor of Nursing Practice Candidate
Program Presentation, Spring 2009
Oregon Health & Science University

Introduction

- DNP Program
  - Why do it?
  - Expectations?
  - End result

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Introduction

- Population focus
  - low income, uninsured individuals with diabetes
  - Grace Clinic

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Clinical Inquiry Project

Program Evaluation: Multidisciplinary Disease Management and Diabetes Care in a Free Medical Clinic

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Background Significance

- Rates of uninsured are climbing
- Rates of diabetes are climbing
- People with lower SES have worse quality of care
- Barriers for free medical clinics to provide chronic care

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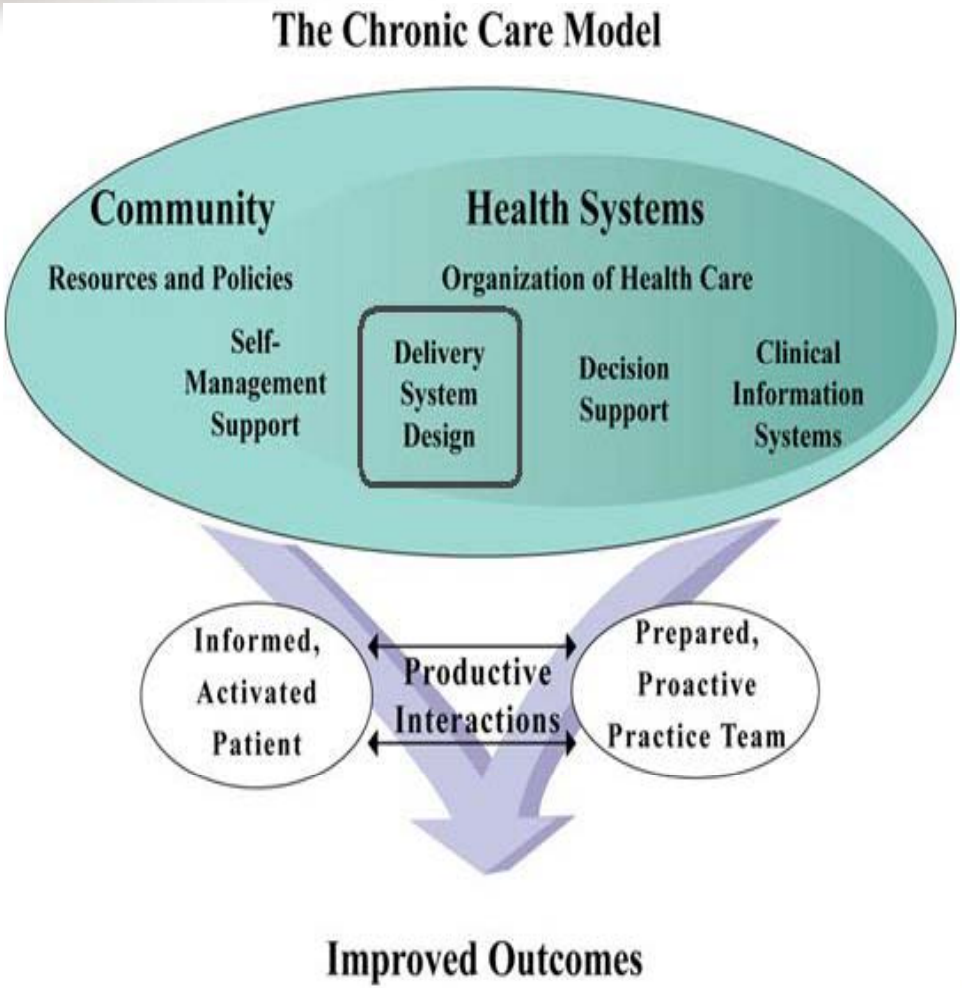
Conceptual Framework

The Robert Wood Johnson Foundation funded research to test the CCM nationally across varied health care settings, creating the national program Improving Chronic Illness Care (ICIC).

Most recent changes occurred in 2003

Identifies essential elements of a health care system that encourage high-quality chronic disease care



Literature Review

Key Study

- Stroebel et al, 2005
  - Similar setting: uninsured patients in a free medical clinic in Rochester, open 2 nights per week, volunteer staffed.
  - Interventions: multiple interventions aimed at all levels of CCM
  - Results: CCM successfully used in FC
    - HgA1c 9.68/8.44 $p<0.001$
    - LDL 174.2/130.6 $P<0.001$
    - BPs 110/97.4 $p<0.001$

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Literature Review

Key Study

- The California Medi-Cal Type 2 Diabetes Study
  - Population: Low income, ethnic minorities
  - Intervention: randomized patients to either intervention with diabetes case management or usual care
  - Results: HgA1c 9.54/7.66 in intervention group and was significantly better than control group $p<0.001$

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Research Questions

1. Does participation in the services provided by a diabetes management team improve glycosylated hemoglobin, lipid profile, blood pressure, and weight among patients with diabetes in a free clinic?
2. What is the feasibility of starting a diabetic management team in a free clinic setting?

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Setting

- Tri Cities Washington
  - Benton and Franklin counties
  - Large immigrant population
- Grace Clinic
  - Free medical clinic for uninsured
  - 100% below federal poverty level
  - Provides primary care, medications, laboratory, mental health counseling, food cupboard, etc

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Sample: Question 1

- Inclusion Criteria
  - Adults
  - Type 2 Diabetes
  - A1C, lipids, BP and wt recorded 1 year prior to DMT program and within the year following the program initiation
- Exclusion criteria
  - Type 1 diabetes
  - Gestational diabetes

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Sample: Question 2

- Diabetic Management Team (DMT)
  - Medical Director, family practice MD
  - Clinic Director, RN
  - Diabetes Specialist, NP
  - Masters prepared nurse
  - Retired internal medicine MD
  - Registered Dietician

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Intervention

- Diabetic Flowsheet
  - Treatment and management algorithms
- Standardize Diabetes Education
- Nutrition counseling
- Insulin clinic
- Access to modified food cupboard

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Design

- Research Question 1
  - Single group
  - Quasi- experimental, pretest-posttest
- Research Question 2
  - focus group
  - qualitative, descriptive design

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Analytical Methods

- Research Question 1 Variables
  - Glycosylated Hemoglobin
  - Lipids
  - Blood pressure
  - Weight
- Descriptive Statistics
- Repeated measures t-test

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Repeated Measures *t* test

- Also called paired *t* tests and correlated *t* test
- Compares differences between two groups.
- “Groups with less variability will be more likely to be significantly different then groups with wide variability”.

  » Chapter 5, pg 139

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Analytical Methods

- Research Question 2
  - Focus Group made up of DMT
  - Open ended questions
  - Themes and exemplar cases

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Protection of Human Subjects/Ethics

- Oregon Health and Science University IRB
- Permission from the Grace Clinic
- Informational consent form for DMT
- No consent needed for retrospective chart review

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Results

- Physiological measures
  - Glycosylated hemoglobin
  - Blood pressure
  - Weight
  - Lipid profile: total, triglyceride, LDL and HDL
- Feasibility

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Research question 1

- Does the DMT interventions improve glycosylated hemoglobin, lipid profile, blood pressure, and weight among patients with diabetes in a free clinic?
- Repeated measure T test

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Results: question 1

Measure	Initial	Final	Change	p-value*
Mean HgA1c (sd)	8.47 (1.97)	7.62 (1.36)	-0.85 (1.43)	0.000
Mean BPs (sd)	132.1(18.55)	121.3 (20.72)	-10.8 (22.56)	0.001
Mean BPd (sd)	82.0 (10.89)	76.4 (11.39)	-5.60 (13.43)	0.005
Mean Wt (sd)	202.5 (48.45)	201.2 (49.37)	-1.3 (9.39)	0.348
Mean TC (sd)	178.8 (31.41)	169.9 (35.08)	-8.9 (33.37)	0.065
Mean Tri (sd)	178.8 (103.15)	150.6 (60.33)	-28.2 (92.86)	0.036
Mean LDL (sd)	101.6 (31.65)	94.8 (30.36)	-6.8 (22.93)	0.103
Mean HDL (sd)	41.0 (8.15)	42.3 (8.47)	1.3 (5.03)	0.093

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Results: question 1 (cont)

- Glycosylated Hemoglobin
  - Statistically significant difference found between groups
  - P <0.001
  - Sample size 50
  - Average pre 8.47. Average post 7.62
  - (-0.85) change

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Results: question 1 (cont)

- Weight
  - No statistical significant change in pre and post groups
  - Average pre wt 202.5, average post wt 201.2
  - (-1.3) change

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Results: question 1 (cont)

- Blood Pressure
  - Systolic
    - Statistical significant change, p< 0.001
    - pre132.1, post 121.3
  - Diastolic
    - Statistically significant change, p< 0.005
    - Mean pre/post- 82.0/76.4

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Results: question 1 (cont)

Lipid Profile: no statistically significant change found

- Total Cholesterol
  - Mean pre/post- 178.8/169.9 p= 0.065
- Triglycerides
  - Mean pre/post - 178.8/150.6 p= 0.036
- LDL
  - Mean pre/post – 101.6/ 94.8 p=0.103
- HDL
  - Mean pre/post – 41.0/42.3 p=0.093

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Results: question 2

Three major themes:

1. Standardization of care
2. Role of team members
3. Challenge of time

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Standardization of Care

- Algorithm infused diabetic flow sheet
  - Track and manage ongoing care
  - Treatment reminders
    - For standards of care
    - For new or “rusty” providers
  - Standardization among variety of providers
- Diabetic Education
  - Standardizing teaching among different providers

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Team Members

Positives

Inter-professional collaboration

- Comprehensive tool development
- Friendships
- Large amount of ideas were generated.
  - ie: diabetes fair

Negatives

- At times too much collaboration caused decreases in production.

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Challenge of Time

- Unanimously the team felt time was the largest challenge to making the DMT feasible
  - Magnified with voluntary groups
- Meetings
  - Once a month, everyother, quarterly?

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Discussion

- Context:
  - volunteer staffed free clinic
  - culturally diverse population

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Interpretation

Data suggests relationship between DMT and improvements in 6 of 8 biophysical markers

Statistical vs clinical significance

Research Questions

1. Does participation in the services provided by a diabetes management team improve glycosylated hemoglobin, lipid profile, blood pressure, and weight among patients with diabetes in a free clinic?
2. Is starting a diabetic management team in a free clinic setting feasible?

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Interpretation

Glycosylated Hemoglobin

- Statistically significant difference found between groups $p<0.001$
- Average pre 8.47. Average post 7.62, (-0.85) change

Blood Pressure

- Systolic
  - Statistical significant change, $p< 0.001$
  - pre132.1, post 121.3
- Diastolic
  - Statistically significant change, $p< 0.005$
  - Mean pre/post- 82.0/76.4

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Interpretation

Lipid Profile: Clinical vs Statistical significance

- Total Cholesterol
  - Mean pre/post- 178.8/ **169.9** p= 0.065
- Triglycerides
  - Mean pre/post - 178.8/ **150.6** p= 0.036
- LDL
  - Mean pre/post – 101.6/ **94.8** p=0.103
- HDL
  - Mean pre/post – 41.0/42.3 p=0.093

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Discussion

- Limitations
  - Not a randomized study
  - Data was averaged
  - Control for other variables
    - Cultural factors
    - Number of visits to the clinic

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Discussion

- Contribution
  - Identified a need for these patients and intervened
  - DMT member
  - Principle investigator

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DNP Program Competencies

The DNP program prepares nurses who will, using leadership and collaboration:

- Practice within an advanced practice nursing specialty in a professional, evidence-based, skilled and ethical manner.
- Influence health and health outcomes of individuals, groups, and populations through clinical inquiry.
- Influence health policy and systems of health care in the local, regional, state, national and international forums.

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In the end….or the beginning…

"This is not the end. It is not even the beginning of the end. But it is, perhaps, the end of the beginning."

»Winston Churchill

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Bringing Christ's love and healing to those in need

November 2, 2008

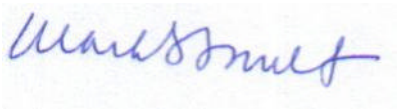
Jessica Johnson, RN, MSN, ARNP
Three Rivers Family Medicine
945 Goethals Dr.
Richland, WA 99352

Re: Research Project

Dear Jessica:

Thank you for the copy of your CI Manuscript outlining the research project that you are undertaking at Grace Clinic. The Clinic is pleased to participate with you in this effort. Thank you for your continued interest in the work of Grace Clinic.

Very Truly Yours,



Mark C Brault
President

509-735-2300 - fax 509-735-2323
email: GraceClinic@GraceClinicOnline.org – www.GraceClinicOnline.org
P.O. Box 6794 – 3180 West Clearwater Avenue, Suite A – Kennewick, Washington 99336 – USA
A United Way Partner Agency

APPENDIX

QUESTIONS AND ANSWERS

Q. How long will the focus group take?

A. The interview will include two open ended questions, with promps to be used if needed. It is extimated that the focus group will take approximately 30 minutes.

Q. How did I get chosen to participate?

A. You are part of the diabetes management team at the clinic, every member of the team is being asked to participate.

Q. How will information from the study be used?

A. You are participating in a research study, investigated by a Oregon Health and Science University, Doctor of Nursing Practice student, in partial fulfillment of the program requirements. Information obtained will be analyzed and presented for publication upon acceptance by the University's research committee.

Q. Will my name appear on any documents?

A. No, you will not state your name on the audio tape, and your the tapes will not be transcribed. Furthermore you will give verbal agreement for participation in this study, so you will not sign a written consent sheet. Your name will not appear on any documents. The audio tape containing your voice answers will be sealed in a confidential envelope and locked in a file cabinet until the completion of the study, at which time it will be destroyed.

Q. Why should I participate?

A. Your participation is important to further nursing research and to provide insight into the feasibility of starting multidisciplinary diabetes management teams in free clinics.

You will have an opportunity to ask additional questions before the interview.

INFORMED CONSENT COVER SHEET

Jessica Johnson, FNP-BS, MN, DNP candidate Oregon Health and Science University
509-432-9641

RESEARCHERS STATEMENT. You are being asked to participate in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to participate in the study or not. Please read the form carefully. This process is called 'informed consent.' You may keep a copy of this form for your records. This study has been reviewed and approved for human subject participation by Oregon Health and Science University Institutional Review Board.

PURPOSE AND BENEFITS

The purpose of this focus group is to obtain information about the feasibility of starting a diabetes management team in the free clinic setting, including what aspects of the program were successful and which were not. As a participant you will not directly benefit from participating in this study. There will be no compensation paid to you for your participation.

PROCEDURES

The interview consists of 2 open-ended questions. It is estimated to take approximately thirty minutes. The interview will be audio recorded to verify accuracy of field notes.

RISKS, STRESS, OR DISCOMFORT

There are no known emotional or physical risks associated with your participation in this study. You may experience some minor discomfort in answering the interview questions.

CONFIDENTIALITY

Recorded information will be kept confidential and available only to the investigator and the faculty committee. Any publications resulting from this study will report group data and will not identify you specifically.

SUBJECT RIGHTS

You may contact the investigators at 509-432-9641 if you have any questions about your participation in this study. Should you have any questions regarding your rights as a study participant you may contact the OHSU Institutional Review Board at ___.

OTHER INFORMATION

The audiotapes from the interviews will be stored separately from the completed demographic questionnaires and signed consent form. Only the investigator and her faculty thesis committee will have access to your audio-tape. The tape will be incinerated when it is no longer needed.

VOLUNTARY PARTICIPATION/WITHDRAWAL

Participation in this study is voluntary and you may withdraw at any time.

Appendix

Nurse practitioner interview guide
Open ended questions

Start Tape Recorder

Investigator's Statement: I am going to ask you a few questions about the feasibility of starting a diabetes management team in your practice setting. There is no right or wrong answer to the questions. Anything you tell me will help me to better understand this important clinical issue. Please feel free to elaborate as much as needed on your answers. Are there any questions?

1. What has gone well with implementation of the diabetes management team?

2. What were the struggles involved in starting a diabetes management team?

OREGON HEALTH & SCIENCE UNIVERSITY
Research Integrity Office, L106-RI
2525 SW First Avenue, Portland, OR 97201
Phone: (503) 494-7887

MEMO

Date: December 22, 2008

To: Gary Laustsen, PHD, MS

From: Susan B. Bankowski, M.S., J.D., Chair, Institutional Review Board, L106-RI
Gary T. Chiodo, D.M.D., F.A.C.D., Director, OHSU Research Integrity Office, L106-RI
Charlotte Shupert, Ph.D., Associate Director, Research Integrity Office, L106-RI
Kara Manning Drolet, Ph.D., IRB Co-Chair, Institutional Review Board, L106-RI
Susan Hickman, Ph.D., IRB Co-Chair, Institutional Review Board, L106-RI
Elizabeth Steiner, M.D., F.A.A.F.P., IRB Co-Chair, Institutional Review Board, L106-RI

Subject: IRB00004847, Program Evaluation: Multidisciplinary Disease Management and Diabetes Care in a Free Medical Clinic

Initial Study Review
Protocol/Consent Form Approval

This memo also serves as confirmation that the OHSU IRB (FWA00000161) is in compliance with ICH-GCP codes 3.1-3.4 which outline: Responsibilities, Composition, Functions, and Operations, Procedures, and Records of the IRB.

This study is approved for 50 records, 30 subjects.

Your protocol is approved for one year effective 12/22/2008 .

Other items reviewed and administratively approved by the IRB include:

- Lay Language Protocol Summary
- Information Sheet
- Interview Guide
- Data Extraction Form
- FAQ Sheet

Other items reviewed and noted by the IRB include:

- Diabetes Education Form and Flow Sheet
- Grace Clinic Support Letter

This study met the criteria for EXPEDITED IRB review based on Categories 5 and 7: Category 5: Research involving records that have been collected, or will be collected, solely for non-

research purposes (such as medical treatment or diagnosis); Category 7: Research employing focus group methodologies.

The requirement to obtain informed consent and HIPAA authorization for 50 records has been waived or its elements have been altered in accordance with 45CFR46.116(d)(1-4) and 45CFR164.512(i)(1)(i). This memo confirms:

- That the research involves no more than minimal risk to the subjects;
- That the waiver will not adversely affect the rights and welfare of the subjects;
- That the research could not practicably be conducted without the waiver;
- That the research could not practicably be conducted without access to and use of the PHI;
- That the use or disclosure of the PHI involves no more than minimal risk to the privacy of the subjects as a result of:

    - An adequate plan to protect the PHI from improper use and disclosure;
    - An adequate plan to destroy any identifiers contained in the PHI at the earliest opportunity consistent with the research;
    - Adequate written assurances that the PHI will not be reused or re-disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted; and
    - Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

This waiver of consent and authorization applies only to the PHI for which use or access has been requested and described in the attached request for waiver.

This memo confirms approval of an alteration to the consent/authorization process for the above referenced protocol (focus groups). The requirement to obtain consent and authorization from research subjects has not been waived. The requirement to obtain a signed consent form has been waived in accordance with 45CFR46.109(c), 45CFR46.117(c)(1-2) and 45CFR164.512(i)(1)(i)as:

- The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Accounting for disclosures is not needed because the information will not be disclosed outside of OHSU.

This approval may be revoked if the investigators fail to conduct the research in accordance with the guidelines found in the Roles and Responsibilities document (http://www.ohsu.edu/research/rda/rgc/randr.pdf). Please note that any proposed changes in key personnel must be submitted to the IRB via a Modification Request and approved prior to initiating the change. If you plan to discontinue your role as PI on this study or leave OHSU, you must arrange either (a) to terminate the study by so notifying the IRB and your department head,

or (b) propose to transfer the responsibility of the PI to a new faculty member using a Modification Request.

OHSU Research Integrity Office, 3181 SW Sam Jackson Road, Mail code L106-RI,
Portland, OR 97239-3098 Phone: 503-494-7887 ◆ Fax: 503-494-5081

LAY LANGUAGE PROTOCOL SUMMARY

Principal Investigator: **Jessica Johnson** IRB#:

Study/Protocol Title: **Program Evaluation: Multidisciplinary Disease Management and Improved Diabetes Care in a Free Medical Clinic**

Please answer all of the following questions using lay language, similar to the language used in a consent form. Please number your responses.

1. Briefly describe the purpose of this protocol.

The purpose is to evaluate a diabetes management program in a free clinic to see if this improves diabetes care as measured by changes in hemoglobin A1C, blood pressure, weight and lipids.

2. Briefly summarize how participants are recruited.

The subjects will not be recruited. They are already patients at the clinic and come voluntarily for health services.

3. Briefly describe the procedures subjects will undergo.

Office visits with medical provider, medication management, laboratory testing. Other services will be available including diabetic education, nutrition counseling, insulin clinics and access to food cupboard.

4. If applicable, briefly describe survey/interview instruments used.

There are no survey or interview instruments needed for this study. A focus group will be interviewed using 1-2 open ended questions (not yet written).

5. If this is a clinical trial using an experimental drug and/or device, or an approved drug and/or device used for an unapproved purpose, briefly describe the drug and/or device.

This study does not use experimental drugs and/or devices, or an approved drug and/or device used for an unapproved purpose

6. Briefly describe how the data will be analyzed to address the purpose of the protocol.

The data will be analyzed with repeated measures T test for the continuous variables and qualitative descriptive design for the focus group. Demographic variables will be analyzed with descriptive statistics.

Note: For GCRC studies, this abstract is submitted to the NIH/NCRR and may be entered into the publicly available CRISP database.

Document Control No.: IRB-LAY-01
Original Date:04/10/2004; Revision Date: 06/30/2004

PPQ#_____

PROPOSED PROJECT QUESTIONNAIRE (PPQ) – PLEASE TYPE

Oregon Health & Science University Research Development and Administration (RDA)

This form must accompany all ☐ grant/contract applications and new protocols submitted for review by ☐ IRB or ☐ IACUC.

GENERAL INFORMATION

Principal Investigator (Last name, First name, Degrees) | **Telephone Number** | **Mail Code** | **Email Address** | **NIH Commons UserID**

Contact for questions during proposal review process (Last name, First name) | **Telephone Number** | **Mail Code** | **Email Address**

School/Unit: | **Department:** | **Division:**

Award Owning Org Name (Name of the org that the Award will be assigned to and that will receive F&A credit unless otherwise specified below): Please see the OHSU Project-Owning Org Finder Tool.

Will F&A be shared by more than one department or unit? * If yes, indicate agreement by having each department/unit head and each internal project PI sign this PPQ. Also include an internal budget showing the distribution of funds requested. ☐ Yes* ☐ No

Project Title (240 characters maximum. Same as project title listed in grant or contract.)

Project Short Title (30 characters maximum. Will be displayed in OGA. Must be unique for each OGA Project under an OGA Award)

Award Short Title (30 characters maximum. Will be displayed in OGA.)

Project Dates *(N/A for industry contracts)*
Initial Budget Period (Next if Non-Competing) From: _____ Thru: _____
Entire Proposed Project Period From: _____ Thru: _____

Keywords (Please provide 3-5 keywords): _____ _____ _____ _____ _____

Applicant Organization
☐ OHSU ☐ Other*
*If Other, please specify pass-through organization that will issue a subcontract to OHSU: _____

Sponsor: _____
(Example: NIH, American Heart Association, Acme Co.)

Sponsor Deadline: _____

Clinical Research Organization (CRO) (If applicable for an industry sponsored clinical drug / device investigation): _____
See Clinical Research Organization definition.

Funding Opportunity Number, Request for Proposal (RFP) #, Request for Application (RFA) #, Program Announcement (PA) #, or URL address for special instructions, if applicable: _____

ACTIVITY AND F&A RATE INFORMATION

Does the funding agency have a published policy requiring the use of an F&A rate that differs from OHSU's federally negotiated rate (See OHSU's F&A Cost Rates**)?** * If yes, please attach the published rate and policy of the funding agency. This does not apply to industry sponsors. ☐ Yes* ☐ No
Funding Agency Rate * _____

Primary location (Building Name) where the work is being performed (See the OHSU Building List**):** _____
% of work performed at this location: _____
Indicate 'Off-Campus' if the work is being performed at a non-OHSU facility.

Is the research primarily Basic or Applied? See Basic/Applied Research Definitions. If the project is not research, select N/A
Please select one: ☐ Basic ☐ Applied ☐ N/A

TYPE OF FUNDING INFORMATION

Funding Mechanism *Click Here to Select Funding Mechanism* * If Other, please specify: _____
If a Program Development Account (PDA) is funding this project, please specify the PDA account number: _____

Grant/Contract Type *Check all that apply*
☐ New – new project not previously funded by this sponsor
☐ Resubmission – revised or amended version of application not funded
☐ Competing Renewal – competitive application for funded project Sponsor Grant# _____
☐ Amendment/Supplement – request for additional funds Sponsor Grant# _____ *(if applicable)*
☐ Non-Competing Renewal * – renewal of a funded project (i.e., NIH progress report) Sponsor Grant# _____
** If this project involves humans and/or animals, please indicate applicable IRB Protocol #(s) _____ or IACUC Protocol #(s) _____*
☐ NIH eSNAP *
** If this project involves humans and/or animals, please indicate applicable IRB Protocol #(s) _____ or IACUC Protocol #(s) _____*

PPQ#_____

COMPLIANCE QUESTIONS	
1. Will human subjects/tissues/data be used in the project? **a.** From the start of the award? (If no, see Preaward Process for Proposals Involving Human Subjects at a Future Time.) **b.** Will the award fund core research or educational resources to be used by multiple independent human research projects (i.e., GCRC, OCI infrastructure, etc.)? All projects involving human subjects/tissues/data must be submitted to and approved by the IRB prior to beginning work on new projects or modifications to existing protocols.	☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No
2. Will animals be used in the project? **a.** * If yes, will non-human primates be used in the project? All projects involving animals must be submitted to and approved by the IACUC prior to beginning work on new projects or modifications to existing protocols.	☐ Yes* ☐ No ☐ Yes ☐ No
3. If this study involves humans or animals, did OHSU personnel design/develop the study protocol? The answer to this question will help determine how to handle the intellectual property terms of the proposal, determine appropriate IRB fees for the study, and allow tracking of this information for reporting and management purposes.	☐ Yes ☐ No ☐ N/A
4. Will this project involve the use of non-recombinant infectious agents or certain biologically-derived toxins (including select agents and infectious proteins, cells, viruses, bacteria, etc.)? See Definition. * If yes, complete the Infectious Agent/Toxin Questionnaire and submit it with this PPQ. **-OR-** Approved IBC registration #: _____	☐ Yes* ☐ No
5. Will this project involve the use of recombinant DNA (rDNA, includes all recombinant plasmids/vectors/viruses)? ***** If yes, complete the Initial rDNA Research Classification Form and submit it with this PPQ. **-OR-** Approved IBC registration # is: _____ **-OR-** This project was previously determined to be exempt and no changes are proposed that will affect the exempt status ☐	☐ Yes* ☐ No
ADMINISTRATIVE QUESTIONS	
6. Does this application or proposal include committed cost-sharing/matching (i.e., is effort being committed without requesting that sponsor support salary at the same level? Are other resources, like new equipment or supplies, being committed without a budget request to support them?) *Does not apply to industry sponsors.* See the OHSU Cost Sharing Procedure. * If yes, see the Department Award Checklist (DAC) provided by RGC for instructions for awards containing cost-sharing. If the cost sharing is from multiple departments, please complete a Cost-Sharing Agreement Form for each Department committing resources and submit with PPQ. If the cost sharing is with the VA, the Cost Sharing Agreement Form should be signed by the appropriate VA clinical service chief and submitted with the PPQ. *(Does not apply to internally funded projects; e.g., Bio-Science Innovation.)*	☐ Yes* ☐ No ☐ N/A
7. Do any of the personnel listed on this project who have paid or unpaid appointments at OHSU also have paid VA appointments? ***** If yes, please provide the most recent copy of the memorandum of understanding (MOU), dated within one year. The MOU is not required if the project is industry-sponsored. Note that if this project is funded, an updated MOU that accounts for effort on this project will be required at time of award. If any persons listed on this project have unpaid OHSU appointments and paid VA appointments, please be sure to complete the VA cost-sharing requirements referenced in Question 6 above.	☐ Yes* ☐ No
8. Does this project involve Portland Veterans Affairs Medical Center (PVAMC) resources? * If yes, please have this PPQ signed by the VA ACOS/R&D (Associate Chief of Staff for Research & Development) and prepare a VA PPQ for submission with the OHSU PPQ. In certain cases, the Research Service at the PVAMC will need to obtain the approval of the VA clinical service chief prior to VA signature on the OHSU PPQ. If this proposal includes research related expenses that will be incurred by the VA, you will need to complete a VA Administrative Review prior to VA signature of the OHSU PPQ. Non-competing renewals do NOT require a VA PPQ or VA Administrative Review. Please check all the following VA resources that apply: ☐ VA Space If checked, please indicate the VA Building Name: *Click Here to Select Building* ☐ VA Equipment ☐ VA patients seen at PVAMC	☐ Yes* ☐ No
9. Is OHSU to subcontract part of the work? * If yes, please include approved administrative materials for all proposed subcontractor institutions. Subcontract materials must be signed off in advance by authorized officials of the subcontract organizations. See the List of Required Subcontract Administrative Materials. *(Does not apply if sponsor is industry.)*	☐ Yes* ☐ No
10. If you are applying to a private foundation, have you submitted an OHSU Foundation Clearance Request Form? If you are applying to a private foundation for funding, please complete an OHSU Foundation Clearance Request Form and email it to rosenbra@ohsu.edu at the OHSU Foundation prior to submitting your application to RDA. The OHSU Foundation clearance process allows the university to ensure the expectations and limited submission policies of foundations are upheld.	☐ Yes ☐ No ☐ N/A

11. Which of the following University Shared Resources has been included in your research plan? (*please select all that apply)*

☐ Advanced Computing - Dir. Gliessman	☐ DNA Microarrays – Dir. Harrington/Searles	☐ Confocal and Deconvolution Microscopy – Dir. Keller
☐ Bioanalytical/Pharmacokinetics - Dir. Koop	☐ Histopathology – Dir. Corless	☐ Proteomics – Dir. David
☐ Biostatistics - Dir. Mori	☐ Oligonucleotide Synthesis – Dir. Keller	☐ Transgenic Mouse Models – Dir. Low
☐ Biomedical Informatics - Dir. Logan	☐ DNA Sequence Analysis – Dir. Keller	☐ None of the above

APPROVALS & CERTIFICATIONS

All signatures below are required prior to institutional approval of the proposal.

As the PI of this project, I certify that the information submitted within the application is true, complete, and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and, if a grant or contract is awarded as a result of this proposal, to comply with the terms and conditions of the award, including providing required progress reports. I understand that I am responsible for ensuring that the project is conducted in full observance of the financial, compliance, and administrative requirements described in the OHSU Roles and Responsibilities in Research document.

PI / Project Director, Date
Name:

The signatures of the Division Head, Department Chair and Unit Dean/Director indicate that:

- the proposed scientific work is appropriate;
- space and/or resources are, or will be, available;
- budgeted salaries and effort levels are appropriate for the personnel named in the application;
- the budget proposed is sufficient to cover the costs incurred in the study,
- and that roles and responsibilities assigned to the Division Head, Department Chair and Unit Dean/Director as described in the OHSU Roles and Responsibilities in Research document will be carried out or appropriately delegated.
- If the project involves resources (faculty, staff, equipment, space) from more than one OHSU Department/School/Unit, each Department Chair/Dean/Director should review the proposal and approve it by signing below.

The signature of the VA Research Service does not represent institutional approval. It simply indicates that the VA Research Service is aware of the proposal and the VA review process has commenced. The work cannot begin at the PVAMC without the approval of the R&D Committee.

Note: All staff with direct involvement in the design and/or conduct of the project (including, but not limited to, the principal investigator, co-investigators, research assistants/coordinators, and collaborators) must:

- Complete OHSU's Responsible Conduct of Research (RCR) Education
- Have a current OHSU Conflict of Interest in Research Disclosure form on file
- See Requirements for Investigators Outside OHSU

Division Head, Date Name:	Department Chair, Date Name:	Dean / Director, Date Name:
Division Head, Date Name: *(if appropriate)*	Department Chair, Date Name: *(if appropriate)*	Dean / Director, Date Name: *(if appropriate)*
VA ACOS/R&D, Date Name:	SON Advisor, Date Name: (*if PI is SON student*)	*Other:*

Running head: IMPROVING ACCESS TO CARE TO THE UNINSURED

Malpractice Insurance for Volunteer Providers:

Improving Access to care to the uninsured in Western Washington

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Oregon Health and Science University

Abstract

Malpractice Insurance for Volunteer Providers:

Improving Access to Care to the Uninsured in Western Washington

Define the Context

There are more than 47 million people without health insurance in the United States according to 2006 data. This represents an increase of more than 2 million from the previous year. The percentage of the population without health coverage has increased from 15.2% in 2005 to 15.6% in 2006 (U.S. Census Bureau, 2007). The decreasing access to primary care services presents a challenge at the local level as well. Information from the 2006 Washington State Population Survey shows that13% of the state's population is uninsured, totaling more than 787,000 people (Kaiser Family Foundation, 2006).

The United States remains the only industrialized country without a national health care plan. While many industrialized countries developed national healthcare in the first half of the 20th century, the United States has lagged far behind in any efforts to provide national healthcare (Blankenau, 2001). According to Navarro (1995), as long ago as 1980 Americans have supported a national health care program, but Congress has failed to enact such a program as early as 1913 when it was first attempted (Emanuel & Fachs, 2005). As far back as 1945 President Truman saw the need of government influence on healthcare and attempted to enact a single payer system which was defeated in part due to the large campaign by the American Medical Association characterizing the bill as "socialized medicine" and capitalizing on public fear of Communism (Truman Library and Museum). The inability to pass a national health plan reflects the disconnect between single payer systems and the American values.

The country's political institutions have played a significant role in the evolution of the current health care configuration. The political structure of the United States emphasizes a

separation of powers among the legislative and executive branches. This power structure, along with political party partisan behavior, results in significant opportunities for opposition and creates a need for monumental mobilization to overcome the status quo (Blankenau, 2001). Special interest groups have evolved to have an ever increasing role in health care policy (Navarro, 1995). Despite multiple failed healthcare reform efforts in the last century and overwhelming public support, the U.S. remains the only industrialized nation without a national health plan. This could change in the upcoming years as the 2008 election brings with it a number of delegate campaigns promising radical reformation and many platforms support national healthcare.

The economic cost of the current healthcare system is overwhelming and is rising at the fastest rates in United States history. The total national health expenditures rose by almost 7% in 2005, two times the rate of inflation. Total health care spending reached $2 trillion about $6,700 per capita in 2005 and if it continues increasing at the same rate, it is projected to reach $4 trillion in 2015. Total health spending represented 16% of the gross domestic product in 2005, compared to 10.9% of spending in Switzerland, 10.7% for Germany and 9.7% in Canada (National Coalition on Healthcare, 2007). The cost to those without insurance and those who pay out of pocket for medical expenses are charged 2.5 times more for hospital care than those covered by health insurance and more than 3 times the allowable amount paid by Medicare (Anderson, 2007).

To combat the problem of the growing number of uninsured, communities have established clinics aimed to help the underserved population. Free clinics are non-profit, community based organizations that provide a variety of medical care, primary care, mental health counseling, pharmaceutical and dental services at little or no cost to low-income,

uninsured people (National Association of Free Clinics, 2007). The majority of free clinics operate with only one or two paid workers, and rely heavily on volunteer practitioners to provide care. In 2003 there was an estimated 1,718 free clinics across the United States, providing care to more than 2.5 million people (Isaacs & Jellinek, 2007).

Volunteerism has a long history in the United States starting when Benjamin Franklin established the first volunteer firefighting company in 1739. The paradigm gained momentum in the years following. In 1881 Clara Barton established the American Red Cross, in 1887 the United Way organization was founded and in the early 1990's the Rotary, Lions and Kiwanis clubs were founded. In the last fifty years significant volunteerism has taken place, including the establishment of the Peace Corps by President Kennedy in 1961 (Points of Light, 2006) and numerous medical missionary groups similar to the International Health Volunteer Organization, an outreach program of the Academy of Medicine which was created in 1959 (International Health Volunteers, 2002) and Doctors without Borders, established in 1971 (Doctors without borders, 2008).

Volunteer health care practitioners have cited many reasons surrounding their desire to volunteer. A large portion of medical volunteers are retired clinicians. Dr, Reynolds (2006) describes volunteering as a therapeutic transition from full time clinic work into retirement. Other reasons clinicians volunteer include the satisfaction found in helping those who are less fortunate, moral or religious convictions, and to give something back to the community (International Health Volunteers, 2002; Reynolds, 2006). Despite the long tradition of volunteering, current data suggests the proportion of doctors willing to provide free services or volunteer at local free clinics has been decreasing (Isaacs & Jellinek, 2007). The literature suggests multiple reasons for the decline of local volunteers, including poor insurance

reimbursement leading to longer work hours and the rising cost of operation in their private practices. Another chief factor leading to the decreasing volunteer rates has been attributed to cost of malpractice maintenance licensure and continuing medical education hours (Isaacs & Jellinek, 2007; Reynolds, 2006).

In 1992, the Washington State Legislature developed the Retired Health Care Provider Liability Malpractice Insurance Program to minimize the costs of malpractice insurance for retired clinicians providing care to low income uninsured patients (Washington State Legislature, 1992). Locally, the program has been managed by the Western Washington Area Health Education Center (WWAHEC), a nonprofit organization working to ensure access to health care for underserved rural and urban populations in Western Washington. This mission is achieved through a number of services, including recruitment of students into health professions, providing education and training opportunities for health professions students and advocating for public policy that addresses the needs of rural and underserved communities (WWAHEC, 2007). WWAHEC is part of the National Area Health Education Center Organization program which was started by Congress in 1971 to recruit and train healthcare professionals committed to underserved populations (National AHEC, 2008).

Since 1992, WWAHEC has managed the malpractice insurance program, called the Volunteer/Retired Providers Program (VRP). The project provides free malpractice insurance to all primary care professionals who provide uncompensated health care services to low-income uninsured patients in Washington State. The VRP eligible providers include doctors, dentists, dental hygienists, physician assistants, nurse practitioners, registered nurses and pharmacists (WWAHEC, 2006).

State the Problem

Access to basic health care is a large problem at the national and local level. In the wake of this disparity free clinics have emerged to provide primary care services to those in need. In order to encourage philanthropy and augment state resources in providing for the health care needs of the uninsured, Washington State has developed an innovative program providing free malpractice insurance to eligible health care professionals who care for the growing underserved population. Through discussion of this subject many substantial concerns become apparent. For instance, the lack of universal basic health, the growing number of uninsured, the litigious nature of society, and the decreasing amount of charity care by providers. For the purpose of this paper, the chief problem of interest is the declining rate of volunteers contributing to the decreased access to care for the uninsured.

The Evidence

The Uninsured Population

The number of uninsured in the United States has increased from 30 million in 1990 to over 47 million in 2006 (Nadkarni & Philbrick, 2005; U.S. Census Bureau, 2007). Roughly 75 million people were without health insurance for at least part of 2001 and 2002, about one in three under the age of 65 (Families USA, 2003). The struggle with the health care system in this population includes a decreased access to care and a decrease in quality of care. Uninsured people are less likely to have a primary care provider and less likely to receive preventative services. They are more likely to delay seeking medical care and have an increase in utilization of emergency department visits (Hadley & Cunningham, 2004; Nadkarni & Philbrick, 2005).

Although the homeless and unemployed often come to mind when discussing uninsured people, demographic information released in 2003 shows that more than 70% of uninsured

people were employed and another 7% were actively seeking employment. A 2003 report (Families USA, 2003) released by the Robert Wood Johnson Foundation , a private foundation working to improve health and heath care of Americans, showed more than half the people whose salaries were less than 100% of the federal poverty level (FPL) were uninsured. Just under half of those falling below 200% of the FPL were uninsured. The rate significantly decreased as salaries increased and at 400% of the FPL the percentage of uninsured was 16%.

According to reports by the Center for Immigration, the nation's total immigrant population was estimated at 37.9 million, 34 % of which lack health insurance coverage (Camarota, 2004). Studies link the high percentage of uninsured immigrants to lack of education and lack of employment based health coverage, reporting that immigrants are more likely to be employed in low wage, service or trade skill that are less likely to offer health benefits (Camarota, 2004; Frostin, 2005). The number of undocumented illegal immigrants is estimated at11.3 million about 30% of the immigrant population (Camarota, 2004).

Washington State data presents a similar picture to that of the national problem. In 2006 787,000 people living in Washington were uninsured, totaling 13% of the population. Eighty-five percent of those without insurance were employed at least part time and about 60% fell 200% below the FPL (Kaiser Family Foundation, 2006). Washington State has a large population of undocumented immigrants, estimated between 175000 and 200,000. This population represents 25% of Washington's uninsured (Passel, Capps & Fix, 2004).

The Free Clinic Interim Solution

The emergence of free clinics in the 1960's has made a significant impact in quality and access to medical care in the uninsured. Evidence has shown that safety net clinics can decrease the inappropriate use of emergency rooms and hospitals (Hadley & Cunningham, 2005) and

improves morbidity and mortality (Nadkarni & Philbrick, 2005). Free clinics are just one component of the safety net for the uninsured, others include federally qualified health centers (FQHC), public hospitals, local health departments, and academic medical centers (Hadley & Cunningham, 2004; Nadkarni & Philbrick, 2005; Soto, Bazyler, O'Toole, Brownson & Pezzullo, 2007). Together these establishments share the responsibility of providing care to those with no or limited insurance, at little or no charge.

The actual number of free clinics is not well documented in the literature. Some studies report 350 clinics (Nadkarni & Philbrick, 2005) while others document the number to be more than 1,700 (Isaacs & Jellinek, 2007). The broad range of estimates is likely due to the financial strain placed upon clinics leading to instability and failure. The volatile nature of these clinics has been documented in the literature. One large survey of free clinics found that more than 75% of clinics had been in operation less than 10 years (Geller, Taylor & Scott, 2004). Other reports have attempted to contact clinics supposedly in operation, only to find that they have closed abruptly (Nadkarni & Philbrick, 2005). The common characteristic found in free clinic contributing to their unpredictable existence is the financial struggle (Isaacs & Jellinek, 2007, Soto, Bazyler, O'Toole, Brownson & Pezzullo, 2007). Most free clinics operate of a very small budget, on average about $500,000 annually (Nadkarni & Philbrick, 2005). Most of which is exhausted on operating costs and patient care services, leaving only a modest amount to go toward a paid staff. Consequently, the clinics rely heavily on volunteer licensed independent practitioners to provide health services, including acute and chronic primary care, preventative care, prescription medications, mental health counseling and dentistry. Many clinics can arrange for their patients to receive additional services, including laboratory, radiology and specialty care (Geller, Taylor & Scott, 2004).

The Philanthropists

A common factor in the successful operation of free clinics in their dependence on volunteers at all levels, from the receptionist to the medical providers. According to a national survey, clinics operate with an average of 156 volunteers broken down to include 33 physicians, 2.7 nurse practitioners, and 20.3 nurses. Providers volunteer services on average one to two times per month (Nadkarni & Philbrick, 2005). Despite their continued need, the proportion of doctors in the United States providing philanthropic care has been declining in recent years (Isaacs & Jellinek, 2007; Nadkarni & Philbrick, 2005). The factors surrounding this trend are attributed to decreased insurance reimbursement and the increasing economic burden of operating costs in private practices and the cost of maintaining malpractice insurance and licensing dues (Isaacs & Jellinek, 2007; Reynolds, 2006).

Cost of Litigation

The likelihood of litigation against medical providers in free clinics is improbable. To date, a review of the literature yields no reports of malpractice suits against volunteer providers. Christine Linquist, the program coordinator at the WWAHEC, reports that the population served at free clinics are traditionally the least litigious of all patient populations. Since WWAHEC started the Volunteer/Retired Providers Program in 1992 there have been no claims (Personal communication, February 5, 2008). Although the risk of a malpractice claim in this population is unlikely, the popularity of payouts in private practice is concerning and is likely the cause of apprehension in volunteer sectors. The United States is in general a litigious nation. In 2007 there was a total of 8,849 paid claims totaling $2.89 billion. The average payout was over $325,000. At the state level Washington is comparable with an average payout of 299,000. There were 127 paid claims in Washington in 2007, totaling $38 million (State Health Facts, 2007).

Exploring Alternatives

The Volunteer/Retired Providers Program

The VRP, which stems from a 1992 law by Washington State Legislature, was established to address the declining rate of volunteer clinicians at free clinics and encourage philanthropic service to improve access to care for the uninsured (Washington State Legislature, RCW 43.70.460). Although free clinics in general are not well published, there have been a couple of reports claiming the burden of maintaining malpractice insurance is a contributing factor in the diminishing volunteer trend (Isaacs & Jellinek, 2007; Reynolds, 2006). The VRP addresses this burden by paying for malpractice coverage for providers volunteering at free clinics.

This policy is not alone in its mission or strategy. The Good Samaritan Law covers licensed health care providers volunteering at community health care settings from civil liability, other than acts of omissions constituting gross negligence or willful misconduct. They are protected by state laws, in Washington the coverage falls under RCW title 18, chapter 18.130 (Washington State Legislature, RCW 18.130). The Federal Tort Claims Act (FTCA) also protects licensed health care providers volunteering at community health clinics. The FTCA medical malpractice protection for volunteer free clinic health professionals was enacted by Congress in 2004. Free clinic volunteers are deemed federal employees for the purpose of the malpractice coverage program and litigation cannot be brought against the clinic or provider directly but must be filed against the United States government (U.S. Department of Health and Human Services, 2008). With other government policies in place that protect providers from malpractice claims, this paper analyzes an alternative approaches to address the aforementioned problem.

National Health Care

The need for a single-payer or national health plan has received a great deal of attention in recent years. As the United States continues to get outperformed by other countries with better functioning, lower cost health care, the need to address the quality and equity of health care continues to grow. The suggestion of a single payer has become increasingly popular and many national organizations are endorsing the idea, including the American Nurses Association (ANA, 2005), the American College of Physicians (American College of Physicians, 2007) and the Physicians for a National Health Program (PNHP, 2008).

Since its establishment in 1987 the PNHP has been advocating for universal health coverage. A 2003 proposal for a single-payer national health insurance program outlines the structure, eligibility, budgeting and financing. They estimate that a single payer system alone would save over 200 billion dollars, more than enough to provide health coverage to all of the uninsured. Under their proposed plan, all Americans would have coverage for all medically necessary services, including clinic and hospital visits, long term care, mental health, dental, vision, and prescription drug costs (PHNP, 2003)

Health care reform has been a large issue in the recent presidential campaign. The democratic delegates are calling for more radical reform then their Republican counterparts. Until recently dropping out of the race, democrat Dennis Kucinich was the only candidate supporting a single payer system. Since his withdraw another democratic candidate has entered the election in favor of a universal payer system. Mike Gravel, the former Alaska Senator joins Senator Clinton and Senator Obama as the democratic delegates. Unlike Clinton and Obama, Senator Gravel's plan would provide healthcare coverage for all citizens through a universal healthcare voucher system, eliminating the need for private insurers or for employer based

coverage. The vouchers would be distributed based on projected individual needs and would be dispersed annually. People are free to chose primary care providers and hospitals, and can purchase additional coverage. His plan would eventually eliminate Medicaid and Medicare and these programs would be phased out (Election ProCon, 2008; Votegopher.com 2007)

Senator Clinton addresses the nation's health care needs by proposing mandatory coverage to all Americans. The Clinton plan allows people to continue their current private or employer based coverage but provides the option of low cost government insurance. Tax credits and subsidies will help the low income population purchase the government provided health insurance. Under the Clinton plan employers would be required to provide health insurance for their employees. To pay for this plan, Sen. Clinton would end some of President Bush's tax cuts for households earning more than $250,000 a year (Kaiser Family Foundation, 2008).

Senetor Obama's platform on health care reform aims to improve access to care by decreasing costs of healthcare, ensuring affordability done through the creation of a National Health Insurance Exchange which would regulate the private insurance market for fairness and transparency. He has emphasized achieving lower healthcare costs through increased insurance competition. Under the Obama proposal a national health plan would be developed to offer affordable insurance for the uninsured or people could chose to continue with their current health coverage. The Obama plan does not mandate health care for anyone except children. Senator Obama would fund his plan by collecting employer contributions from businesses that do not cover their employees' insurance and repealing President Bush's tax cuts for households earning more than $250,000 a year (Kaiser Family Foundation, 2008).

Discussion

Project the Outcomes

The ultimate goal is to increase access to care for the uninsured. The current policy under Washington legislature aims to improve access to care for the uninsured by increasing the number of volunteer providers through allocation of financial resources to cover malpractice insurance costs. If the current policy was continued unaffected the outcome would potentially improve access to care to a small percentage of the uninsured population. Volunteers may provide more hours of service because of the decreased burden of having to pay for malpractice insurance.

Single payer plans, like the voucher system proposed by Senator Gravel, would provide access to health insurance for all Americans, allowing free clinics and their volunteers to focus their efforts on the undocumented immigrants who are not eligible for government programs. Free clinics would still be needed, especially in areas with high immigration rates such as Washington which has an estimated 200,000 undocumented immigrants (Passel, Capps & Fix, 2004). Nationally, there are 38 million immigrants, 11 million of which are estimated to be illegal (Camarota, 2004). The legal immigrants eligibility in government programs is limited by the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 which limits participation in the proposed government health plan until they have been in the country for five years (Frostin, 2005). Under this policy option, the illegal or undocumented immigrant population would continue to rely on free clinics or other safety net clinics for their health care needs.

The voucher plan would have additional positive outcomes in the workplace. Employers would no longer need to provide or contribute to the health care coverage of their employees.

Workers will have the freedom to change jobs and pursuit alternative employment option such as part time of self employed without losing health coverage. The economical benefits of the plan would be substantial and could save billions of dollars by eliminating insurance carriers. Since people will have their choice of insurance plans with guaranteed acceptance, the hundreds of smaller insurance companies will naturally be eliminated. The voucher system will reduce inefficiencies in government programs such as Medicaid, which has been known to spend billions each year determining eligibility (Emanuel & Fuchs, 2006).

The Clinton and Obama plans which would provide universal coverage through a mix of private and expanded public programs would similarly increase access to care for all Americans. Free clinics would still exist to care for the illegal immigrants and with reduced numbers of uninsured, their impact on those left without insurance would greatly improve. Senator Clinton and Senator Obama emphasize free choice of providers through their expanded public programs, however providers will still be able to close their practices to these government provided insurance programs, which has been then trend in recent years (Schueler, 2004), and the overall access to care may still be an issue for not only the current people using these programs but the influx of uninsured that will be newly covered.

Evaluate the Outcomes

Evaluation of the current policy, the VRP, reveals that it successfully contributes to the health needs of the uninsured. Literature has shown that the amount of charity care provided by physicians has decreased in recent years (Isaacs & Jellinek, 2007). According to data provided by Christine Linquist, the WWAHEC Volunteer Provider Program Coordinator, the program has been successful in attaining there expected goal of increasing volunteers thus increasing access to care (personal communication, February 5, 2008). In recent years, the number of new

volunteer providers enrolled in the VRP has been increasing (Figure 1). Accordingly, the total number of volunteer hours has increased (Figure 2) and more importantly, the number of patients served by VRP providers has increased to over 50,000 in 2007 (Figure 3).

As the data suggests, the actual results are small but comparable to the resource expenditure, that is, the VRP is not associated with large initiation or operating costs. On the surface, the proposed policy appears to be effective, meeting the objective to increase volunteerism and increase access to care for the uninsured. However the significance of the increase is questionable and insufficient data prior to 2004 makes interpreting the impact that this policy has had impossible. One evaluation explained that even though additional clinics are being developed and providers are volunteering, free clinics do not, under the current healthcare system, have capacity to have a significant impact on Washington States uninsured (Schueler, 2004)

A single payer plan such as that proposed by Senator Gravel is relevant to the population at need and would improve access to care for all citizens. The cost to start the program would be great but would quickly be regained through reduced costs within the government and insurance bureaucracies. The voucher system would be extremely effective in providing insurance to the uninsured and the overall impact would be considerable, resulting in a more efficient industry.

The universal coverage plans proposed by Senator Clinton and Senator Obama would have significant impact on the target population. The Clinton plan would likely have a greater impact by making health insurance mandatory compared to the voluntary plan under Obama's platform. Both plans would provide universal coverage greatly increasing the access to care for many of the Nation's 45 million uninsured. However, if reimbursement to private providers stays similar to the current government reimbursement rates, private office will likely limit the amount

of patients with government insurance, a concern that has already been documented under the current system. Washington State's Office of Community and Rural Health has documented dramatic declines in the percentage of primary care physicians willing to accept new patients with government insurance (Schueler, 2004) and shows that in 2004 more than half of all primary care physicians were no longer accepting new Medicare patients (Schueler, 2005).

Weight the Outcomes

With the primary target being to increase access to care for the uninsured, three policy options have been evaluated. The current policy in place, Washington's VRP, does not adequately address the needs of the uninsured. Although the actual risk of litigation is small, the fear of a malpractice suits and having to provide malpractice coverage has been identified by clinicians to be a significant burden and a contributing factor to the declining rate of volunteer providers. The VRP attempts to address this concern by paying for malpractice insurance, however it is redundant in its efforts as both the Federal Tort Claims Act (U.S. Department of Health and Human Services, 2008) and the Good Samaritan Law (Washington State Legislature, RCW 4.24.300) also protect licensed health care providers volunteering at community health clinics.

Additionally, the amount of volunteer hours needed to make significant impact on access to care for the uninsured would have to be much more considerable. In 2003 there were a reported 1,718 free clinics in operation (Isaacs & Jellinek, 2007) providing care to an average of 2311 patients per year (Nadkarni & Philbrick, 2005). The estimated number of patients receiving care at free clinics is just under 4 million, less than 10% of the uninsured population.

The other options addressed are universal coverage either by a single payer voucher system or with a combination of private employer based and expanded public insurance. The

projected outcomes are similar in that these options contribute to the needs of the primary objective to a greater extent then the VRP policy. The universal coverage plans of Obama and Clinton, in which there is not a single payer could lead to an overwhelming number of patients with insurance unable to find a primary care provider that accepts their insurance's. Literature has documented dramatic declines in the percentage of primary care physicians willing to accept new patient with government funded insurance (Schueler, 2004). Finally, none of the universal coverage options offer a solution to the uninsured immigrant population and they would still seek care from safety-net clinics and volunteer providers.

Decision

A universal coverage health plan would greatly reduce the population needing services from free clinics. There are approximately 11 million undocumented immigrants living in the United States (Camarota, 2004) that would not be eligible for government assisted programs. The free clinics which are caring for an estimated 4 million patients per year could now serve almost 40% of the needs of the uninsured versus less than 10% before universal coverage.

Of the alternative options discussed, a universal coverage, single payer voucher system, like that proposed by Presidential candidate Mike Gravels is chosen as the most comprehensive option to achieve desirable outcomes without major anticipated challenges. The plan is the most relevant to the needs of the uninsured and will produce the most significant impact. In addition, the policy has additional benefits. The plan will release employers from the strain of providing or contributing to employee health coverage. It will allow employed people to work part time or go into business for themselves without sacrificing health insurance coverage. The benefits extend to large insurance companies which can expect millions of newly insured paying consumers. Medical clinics will run with better efficiency as the reimbursements will be predictable and the

hassle with insurance contracts improves. Finally state spending will improve as it relieves millions spent on Medicaid programs.

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Figure 1. New VRP volunteers by year

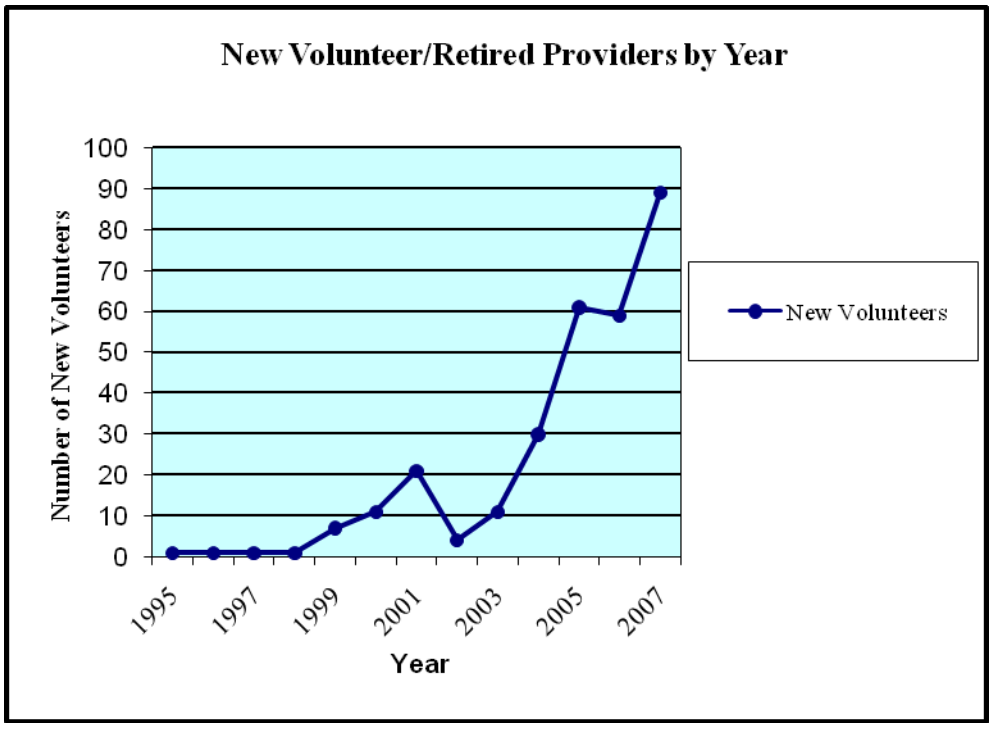


Figure 2. VRP volunteer service hours by year

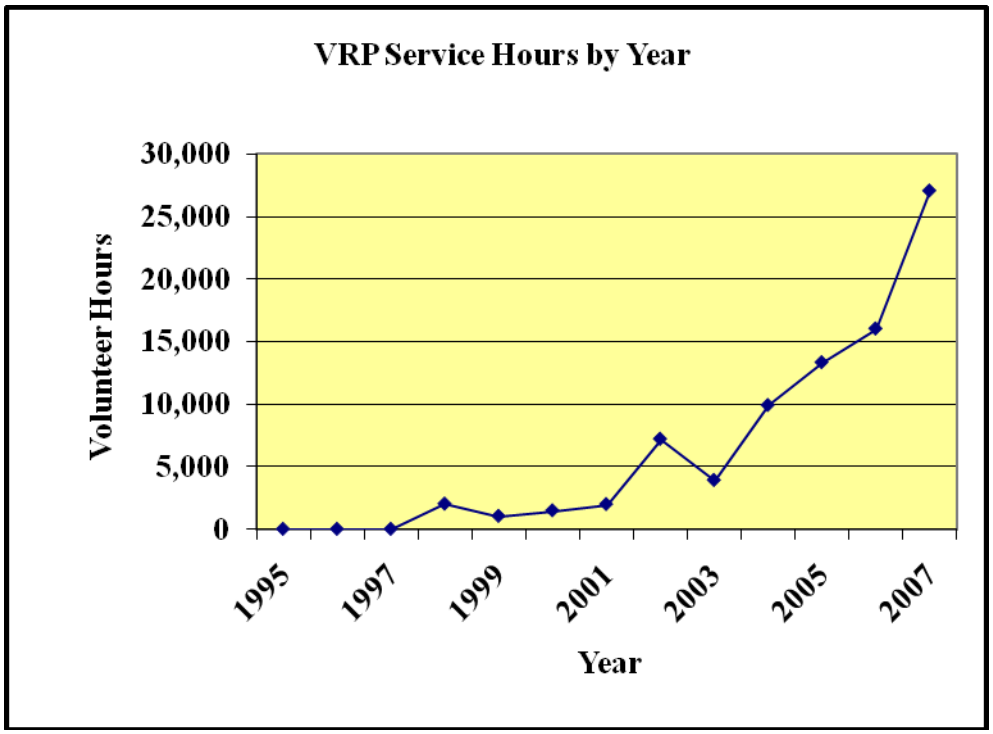
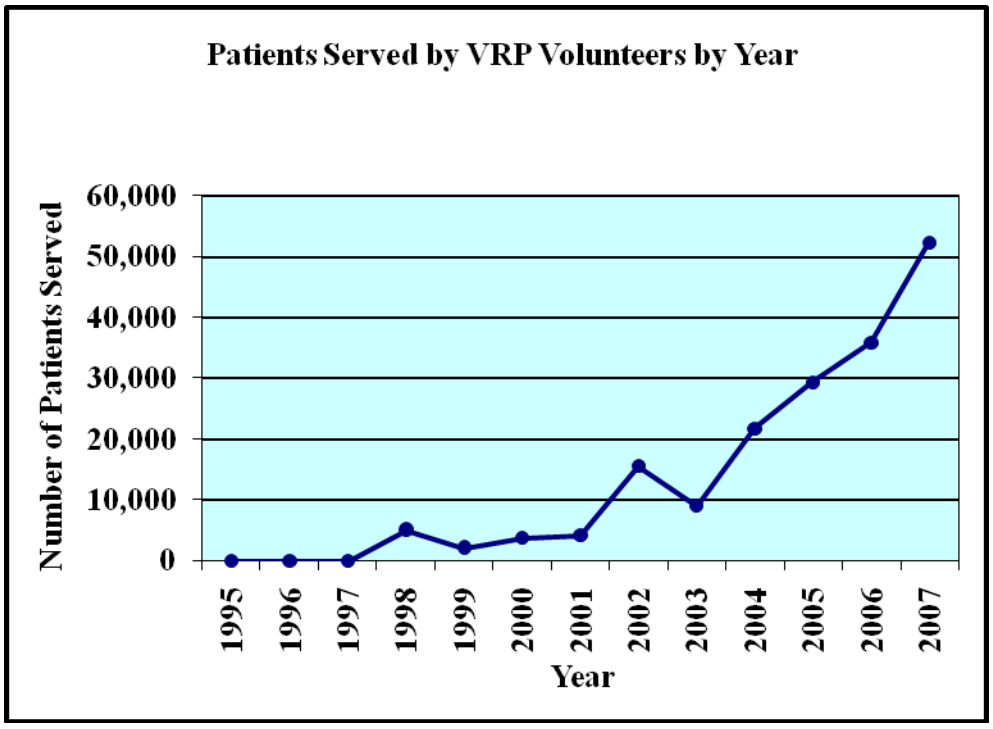


Figure 3. Patients served by VRP providers by year.



Clinical Ethics Case Study:
Pain Management in a Suicidal Patient

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Abstract

Anne is a 48 year old woman who has been newly diagnosed with extensive stage small cell lung cancer, which at the time of diagnosis has already metastasized to her brain. Chemo and radiation therapy were attempted and her headaches and pain are getting worse. She has attempted suicide by overdosing on short acting narcotic medications given to her by her PCP and shortly after being released from the hospital she presents requesting additional pain medications.

Emanuel (2005) explains several ethical principles for considerations in the treatment of pain in end of life care. The clinician's obligation to comfort the patient when curative treatments are not available is foremost. Many medical and nursing declarations support this view to comfort, including the nurses code of ethics, provision 1.3 (American Nurses Association, 2005). Ann's cancer is not curative and her prognosis is very poor. Treatment for her pain should not be withheld secondary to her attempted suicide. Emanuel also writes of the duty to avoid harm. The clinician must be aware of the potential harm that can arise with management of pain. In this case, the potential for suicide poses the greatest risk.

The PCP has legal issues to consider also, as clinician assisted suicide is illegal in all states excluding Oregon (Bruce, Hendrix, & Gentry, 2006; Emanuel 2005) and argument could be made that Ann's intention to commit suicide were well known and the PCP provider her with the means to make this happen. Should her primary care provider continue to prescribe pain medication given the likelihood that she may attempt suicide again? How should her pain be managed in order to keep her pain controlled?

ETHICAL CASE STUDY

Case Presentation

Ann is a 48 year old female who has been a patient at Two Rivers Clinic for many years. She presented to the clinic in January with chief complaint of a cough that started two months prior. She had been seen at an urgent care clinic a month ago and was started on albuterol and a course of antibiotics. The treatment improved her symptoms for a period of time, but the cough has returned and is now much worse. She has associated symptoms of occipital headaches that are described as pounding, rated as severe and are worsening over the last couple of weeks. During the visit she reports that she quite smoking last summer and was able to make it through the stressful holidays without relapsing. She has smoked a pack of cigarettes per day for the past 30 years.

Her exam reveals decreased lung sounds in the bases and a deep harsh nonproductive cough. She was started on broad spectrum antibiotics for an acute exacerbation of chronic bronchitis and a chest x-ray was ordered. The x-ray showed a large eight centimeter well-circumscribed, lobulated, soft tissue mass over the left hilar region. There was also a two centemeter nodular mass in the retrosternal region. A chest CT scan was ordered the following day identifying many lung nodules and mediastinal adenopathy. A CT of her brain was obtained the subsequent day and revealed numerous metastatic lesions in both cerebral and cerebellar hemispheres.

After being seen by pulmonology and undergoing a bronchoscopy and biopsy, she was diagnosed with metastatic small cell lung cancer. She was referred to oncology and to the regional cancer center for evaluation. Her cancer was widespread and could not be cured. Ann opted for palliative treatment with radiation and chemotherapy to decrease the

cancer size and provide her with more time with her family. Pain management for her headaches was still being handled by her primary care provider at TRFM. She finished 12 radiation treatments which successfully decreased the size and number of her brain tumors. She underwent three rounds of chemotherapy before stopping secondary to the side effects.

A week after her last chemotherapy treatment she was brought to the emergency department by her neighbors who found her with altered and decreasing mental status, attempting to put the car exhaust pipe in her mouth. Prior to losing consciousness Ann told her neighbors that she had taken 60 of her pain pills. She was treated for narcotic overdose and admitted to the telemetry unit for one-to-one observation where she told nurses and hospital staff that she wanted to die and that they could not stop her from trying again. She refused to wear the telemetry devise and refused all treatments except for pain medication.

After psychiatric evaluation, she was released in the care of her son who lives in the area. She presents to her primary care clinic five days after her attempted suicide requesting pain medications. Should her primary care provider continue to prescribe pain medication given the likelihood that she may attempt suicide again? How should her pain be managed in order to keep her pain controlled?

Review of Topics

Medical Indications. Ann has been diagnosed with extensive stage small cell lung cancer (SCLC) with at least 20 identified metastasized lesions in her brain. She has undergone many radiation treatments and few chemotherapy treatments which have been stopped secondary to severe side effects. In addition to these treatments, her primary care

has intermittently treated her with steroids to control her brain swelling and short acting narcotic pain medication to improve her pain. Her past medical history prior to current diagnosis and treatment is unremarkable for any serious medical illnesses, surgeries or hospitalizations.

Lung cancer is the leading cause of cancer related deaths in women, surpassing breast cancer in 1987. Cancer of the lung is classically divided into two types, non-small cell and small cell. Small cell lung cancer accounts for 17 percent of lung cancer in women, is highly associated with smoking and is associated with a much poorer prognosis (Novello & Baldini, 2006; America Cancer Association, 2006). It is staged based on the severity of progression. If the cancer is limited to half of the thorax and is within one radiation window, it is said to be limited stage. More commonly the disease is found having already spread through the thorax and has metastasized, it is then classified as extensive stage. More than 60 percent of the cases are in the extensive stage at time of diagnosis. The average five year survival rate for such patients is between one and two percent with a mean survival of approximately nine months (Collins, Haines, Perkel, & Enck, 2007; Merck Manual, 2005; Rosti et al, 2006).

Brain metastases occur in greater than 40 percent of patients diagnosed with SCLC (Kvale, Simoff, & Prakash, 2003). The most common symptom of brain metastases is headaches which are caused by increase intracranial pressure. Other symptoms can include nausea, vomiting, mental status changes and fatigue. Tumors can also cause focal damage to the neurons which may result in neurologic impairment, including visual field defect and seizures. The survival rate of patient with brain

metastases is typically less than two year and treatments are aimed at prolonging quality of life and reducing pain (Kholsa, 2007).

Patient Preferences. Shortly after her diagnosis was made, Ann and her primary care discussed her advanced directive and a Physician Orders for Life Sustaining Treatment (POLST) form was filled out indicating that she did not want to be resuscitated or have life sustaining measures taken. Her family is aware of her preferences and supports her decision. Ann has opted for treatment to improve her quality of life and has been successful in decreasing the number and size of many of her brain tumors.

Ann was brought to the emergency department by her neighbors with decreased mental status. She received appropriate treatment for narcotic drug overdose and did not require ventilation. When she became more alert she made statements that they should have let her die and there is nothing they can do, she is going to die. She adamantly denies telemetry monitoring and is watched with one to one observation. She was released in the care of her son who lives in the area with close follow up with mental health. She is quiet and to herself after recovery but does not show remorse for her attempted suicide.

Ann is mentally and legally competent to make decisions for herself. It could be argued that the brain metastases are causing neurological impairment but any assessment would likely show her to be mentally intact.

Quality of Life. Prior to her diagnosis and treatment, Ann worked as an administrative assistant as a large project management group. She had worked there for the last 12 years and was well regarded. During the last three months that she has been off work her co-workers have pooled their sick hours and she has not yet had any

decrease in her wages. She often gets cards and flowers from those she used to work with.

Ann has three children and eight grandchildren. One of her son's lives in the area with her two granddaughters. They get together every Sunday for church and lunch and often will have dinner during the week. Her other two children live out of town. In the year following Ann's husbands death, the entire family has been together on multiple occasions.

Since her diagnosis, Ann's quality of life has diminished. Her headaches have gotten worse, radiation treatments have been successful at decreasing the size and number of the tumors but have caused stomach irritation and insomnia. Chemotherapy was stopped after the second round due to the severity of symptoms, including nausea and fatigue. Her doctors have told her that she can not drive because of her seizure risk and she is no longer able to work. There is no chance that Ann's life will return to what it was. She has days where she feels fine and wishes she could return to work, but most days she is not able to get out of bed. Treatment has been focused on improving the quality of her life, decreasing her pain and providing her more time with her family.

Contextual Features. Ann has lived alone for the last year. Her husband died just over a year ago in a car accident. She has three grown children and eight grandchildren. All of her children have families of their own and busy lives but have accompanied her to many of her appointments. None of her children currently have room to have Ann live with them, but do have monetary means to help provide any care that she needs.

Ann has a significant amount of pain, which will continue to get worse. She has been using Percocet, two tabs as needed every six hours for this pain. In the last three

months the amount of pills she has required each month has increased from 30 to 120. She has recently tried to commit suicide by ingesting 60 of these pills.

Case Analysis and Recommendations

Ann has severe pain that is only going to get worse. She still does have some good days in which she requires very little medication, but those days are radically reducing. Her chemo and radiation therapy have been stopped and she is refusing care for anything other than her pain medications, which she has recently used to attempt suicide.

Patients' right does not apply to the entirety of this case. Ann has stated that she wants and intends to end her life, however suicide is not a permissible autonomous act and if brought to the Emergency Department for another attempt, all measures will be taken to revive her (Jonsen, Siegler, & Winslade, 2006). Ann does have a right to refuse medical intervention and has exercised this right through her POLST directive (Potter, 2005).

Consideration needs to be given to the ethical implications for the provider. Ann's PCP has a duty to comfort and help her die peacefully. Providing pain medications to her for treatment of her pain is ethically appropriate. The doctrine of double effect is germane; it makes the distinction between intended and unintended effects of an intervention (Bruce, Hendrix, & Gentry, 2006; Fohr, 1998). In Ann's case, the PCP can chose to continue her treatment with pain medications even though the actual effect might be hastening of death, in this case by suicide.

However there are legal implications that are of concern to the PCP. In 1997, the US Supreme court ruled against clinician assisted suicide but allowed each state to makes individual decisions about its legality. Currently the state of Oregon is the only state in

which clinician assisted suicide is legal (Bruce, Hendrix, & Gentry, 2006; Emanuael, 2005). In recent years, the Drug Enforcement Agency has presented many initiatives to prevent clinician assisted suicide. The use of controlled substances for assisted suicide can result in the termination of the provider's license. If the PCP is aware of the intended use, then he or she may be found as having assisted in the suicide.

It is recommended that the PCP continue to treat Ann's pain, as it would be unethical to do otherwise. In order to maintain trustworthiness and nonmaleficence, the PCP should aim to treat her pain without arming her with the means to successfully end her life. In addition to providing mental health treatment, certain medications could be used that reduce the risk of suicide. For example, treating with narcotic transdurmal patches which provide 72 hour pain relief would limit the need for shorter acting break through medications. The PCP could also limit the quantity to one or two week's worth of medication at a time to reduce the likelihood of overdose. As her condition progresses and her pain becomes unmanageable, palliative sedation may be an option.

Ethical Essay

Emanuel (2005) explains several ethical principles for considerations in the treatment of pain in end of life care. The clinician's obligation to comfort the patient when curative treatments are not available is foremost. Many medical and nursing declarations support this view to comfort, including the nurses code of ethics, provision 1.3 (American Nurses Association, 2005). Ann's cancer is not curative and her prognosis is very poor. Treatment for her pain should not be withheld secondary to her attempted suicide. Emanuel also writes of the duty to avoid harm. The clinician must be aware of

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Therefore, it is recommended that the PCP continue to treat Ann's pain, as it would be unethical to do otherwise. In order to maintain the duty to comfort and the duty to avoid harm, the PCP should aim to treat her pain without arming her with the means to successfully end her life. In addition to providing mental health treatment, certain medications could be used that reduce the risk of suicide. For example, treating with narcotic transdurmal patches which provide 72 hour pain relief would limit the need for shorter acting break through medications. The PCP could also limit the quantity to one or two week's worth of medication at a time to reduce the likelihood of overdose.

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Jessica Johnson

Organizational Change: Germane Communication

OHSU Nursing 733 Health Systems

November 12, 2007

ORGANIZATIONAL CHANGE: GERMANE COMMUNICATION

Many of the basic elements that help health care settings function are improvised and adapted to be used in the free clinic setting. The result is a stew of equipment, volunteers and financial resources that are inconsistent and constantly changing based on donations of time, money and office equipment. In such a dynamic environment, changes are made daily, and require communication between all the parties involved in order to be successful. This paper will analyze one such change effort within a free clinic setting. The change identified is the implementation of a faith based depression recovery program for clients with diabetes.

The program was initially designed by one of the healthy living counselors at the free clinic with the support of the medical director. It is a free service for those using the clinic and has been developed as an eight week program specifically for those with diabetes. The healthy living clinic is a pseudonym for mental health services and is ran by volunteer mental health counselors and psychiatric nurse practitioners, which the clinic refers to as healthy living counselors. The healthy living clinic and depression recovery program is dependent on patient screening and referral from volunteer licensed independent practitioners (LIP) in the medical clinic.

The program was developed to improve depression and impact the diabetic outcomes. It is well known that chronic illness, like diabetes, significantly increases the patient's risk of developing depression. The problem identified in this free clinic is that there is inconsistent screening for depression among clients with diabetes, which results in untreated depression and related complications. The significance of this problem is

great considering the vast number of patients with diabetes and the morbidity and mortality that this disease carries with it.

There are approximately 20.5 million people in the United States living with diabetes and another 50 million more with prediabetes. Each year more than 220,000 people will die from diabetes related complications; a number that most think is grossly underestimated. It is the fifth leading cause of death by disease in the United States and a leading cause of morbidity; associated with an increased risk of heart disease, kidney disease and blindness (American Diabetes Association, 2007). The economical burden of this condition is estimated at over 132 billion dollars per year (American Diabetes Association, 2003).

An abundant body of evidence demonstrates the increased risk of depression in people with diabetes. Anderson, Freedland, Clouse and Lustman (2001) conducted a meta analysis of 42 studies to evaluate the prevalence of depression among diabetic patients. Their findings indicate that the presence of diabetes doubles the risk of developing depression. Other studies indicate that type two diabetics may have more depression then those with type one (Albanesi de Nasetta & Morales de Barbenza, 2006) and those clients with type two diabetes using insulin have even higher rates of depression. Noh et al., (2005) demonstrates an overall prevalence of diabetes with comorbid depression at 32.4 percent. The insulin group showed frequency of depressive at 48.0 percent, significantly higher than the oral drug group at 27.3 percent.

More concerning is the literature suggesting diabetic patients with comorbid depression have an increase in mortality. Black and Markides (1999) studied depression and diabetes in a Mexican American population. The results of their work demonstrate

that clients with diabetes and concomitant depression are three times more likely to die then diabetics without high levels of depressive symptoms. A recent study (Bogner, Morales, Post, and Bruce, 2007) published data from the Prevention of Suicide in Primary Care Elderly: Collaborative Trial (PROSPECT) which illustrates that diabetic patients with untreated depression have an increased risk of mortality then those with treated depression.

Implementation of the depression recovery program was intended to identify and improve depression, thus hopefully resulting in an improvement with adherence to diabetic medication, diet and exercise. This in turn, would ultimately improve diabetic control and have significant impact on diabetic outcomes and morbidity and mortality. The intended outcome was that depression screening would be consistent among those clients with depression. The actual outcomes were varied and included inconsistent screening, poor communication about the initiation of the depression recovery program, and lack of follow up once referrals were made.

A system level analysis was completed using an ecological environmental perspective adapted from Bronfenbrenner (1979). Using this paradigm the organizational structure of the free clinic was mapped out to illustrate the different systems within the organizational model. These included the microsystem, mesosystem, exosystem and the macrosystem. The microsystem consisted of the LIPs, healthy living counselors and nurses that for the interpersonal relations with the diabetic clients. The mesosystem encompasses the healthy living department and the diabetic department within the larger free clinic organization. The organizational structure, including the clinic policies and board, formed the exosystem. Finally, the macrosystem was identified which is

comprised of the organizational culture of volunteerism and offering services to the underserved.

The systems inputs and outputs were mapped between these systems within the organizational model. The inputs and outputs identified consisted of the current evidence that is available for screening diabetic patients for depression, the attitudes and beliefs of the LIPs and communication of the change effort. These inputs and outputs flow back and forth through each system. Facilitators to the change effort would be the health living counselor that initially wanted to develop the program, the medical director who supported this and emailed the providers. There are many barriers for change in the clinic, including the large number of LIPs, lack of incentive, funding limitations.

The free clinic is a large organization, with more than 70 LIPs who volunteer from zero to eight hours per month. There are some providers who are very invested in the clinic and others who do not demonstrate much commitment with the clinics core values. Unfortunately the clinic had a need for volunteer providers and tries to be very accommodating, even to those LIPs who do not have “buy in” to the mission. Without funding, part time paid positions cannot be established which would improve “buy in” and accountability.

A root cause analysis was completed using a flow charting, system walk approach. One predominate theme was identified as being the key contributing factor in the failure of the change effort. Communication errors could be tracked within systems as well as between systems. Through stakeholder interviewed it was found that some LIPs simply did not know about the newly started program and thus did not refer to the program. These were likely the LIPs who were less invested in the clinics missions and

thus did not take the time to read all the change information that the medical director sent out. Other LIPs knew of the program and were making appropriate referrals, but the follow through was not done. The work flow of the clinic is such that the LIPs make referrals, write it in the plan section of the encounter notes and then the nurses follow through making sure the appropriate referrals are made. At each roadblock the key issue was errors in communication.

Another theme that was not as predominant was that of accountability and commitment. LIPs do not always know about the changes that happen in the clinic because they are dedicating a small percentage of their time to the clinic. Keeping current with all the changes requires a level of dedication that a lot of the infrequent volunteers do not have. Additionally, there is no provider accountability to keep them dedicated. If LIPs were paid employees they could be held accountable and have consequential actions if tasks were not performed. In a free clinic setting which relies solely on volunteerism, it is a 'take what you can get' kind of attitude and usually the clinic is just happy to have providers at all.

Although the change effort has yet to be successful, the organization does appear ready for change. The healthily living counselor discussed the program with the medical director who then added this information to the monthly email update that was disseminated to the volunteer providers. This analysis indentified the relevance of communication and demonstrated the importance of this, especially in a dynamic and fluctuating volunteer ran clinic. It also demonstrates the need to fill the positions with people who have similar core values.

The original problem was thought to be lack of depression screening among clients with diabetes. Through a root cause analysis and stakeholder interviews it was apparent that the initial assumption was only partly correct. There was a lack of screening by some LIPs, but others were screening and making appropriate referrals only to have another roadblock in the form of communication errors occur and the referral not get followed through.

The main system level strategy that is needed to improve the outcome of the change effort is improved communication. This paper has stressed germane communication especially in a dynamic environment like that of a volunteer run free clinic. MacPhee (2007), on a paper regarding strategies to manage change discusses the role of the leader, the follower, and the organization. Throughout all these different groups communication is the key concept that keeps change running smoothly. The article indentifies face-to- face communication as being especially important for stake holders.

The clinic is ready for change; in fact it makes changes on a weekly basis. However this change effort which involved communication between two systems was unsuccessful. In order for this change effort to be successful, there needs to be more provider ‘buy in’ and dedication. This can be improved by asking volunteers to commit to a six month or one year term of at least four hours per month. Although this might decrease the number of volunteers, it will improve the quality of volunteers and improve change efforts to come.

Communication needs to continue, and needs to improve. The main communication tool that the clinic uses is through group emails. The emails may work

better once LIP dedication improves but as MacPhee (2007) discusses, communication should also occur face to face. The addition of a quick team meeting to discuss recent changes prior to the arrival of the first patient could easily be done and would improve communication and would keep all the stakeholders on the same page with organizational change efforts.

In conclusion, evidence from literature demonstrates that the presence of diabetes doubles the risk of comorbid depression. Depression affects more than one quarter of the diabetic population, making its recognition and treatment clinically significant. The change effort at one free clinic to implement a faith based depression recovery program from their diabetic clients failed due to errors in communication and lack of LIP dedication to the clinics mission. With improvement in both LIP dedication and communication as described above, the faith based depression recovery program and future change efforts will be successful.

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RUNNING HEAD: diet and weight management in uninsured

Evaluation of Diet and Weight Management Interventions in Low Income, Uninsured, Type 2 Diabetics Utilizing a Free Clinic

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Diet and Weight Management Interventions in a Low Income, Uninsured Population of Type 2 Diabetics Utilizing a Free Clinic

Type 2 diabetes is a prevalent condition affecting approximately 17.5 million people nationally (ADA, 2008), including more than 340,000 in Washington State (Washington State Department of Health, 2008), including 8,800 people in Benton and Franklin counties (Washington State Department of Health, 2007). The rate of diabetes has been increasing at alarming rates in the last decade (Cowie, Rust, Byrd-Holt, Eberhardt, Flegal, & Engelgau, et al., 2006). The Center for Disease Control lists diabetes as the fifth leading cause of death by disease in the United States (National Center for Health Statistics, 2006). Obesity and weight gain are major contributors to the development of diabetes (Anderson, Kendall and Jenkins, 2003; Mokdad, Ford, Bowman, Dietz, Vinicor, & Bales et al., 2003) and as many as 90% of newly diagnosed type 2 diabetics are overweight (American Diabetes Association, 2008). Weight management is a key component in the chronic management of diabetes (Anderson et al, 2003).

A growing number of people with type 2 diabetes are without health insurance, leaving the burden of chronic illness management to safety net clinics and free clinics which traditionally have been designed to treat acute illnesses. The uninsured are disproportionately more likely to develop diabetes (Cowie et al, 2006; Rabi, Edwards, Southern, Svenseon, Sargious, & Norton et al., 2006). Nationwide the prevalence of uninsured patients with diabetes is estimated at over 600,000 (Harris, Cowie, & Eastman, 1994).

The free clinic in Benton and Franklin county has been in existence since 2002 and has been growing significantly since. The first year just over 300 patient visits were recorded; in 2007 there were over 3,400 patient visits. The population demographics for 2007 showed users of the clinic were 65% female. Ethnicity was fairly evenly divided between Hispanic and Non-

Hispanic populations, 35% of the patients seen did not speak English. In the last couple of years the free clinic has grown significantly and has had to move into a large new building which has increased the public knowledge of the services provided and opened the clinic to professional scrutiny. There are groups of health care providers in the community who have expressed concerns that the chronic needs of diabetic patients are not being addressed sufficiently. These concerns prompted the development of a diabetic management team to better address our patients' chronic needs. The diabetic management team has implemented a diabetic flowchart into practice and work flow improvements so that labs from our diabetic clients are responded to timely. We have initiated and standardized diabetic education sessions and nutrition counseling with a dietitian in addition to providing food from our food bank keeping into mind the diabetic patients dietary needs.

The purpose of this practice improvement project is to evaluate diet and weight management interventions in low income, uninsured, type 2 diabetics utilizing a free clinic in two bordering Washington State counties. Interventions include individual diabetic education, individual dietitian counseling and access to the clinics food cupboard. The goals of the project will be to ascertain the following questions; what is the feasibility and acceptability of weight management interventions in this setting and with this population? Do these interventions result in improved dietary knowledge? Do the interventions result in improvement in physiologic parameters such as weight maintenance or reduction?

Conceptual Framework: The Chronic Care Model

This practice improvement project will be guided with an adapted chronic care model (CCM) (Figure 1). The CCM was initially conceptualized by the MacColl Institute for Healthcare Innovation and has gone through a number of refinements over the subsequent years. The Robert Wood Johnson Foundation funded research to test the model nationally across varied

health care settings, creating the national program, Improving Chronic Illness Care (ICIC). The most recent changes occurred in 2003 when ICIC and a small panel of experts modified the CCM to reflect evidence based research and more specifically define the models concepts (Wagner, 2004).

The CCM identifies essential elements of a health care system that encourage high-quality chronic disease care. The complete model elements include the community, the health system, self-management support, delivery system design, decision support and clinical information systems (ICIC, 2008; Wagner, 1998; Wagner, 2004). For the particular setting and population focus of this clinical problem, the model will be adapted to include three of these original elements; community, self-management support and delivery system design. In addition to this adaptation, the conceptualized framework will emphasize the role of social support in chronic diabetes management.

The CCM has been tested in diabetes management and has been found to be effective in improving outcomes in primary care settings (Nutting, Dickinson, Nelson, King, Crabtree, & Glasgow, 2007) as well as in free clinic settings with uninsured populations (Stroebel, Gloor, Freytag, Riegert-Johnson, Smith, & Huschka et al., 2005). Social support has been shown to be a significant predictor in improving diabetic care (Van Dam, Van der Horsta, Knoops, Ryckman, Crebolder, & Van den Borne, 2004), specifically with informational support such as diet education (Baker, Vallbona, Pavlik, Fasser, Armbruster, & McCray et al., 1993; Cramer, Sibley, Bartlett, Kahn & Loffredo, 2007), informational and emotional support with group visits (Clancy, Cope, Magruder, Huang, & Wolfman, 2003; Clancy, Yeager, Huang, & Magruder, 2007).

The CCM and will provide the foundation for practice improvement in this medically underserved population of type 2 diabetics. Key concepts include the community, delivery system design, self-management support and diabetes outcomes. Community resources are one element of the health care system that focuses on finding and organizing local resources in order to meet patients' needs. The community resources pertaining to this clinical phenomenon are the free clinic system and the food cupboard and will be measured through the number of patient visits to the clinic and the number of patients utilizing the food cupboard as well as the number of returning users to each.

The goal of self-management systems is to prepare patients to manage their health and health care through educational interventions. This is meant to emphasize the patient's role in the care of their chronic disease and improve their self-management techniques. It includes the use of programs that provide basic information, emotional support, and strategies for living with chronic illness (ICIC, 2008). Specifically with the working population and setting, this will be provided through information support of ongoing diabetes education classes and nutritional weight loss class taught by a registered dietitian, in addition to their regular follow up care with a primary care provider. The classes are free and open to diabetic patients and their families. The nutrition for weight loss class is open to all users of the free clinic. The patients will be provided with information to improve knowledge and will be active in goal setting and treatment plan development. Measurement will be based on the number of visits the patient attends and the total number of minutes spent in class.

Delivery system design aims to provide effective, and efficient clinical care through a team member approach, using evidence based care and ensuring regular follow up by the care team. The formation of a diabetic case management team lead by the clinic's medical director

and including a primary care nurse practitioner, an advanced diabetes management certified nurse practitioner, a diabetes educator and a registered dietitian was formed to implement programs to improve the efficiency of care. Group visits providing informational support and emotional support through the small group feel were incorporated into the regular primary care follow up appointments. An operational measurement of the success of this program will be determined through patient satisfaction scores and return rates.

The three central concepts chosen to help guide and direct the proposed clinical inquiry are interrelated and woven together providing improvement in diabetic outcomes. The community resources of the free clinic provides basic access to health care for this medically underserved population, while providing additional resources and tangible aid such as the food cupboard. The goal is not only to provide informational support but to provide a balance and mixture of informational, tangible and emotional support. The delivery design system includes a dynamic diabetes team which has incorporated group visits into the patient's encounters. The group visit information included nutrition for weight loss program taught by a registered dietitian and diabetes education classes which will enable and prepare the patients for self-management of their chronic disease.

Literature Review

Diabetes and obesity are significant causes of morbidity and mortality in the United States (National Center for Health Statistics, 2005). Obesity is directly related to between 60-90% of type 2 diabetes and weight management has been cited as being the most important therapeutic task for obese diabetic patients to reduce their risk of diabetes. (Anderson et al, 2003). Obesity has become a national public health concerns and like type 2 diabetes, the incidence of obesity is escalating. The Behavioral Risk Factor Surveillance System conducted

survey of over 195,000 adults and reported the prevalence of obesity increased to 20.9% in 2001, an increase of 74% since 1991 (Mokdad et al., 2003). Literature has demonstrated that uninsured people are disproportionately more likely to suffer from chronic diseases and obesity (Cowie et al, 2006).

There are more than 47 million people without health insurance in the United States according to 2006 data. This represents an increase of more than 2 million from the previous year. The percentage of the population without health coverage has increased from 15.2% in 2005 to 15.6% in 2006 (U.S. Census Bureau, 2007). The decreasing access to primary care services presents a challenge at the local level as well. Information from the 2006 Washington State Population Survey shows that13% of the state's population is uninsured, totaling more than 787,000 people (Kaiser Family Foundation, 2006).

To combat the problem of the growing number of uninsured, communities have established clinics aimed to help the underserved population. Free clinics are non-profit, community based organizations that provide a variety of medical care, primary care, mental health counseling, pharmaceutical and dental services at little or no cost to low-income, uninsured people (National Association of Free Clinics, 2007). Since their emergence in the 1960's relatively little has been published about them. A small body of evidence suggests free clinics have made significant impact in quality of care and access to medical care in the uninsured, showing a decrease in emergency room and hospital use (Hadley & Cunningham, 2005) and improvement in morbidity and mortality (Nadkarni & Philbrick, 2005). Results from the Charlottesville free clinic study showed that the proportion of patients seen for chronic illness steadily increased each year of the clinic's existence. Diabetes was one of the principle diagnoses among patients utilizing this free clinic (Nadkarni & Philbrick, 2003).

The Chronic Care Model: Conceptual Framework

The CCM has been found to be useful in improving chronic illness outcomes, including type 2 diabetes. Many of studies have been done implementing components of the CCM into primary care settings and have shown success in diabetes outcomes (Nutting et al., 2007; Parchman, Pugh, Wang, & Romero, 2007; Piatt et al., 2006; Solberg, Crane, Sperl-Hillen, Hroscikoski, Engebretson, & O'Conner, 2006; Vargas et al., 2007). A meta-analysis of chronic care interventions containing components of the CCM supports the use of this framework to guide chronic disease management. Although statistical analysis did not dictate which elements of the CCM were most responsible for the improvements in outcomes, delivery system design and self-management support were more strongly associated with improvements (Tsai, Morton, Mangione, & Keeler, 2005). Other data has shown that clinical information systems and decision support were two of the CCM elements most significantly correlated with improve diabetes measures (Solberg et al., 2006).

Piatt et al (2006) randomized primary care patients into three groups, CCM intervention, provider education only or usual care group. The results demonstrated improvement in physiologic parameters including glycoselated hemoglobin levels and HDL cholesterol in the CCM group compared to the other two groups. The CCM group also showed improvements in diabetes knowledge test scores and empowerment scores when compared to the usual care and provider education groups.

There is much less literature on the use of the CCM in free clinic settings with low income and uninsured populations. Stroebel et al (2005) conducted a pilot study to determine the feasibility and effectiveness of an adapted chronic care model applied to uninsured patients in a free medical clinic setting. The authors studied 149 patients, 91 (88%) of which were diagnosed

with diabetes. Intervention included case management by two registered nurses providing disease management using evidence based guidelines. More than 50% of the diabetic patients completing the study reduced their hemoglobin A1C values by at least 1%. The chronic care model was found to be useful template for the delivery of effective diabetes care to uninsured diabetic patients utilizing a free medical clinic.

Delivery Design: Group Visit

Evaluation of group visit interventions has been shown to improve patient satisfaction and perception of care (Clancy et al, 2007; Beck, Scott, Williams, Robertson, Jackson, & Gade et al., 1997) as well as improve adherence to American Diabetes Association standards of care (Clancy et al., 2003). One study was able to demonstrate improvement in metabolic control, increased knowledge of type 2 diabetes and improvements in quality of life (Trento, Passera, Tomalino, Bajardi, Pomero, & Allione et al., 2001). Other studies have not been able to demonstrate differences in physiologic diabetes measurements (Clancy et al, 2003; Beck et al., 1997). The research to date suggests that group visits are at least equivalent in clinic outcomes to usual care and may have favorable outcomes on diabetes care.

Clancy et al (2007) studied the acceptability of group visits in 186 uninsured or underinsured diabetic patients at a primary care center at the Medical University in South Carolina. Results show patients randomized to the group visit intervention had more positive perceptions about the care received than did the usual care group. The attendance rates at the group visits ranged from 62% to 79%, indicating that group visits may be feasible in a low income population in a primary care setting. However the sample characteristics indicate that more than 70% of the patients did have employment or government insurance so the applicability to a truly uninsured population is unknown.

Informational Support: Diet Counseling

Dietary education appears to be marginally beneficial at achieving and maintaining weight reduction for people with type 2 diabetes. Dansinger, Tatsioni, Wong, Chung and Balk (2007) conducted a large meta-analysis of 46 randomized control trials to better understand the effects of dietary counseling on sustained weight loss. Of the 46 studies, 10 included patients with diabetes. The researchers found that compared with usual care, dietary counseling resulted in approximately 6% weight loss at 12 months. This net effect diminished overtime and was less significant in studies which including participants with diabetes. Studies with diabetic participants reported half the net weight loss as did studies that did not include participants with diabetes. The absence of diabetes, increased frequency of support meetings and fewer recommended calories per day were independent predictors of weight loss. Interestingly, the additional of diet and exercise versus diet alone was not associated with greater weight loss. The absence of diabetes and fewer recommended calories were independent predictors of slower weight regain.

The Finnish Diabetes Prevention Study was able to demonstrate a 58% reduction in the risk of diabetes with lifestyle interventions targeted at dietary improvements and exercise (Lindstrom, Louheranta, Mannelin, Rastas, Salminen, & Eriksson et al., 2003). The results of that study prompted a nationwide diabetes prevention program. Absetz, Valve, Oldenburg, Heinonen, Nissinen, and Fogelholm et al (2007) recruited 352 Finnish participants with increased type 2 diabetes risk for a lifestyle implementation study to demonstrated whether the Diabetes Prevention Study results could be duplicated in a primary care setting. Nurses held six small group counseling and educational sessions over the study duration. The five primary goals were to decreased total and saturated fat intake, increase fiber, increase physical activity and

decrease weight by greater than 5%. After 12 months the study resulted in 20% of participants achieving at least four out of the five lifestyle outcomes. Weight loss was the least frequently achieved goal, reached by 12% of participants.

Similarly, Cramer, Sibley, Bartlett, Kahn and Loffredo (2007) were unable to demonstrated clinically significant weight reduction in their RCT of 67 low income, uninsured, type 2 diabetic patients. Although the net loss of 2.5 pounds (2.69%) was statistically significant it did not meet the studies objective of obtaining 7% weight reduction.

Diet Intervention for Weight Control

Rates of diabetes and obesity are have increased rapidly among the uninsured (Rabi et al., 2006) and in low income communities (Designed for Disease, 2008). A recent publication from the California Center of Public Health Advocacy has demonstrated a link between the food environments of lower-income communities and the increasing rates of diabetes and obesity. Lower income communities tend to have a disproportionate number of fast-food restaurants and convenience stores compared to grocery stores and produce markets. The disparity in food access contributes to the residents choosing higher calorie and lower nutrient foods which leads to increases in obesity, diabetes and higher mortality rates (Design for Disease).

The California Center for Public Health Advocacy research indicates that improving food sources would have a positive impact in the prevalence of diabetes in the lower income populations. Cheskin, Mitchell, Jhaveri, Mitola, Davis, and Lewis et al (2008) conducted a controlled clinical trial of 112 overweight and obese type 2 diabetic patients. Patients were randomly assigned to standard self selected diets or portion controlled meal replacement diets. The authors' findings showed weight loss and weight maintenance 1 year after intervention was significantly better in the portion controlled diet group versus standard diet group. At the

conclusion of the active phase, the intervention group lost 6.84% of weight versus 3.70% in the standard diet group.

Diabetic Education

Results from a meta-analysis suggests that education intervention in type 2 diabetics produces a statistically significant decline in hemoglobin A1C values of 043%. When weighing studies by samples size, fasting glucose levels decreased by 24mg/dL and weight was reduced 3 pounds (Gary, Genkinger, Guallar, Peyrot, & Brancati, 2003). The study identified 18 randomized control trials producing 2720 participants. The interventions lasted on average 5 months during which time there was a mean of 8.5 visits to either group educational sessions or individual counseling. There was not a statistically significant difference between group and individual counseling methods. Education was most commonly delivered by nurses, registered dietitians and physicians. Physician educational intervention produced the most dramatic change likely due to the additional manipulation of medications. There were no differences found between outcomes of nurse and registered dietitian education.

Davies, Heller, Skinner, Campbell, Carey, and Cradock et al (2008) conducted a large multi-centered randomized control trial of 824 type 2 diabetic patients randomized to receive a structured group education program or usual care. Two trained healthcare professionals conducted a 6 hour educational course aimed at newly diagnosed type two diabetics. These participants were followed for a year with data collection at 4, 8 and 12 month from intervention. The intervention group showed a statistically significant weight a loss of 2.98 kg compared with 1.86kg in the usual care group. Hemoglobin A1C levels at 12 months had decreased by 1.49% in the intervention group, which was not found to be statistically significant.

What are the gaps in research?

Chronic diabetes care literature is abundant and the importance of weight management has been well established. The majority of literature has been focused at the primary care setting with insured patients although the incidence of obesity and diabetes disproportionately affects the socioeconomically disadvantaged (Rabi et al., 2006). There are limited studies directed at the low income and uninsured population and even less about free medical clinics. Only one study to date has looked at the chronic care needs of uninsured patients utilizing free medical clinics and showed that the use of the chronic care model can be successfully used as a template in the management of chronic disease in this setting.

Free medical clinics are widely under published despite evidence of health disparities faced by the population of people utilizing the clinics. Free medical clinics are generally volunteer ran with very limited resources and primitive records making data collection difficult. The population of patients utilizing free clinics is dynamic leading to high attrition rates. Language, educational and cultural barriers make research and data collection difficult.

Summary

Free medical clinics are an important resource for growing number of uninsured people in this country. Despite their conception in the 1960, little has been published about free clinics. The chronic needs of the uninsured are growing burdening the free medical clinics with the challenge of managing chronic disease with very little resources. The chronic care model has been tested in the use of diabetes and has been shown to be feasible in this patient population and setting (Stroebel et al, 2005). Focused interventions are needed to evaluate the accessibility and feasibility of applied interventions in this population and setting.

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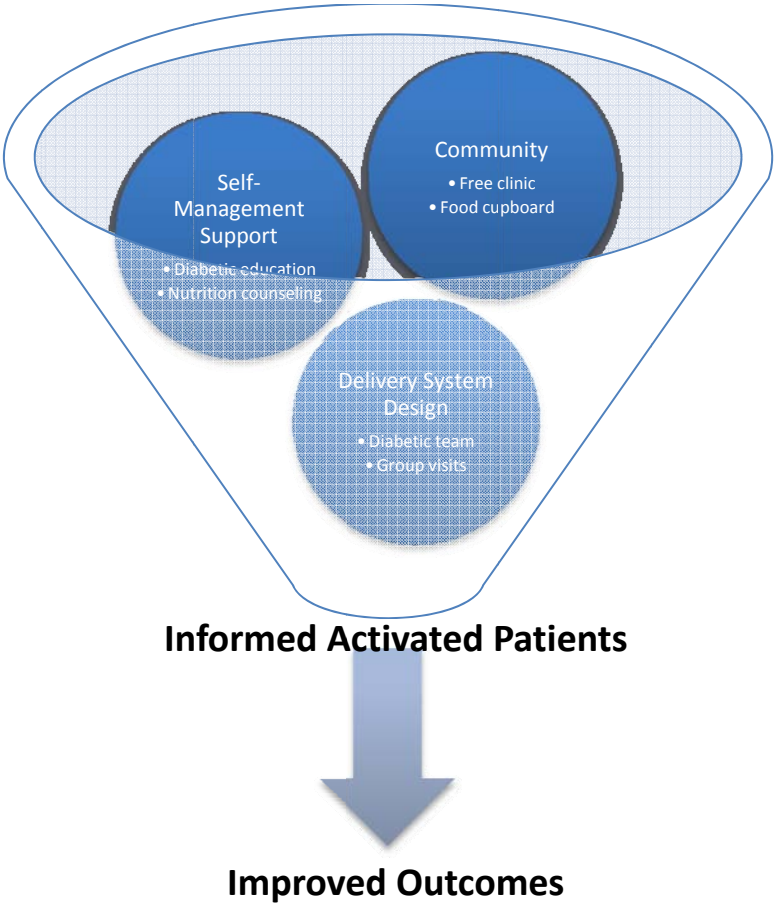
Figure 1. Adapted chronic care model applied to diabetes management in a free medical clinic



Running head: HEALTH DISPARITIES

Health Disparities: Uninsured Diabetics

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Case Study

Maria* is a 45 year old Hispanic, Spanish speaking women who presents to my office as a new patient. She is in today with her niece who acts as translator for Maria. Maria's niece is a patient of mine and brought her in today for follow up from Maria's recent hospitalization. She was taken to the emergency room after her family found her confused and disoriented and "acting strangely". While in the emergency department blood work revealed she had diabetes. Her blood sugar on admission was 480. Her Hemoglobin A1c was 11.5. After initially receiving insulin in the hospital, she was discharged home with metformin, glyburide and told to follow up with her primary care provider within two or three days.

Maria's history is remarkable for having "large babies". She has three children, all two of which were over 10 pounds at birth. She denies having had gestational diabetes. She tells me her mother and her father both had diabetes and died of heart disease years ago. Within the last 6 months Maria has lost 50 pounds and reports having polyuria, polydipsia and nocturia. She admits to thinking something was wrong with her health but delayed seeking treatment because she was busy with work and worried about her financial situation and medical bills. She and her niece have very little understanding of diabetes. They do have a glucometer given to them in the hospital but went to the pharmacy to fill the test strip prescription and did not get these because of cost.

Maria does not have health insurance. She moved from Mexico 5 years ago with her husband to live with extended family. She does have a social security number recorded but is hesitant to talk about her citizenship and it is thought that this may be a false number. She works part time at a local grocery store and her husband is employed

seasonally as a field worker. She is worried about her financial situation and her niece tells me she can only fill one of her medications from the pharmacy.

Introduction

According to 2006 data, there are more than 47 million people without health insurance living in the United States (U.S. Census Bureau, 2007), an increase of more than 2 million from 2005. The percentage of the population without health coverage has increased from 15.2% in 2005 to 15.6% in 2006 (U.S. Census Bureau, 2007). The rising rate of those without insurance is a local concern as well. Information from the 2006 Washington State Population Survey reveals 13% of the state's population is uninsured, totaling more than 787,000 people (Kaiser Family Foundation, 2006; Washington State Office of Financial Management. 2006).

There are approximately 20.5 million people in the United States living with diabetes and another 50 million more with prediabetes (American Diabetes Association, 2007). Each year more than 220,000 people will die from diabetes related complications; a number that most think is grossly underestimated. It is the fifth leading cause of death by disease in the United States and a leading cause of morbidity; associated with an increased risk of heart disease, kidney disease and blindness (American Diabetes Association, 2007). Expenses are not limited to morbidity and mortality of the disease, the economical burden of this condition is estimated at over 132 billion dollars per year (American Diabetes Association, 2003).

The United States remains the only industrialized country without a national health care plan. While many industrialized countries developed national healthcare in the first half of the 20th century, the United States has lagged far behind in any efforts to

provide national healthcare (Blankenau, 2001). According to Navarro (1995), as long ago as 1980 Americans have supported a national health care program, but Congress has failed to enact such a program as early as 1913 when it was first attempted (Emanuel & Fachs, 2005). As far back as 1945 President Truman saw the need of government influence on healthcare and attempted to enact a single payer system which was defeated in part due to the large campaign by the American Medical Association characterizing the bill as "socialized medicine" and capitalizing on public fear of Communism (Truman Library and Museum).

The country's political institutions have played a significant role in the evolution of the current health care configuration. The political structure of the United States emphasizes a separation of powers among the legislative and executive branches. This power structure, along with political party partisan behavior, results in significant opportunities for opposition and creates a need for monumental mobilization to overcome the status quo (Blankenau, 2001). Special interest groups have evolved to have an ever increasing role in health care policy (Navarro, 1995). Despite multiple failed healthcare reform efforts in the last century and overwhelming public support, the U.S. remains the only industrialized nation without a national health plan.

Maria's story is not unfamiliar in this area of Southern Washington where migrant work brings in a large undocumented immigrant population. Without health insurance, citizenship and facing a serious health condition, the resources available to Maria are limited. Washington State has a large population of undocumented immigrants, estimated between 175000 and 200,000. This population represents 25% of Washington's uninsured (Passel, Capps & Fix, 2004). The struggle with the health care system in this

population includes a decreased access to care and a decrease in quality of care. Uninsured people are less likely to have a primary care provider and less likely to receive preventative services. They are more likely to delay seeking medical care and have an increase in utilization of emergency department visits (Hadley & Cunningham, 2004; Nadkarni & Philbrick, 2005).

Recommendations

The literature demonstrates adverse outcomes for people without insurance. Diabetes is a complex disease requiring comprehensive treatment to manage and prevent complications. The nurse practitioner (NP) will need to address access and quality of care, two areas which have been identified in the literature as being inadequate in the uninsured population. The desired outcome is that Maria have access to quality health care; obtaining the education needed to understand disease process and self monitoring and treatment, obtain medications and improve medication adherence. These would ultimately improve her diabetes outcomes and prevent disease complications.

There are a number of ways in which the NP could intervene to improve Maria's health outcomes. The NP could see her in the office free of charge and provide her with sampled medications if employment contracts do not otherwise binding. This would improve care to Maria but is not feasible to do for every patient in Maria's situation. Literature has shown that the amount of charity care provided by physicians has decreased in recent years (Isaacs & Jellinek, 2007).

Another option includes referring Maria to resources where she can get the care she needs. The free clinic serving Southern Washington has a comprehensive diabetes program including diabetic education class, nutrition classes, prescription medications

and access to primary care. The services are provided for free to people like Maria who are in low socioeconomic class and do not have health insurance. There are other safety net clinics available in the area, such as the community health clinic and the emergency department, however there would be a fee accrued from these visits and may result in Maria's failure to follow up. Giving Maria and her niece information about the free clinic, location, times they are open and assuring them that they will not charge her for the services provided is one strategy to improve access to care and get Maria the services she needs.

The emergence of free clinics in the 1960's has made a significant impact in quality and access to medical care in the uninsured. Evidence has shown that safety net clinics can decrease the inappropriate use of emergency rooms and hospitals (Hadley & Cunningham, 2005) and improves morbidity and mortality (Nadkarni & Philbrick, 2005).

Implications

Advance practice nurses will undoubtedly come in contact with patients of lower socioeconomic standing and will need to be mindful of the resources available and the barriers they face. In the example of Maria, the NP could see her in the office, have her nurses do all the disease education and give her samples of medication and charge her the regular encounter fee. However the implications of this may result in Maria's inability and unwillingness to follow up in the office for medication management and may result in greater economic stress for her and her family. Additionally, the education provided by the office nurses regarding dietary needs of diabetic patients may not be culturally or economically feasible for Maria's situation and a more tailored intervention is needed.

Healthcare coverage was a major platform in the recent presidential election. With the election of President Obama comes a promise to increase access to care to the millions without health insurance and decrease health care expenditures through the adoption of improved information technology, improved preventative care and chronic disease management, and insurance reform (Obama for America, 2008). As vested stakeholders in the changing face of healthcare, NPs needs to be actively involved in order to influence the shape health reform takes in the upcoming months.

Personal Reflection

In order to truly understand and get involved with Maria's case and treat her as the unique patient she is, one must possess both personal and professional leadership skills. It is possible to treat her with basic clinical judgment and professional competency however the implications are far greater when taking into account other contextual features such as her socioeconomic status. The leadership skills applied in her case includes interpersonal relationships, communication, resourcefulness and critical anaylsis. In order to develop Maria's case to one that has potential to affect other people in her situation, the nurse practitioner must have interpersonal and communication skills to adequately articulate the need for intervention and effectively communicate with the patient, families and other health care members. Without that communication and development of interpersonal relationships, Maria and her niece might question being referred out to another facility and may be hesistant to follow up.

Critical analysis of the situation is needed. It is possible to treat her as one would any other patient that comes in the door, start medication without concern of cost, order diabetes education and have her follow up as insured patients do. However, in this

case, just treating her in the office would end up leaving the patient confused, financially stressed and turned off from further medical care. Directing her care to the free clinic will provider her with the treatment she needs and the peace of mind that she is not going to have large medical bills.

Being resourceful and knowing about the spectrum of resources available is needed when dealing with patients. This is one area where I can increase my awareness. Although alert to the availability of the free clinic I am not well versed as to other resources for people in Maria's situation. There are programs for people to get them free medications or even to get them insurance coverage under some of the state programs if they have serious medical conditions. I referred her to the free clinic where the providers will know about these programs and can get her the help she needs.

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Running head: CHRONIC BERYLLIUM DISEASE

Chronic Beryllium Disease: Not Gone but Forgotten

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Abstract

Purpose: Chronic Beryllium Disease is a chronic and progressive pulmonary and systemic granulomatous disease caused by exposure to beryllium dust or fumes. CBD can be latent for decades after initial exposure making its recognition by primary care providers important.

Data Sources: Data sources included articles from medical journal database PUBMED as well as Hanford Site online information from the Department of Energy.

Conclusion: The Hanford Site contamination is a serious public health concern. The affected workforce is unknown but estimated in the thousands.

Implications for practice: Nurse Practitioners need to consider environmental and occupational exposure etiologies.

Keywords: Beryllium, Chronic Beryllium Disease, Hanford

Chronic Beryllium Disease

Introduction

Beryllium is a relatively rare metallic element primarily used as a hardening agent in alloys, the most common being beryllium copper. It has many applications due to its strength, lightweight, relatively high melting point, corrosion resistance, thermal conductivity and machinability. It is used in a number of industries including aerospace, telecommunication, biomedical, defense and automotive (Weston et al., 2005), and can be found in a variety of objects such as electrical, machine and aircraft parts, nuclear weapons, hammers, golf clubs, camera shutters, mirrors and dental prostheses (Lang, 1994). Beryllium and beryllium compounds are known carcinogens in animals and humans (Kuschner, 1981).

The Hanford site is a 586 square mile area of land along the Columbia River in southeastern Washington State used as a plutonium producing plant during the cold war. It housed the B-reactor, the first full-scale plutonium production reactor in the world (Hanford Site, 2008a). The project expanded to include nine nuclear reactors and five plutonium processing facilities, which were responsible for producing most of the nuclear arsenal for the US government (Hanford Site, 2008b). Beryllium was used in these nuclear reactors between 1960 and 1986. There are currently no active beryllium operations at Hanford. However, the risk of exposure still exists as there are 12 known facilities on site evaluated as contaminated or possibly contaminated with beryllium (Hanford Beryllium, 2008a). The Department of Energy has taken over the Hanford site and is currently engaged in the world's largest environmental cleanup project to remove more than 53 million gallons of radioactive waste, 2,300 tons of spent nuclear fuel, 9 tons of plutonium and 80 miles of contaminated groundwater (HanfordSite, 2007a).

Exposure to beryllium fumes or dust can cause sensitization to the element which can lead to Chronic Beryllium Disease (CBD). CBD is a pulmonary and systemic granulomatous disease

that can occur years or even decades after exposure to beryllium. The number of workers who were exposed to beryllium during the plutonium production is unknown but estimated in the thousands. Today, the Hanford cleanup project employs 10,000 local workers (Hanford Site, 2008b). The Hanford site contamination is a serious public health concern and the environmental risks associated with it are enormous. The political, economical and ethical dimensions related to the Hanford project will be discussed in-depth in the body of the paper.

Epidemiology

Chronic Beryllium Disease is caused by inhalation of beryllium fumes or dust into the lungs. Sensitization occurs after exposure to beryllium as the body mounts an immune reaction to the beryllium compound. The mode of transmission is most commonly through inhalation into the lungs, however some research has linked beryllium splinters to sensitization (National Institute for Occupational Safety and Health [NIOSH], 2005). Once sensitized, the latency to CBD can range from a few months up to 30 or more years (Lang, 1994). The number of people with occupational exposure to beryllium in the United States is unknown but it is estimated to be around one million (Fontenot & Maier, 2005).

The prevalence of sensitization to beryllium is unknown and varies across different industries. In 2000, the National Institution for Occupational Safety and Health (NIOSH) surveyed employees at a copper-beryllium alloy strip and wire finishing plant. In this population 7% tested positive for sensitization and 4% were found to have CBD (NIOSH, 2005). A large study of three Department of Energy nuclear facilities, including Hanford, revealed a sensitization rate of 2.2 % (Welch et al., 2004). Another study in a beryllium processing facility in Pennsylvania reported 7.6% of the sample had CBD and another 7% were sensitized without CBD (Rosenman et al., 2005). Beryllium machinists seem to have the greatest risk of

occupational exposure and have the highest rates of beryllium sensitization and CBD, although research has shown sensitization in individuals with incidental exposure indicating the amount and duration of exposure is not necessarily a predicator of disease susceptibility (Newman, Mroz, Balkissoon, & Maier, 2005). At Hanford the groups at risk are those who worked at the site between 1960-1986 when beryllium was used and stored and those workers who are actively involved with the Hanford site cleanup.

There do not appear to be differences in disease susceptibility between age, sex, race, or ethnicity (Newman, Mroz, Balkissoon & Maier, 2005). Individual genetic differences do however play a central role in the pathogenesis of CBD. Disease susceptibility has been associated with Human leukocyte antigen (HLA) genes. HLA-DPβ1*0201 is associated with the development of CBD whereas HLA-DPβ1*0401 appears to be protective. Eighty-five percent of patients with CBD have an HLA-DPβ1 allele variant with a glutamic acid for lysine substitution at position 69 (Newman, 1996). A large portion of people with CBD who do not express the glutamic acid containing HLA-DPβ1 allele show a similar glutamic acid variation at the 71 position of the HLA-DRβ1.Other MHC genes, such as tumor necrosis factor (TNF) have also been associated with CBD susceptibly, disease severity and could potentially influence progression from beryllium sensitization to disease (Fontenot & Maier, 2005).

Although genetic testing to screen for exposure risk is not yet available, there are other ways to reduce exposure and risk of sensitization. Limiting the amount of exposure has been at the forefront of occupational safety. Prior to the Occupational Safety and Health Administrations (OSHA) guidelines for industrial exposure limit, it was not uncommon for beryllium air concentration levels to be greater than 1000 $\mu g/m^3$ (Lang, 1994). In contrast, the current OSHA exposure limit for airborne beryllium is $2\mu g/m^3$ based on a eight hour time weighted average

(OSHA, 2008). Research has shown that even at this level individuals are not protected (Rosenman et al., 2005). To further reduce exposure risk some have recommended initiating administrative controls limiting the number of workers allowed into contaminated areas, improving ventilation systems to reduce dust and providing personal protective equipment when exposure cannot not be controlled (Cummings et al., 2007). To minimize contact exposure one facility has initiated double gloving policies and gloving prior to disrobing in order to reduce the risk of sensitization and CBD (NIOSH, 2005).

Case study

Mr. S, a 65 year old male comes into the clinic as a new patient. His long time primary care provider recently retired and he is searching for a replacement. He is married with three grown children and is a retired engineer. He has concerns about his asthma exacerbations. In the last 10 years he has been treated with a polypharmacy regimen including short and long acting bronchodilators and inhaled corticosteroids. In addition, he reports being treated with oral steroids and antibiotics at least 2 times per year during his exacerbations. His medical history is significant for hypertension and benign prostatic enlargement. In addition to his inhaled medications, he reports taking hydrochlorothiazide 50mg daily, lisinopril 20mg daily, tamsulosin 0.4mg daily and dutasteride 0.5mg daily. Mr. S employment history is significant for working at the nuclear plant from 1972 until 2 years ago when he retired. He has been told he was exposed to a number of occupational toxins. He has had worsening paroxysmal nocturnal cough and shortness of breath with exertion in the last 5 years. He is in for evaluation of his deteriorating asthma symptoms.

Discussion

There are a number of ethical, economic and political considerations related to beryllium exposure at Hanford. Ethical concerns have historical context dating back to the 1930's when the

United States failed to react to foreign published data linking beryllium inhalation and lung disease (Lang, 1994). Additional historical ethical concerns include the secrecy of the plutonium producing facilities. More than ninety-nine percent of individuals working at Hanford during the plutonium producing years were unaware of the true nature of the project and exposure risks (Hanford Cultural Resources Program, 2002). More recently, the identification of genetic polymorphisms increasing the risk of sensitization to beryllium have raised ethical concerns surrounding screening practices and the potential consequence the dissemination of that information could have on the individual's ability to obtain health insurance and disability insurance (Lang, 1994).

Enormous individual economic losses are realized with chronic beryllium disease, including loss of productivity from time missed, disability, and continual medical expenses. In addition to multi-individual losses, the federal expenses related to the concentrated efforts to decontaminate Hanford are enormous. As the largest environmental cleanup project in the world, the Department of Energy spends 1.8 billion dollars annually (Hanford Site, 2007a).

The other major governmental agency interface associated with beryllium exposure is the Occupational Safety and Health Administration branch of the U.S. Department of Labor. Historically government efforts to limit exposure have not been encouraging, despite the role government nuclear sites and plutonium producing facilities had in exposing thousands of workers. The current OSHA exposure limit of $2\mu g/m^3$ of workroom air for an 8 hour work shift was adopted in 1949, years after beryllium associated deaths were first reported and more than a decade after research linking beryllium exposure and lung disease was published (Lang, 1994). Despite abundance of evidence suggesting this level is not protective, OSHA has failed to adjust the recommendation putting more workers at risk for beryllium sensitization and CBD. Other

organizations have recommended or implemented more stringent guidelines. The Department of Energy has established independent limits of 0.2µg/m^3. The American Conference of Governmental Industrial Hygienists, an independent organization of experts in the field of occupational health, has proposed a threshold limit value of 0.05µg/m^3, 40 times lower than the current OSHA limit (Rosenman et al, 2005). Recent governmental efforts have been more promising. In 2001 Congress passed the Energy Employees Occupational Illness Compensation Program Act which provides compensation for workers in government nuclear sites with chronic beryllium disease (Hanford Site, 2007b).

Recommendations and Implications

Chronic Beryllium Disease has become a large health concern, especially in nuclear sites such as Hanford as well as in other industries utilizing beryllium metal. Employers are actively educating employees about the risks and taking measures to decrease exposure and screen for sensitization. The efforts are largely confined to the industry's occupational health providers and often primary care providers are not as educated about beryllium disease. Because CBD can be latent for decades after exposure, it is important to increase awareness to primary care providers who will be treating a large proportion of the retired workforce. Nurse practitioners need to consider environmental and occupational etiologies and be aware of the possibly of CBD when seeing patients with previous exposures like Mr. S. Early diagnosis is important to limit disease progression and to get patients enrolled in employer based assistance programs that may provide compensation for their medical care.

It is recommended that OSHA adopt a more stringent beryllium exposure limit given the evidence examined in the body of the paper that the current limits may not be adequate. Specifically, it is recommended that beryllium exposure limit of workroom air for an 8 hour shift

be reduced to 0.05µg/m^3 as suggested by The American Conference of Governmental Industrial Hygienists. In addition, OSHA needs to enforce and encourage more personal protective equipment to improve contact sensitization. Nurse practitioners, in addition to their role in primary care and diagnosis, need to have an active role as lobbyist for policy change and increased safety in the workplace.

Personal Reflection

The personal and professional leadership skills needed to asses Mr. S's health needs are minimal, and require professional competency and sound clinical judgment. However, in order to take the information that is learned from Mr. S and apply it to the entire population affected requires many leadership skills including interpersonal relationships, communication, and determination. In order to develop Mr. S's case to one that has potential to affect society, the nurse practitioner must have interpersonal and communication skills to adequately articulate the need for intervention. In this case, in order to address making workplace environments adopt a more stringent exposure limit, the NP must have the skill set and the know how to lobby for quality control. Determination and persistence are required as many change efforts are not responded to quickly. Influencing government control to reduce exposure limits has the potential to take a very long time.

Determination and persistence are areas I need to develop and improve proficiency. Daunting tasks that require patients and persistence tend to get overshadowed with doubt that they may never be achieved. Leaders need to have the vision to see tasks through and to know their efforts can, and will, eventually produce change.

Communication and interpersonal skills needed to connect with patients, their families and, governemental agencies and administrators is an area of leadership that I feel is fairly well

developed. From early on in my career, communication has been an area that has been emphasized. These skills have evolved from communicating with individuals to learning how to communicate with offices or those entities were a name is not necessarily attached. Learning to communicate through writing is an area where I need to improve on as this will be key in the dissemination of information that can facilitate change.

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Running head: ARNOLD CHIARI-1 MALFORMATION

Arnold Chiari 1 Malformation: Clinical Case Review

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Arnold Chiari 1 Malformation: Clinical Case Review

Chiari malformation (CM) includes a group of disorders characterized by a 5 mm herniation of the cerebellar tonsils through the foramen magnum into the spinal canal (Caldarelli & Rocco, 2004; Strayer, 2001). Herniation leads to decreased cerebrospinal fluid in the brain and can lead to the formation of a cavity, called a syrinx, within the spinal cord. There are three main types of CM, differentiated based on severity of malformations. Chiari malformation type 1 (CM1) is the simplest and most prevalent form. It is considered a congenital malformation, although it is generally not apparent at birth (Caldarelli & Rocco, 2004; Strayer, 2001).

Chiari malformation type 1 was first described by Hans Chiari in 1891 (Strayer, 2001). It was thought to be a fairly rare occurrence but in recent years, with the increased availability of magnetic resonance imaging, the prevalence has risen sharply. It is currently estimated that between 200,000 to 2 million Americans have this condition (Chiari Institute, 2007). Genetic studies support a hereditary tendency with a transmissibility rate of 12 percent. Women are affected three times more often than men. (Chiari Institute, 2007). Many patients with CM1 are identified incidentally. However, some patients present with the classic neurological findings, such as headache, cervical pain, extremity pain or paresthesias, pyramidal or cerebellar signs, cranial neuropathy, and signs of elevated intracranial pressure. (Caldarelli & Rocco, 2004; Strayer, 2001). Because of the complexity of the disorder, the symptoms experienced may be vague and variable among individuals. Often symptoms are slowly progressive and misdiagnosed as multiple sclerosis, myasthenia gravis, or somatic disorders. The symptoms are generally present for months to several years prior to diagnosis (Taylor & Larkins, 2002)

In the case study presented in the body of the paper, the subject has experienced persistent and worsening headaches over the last two years. The incidence of persistent headaches with

CM1 is a common clinical manifestation. Garland and Robertson (2001) reported that 81% of study individuals with CM1 complain of suboccipital headaches. The headache associated with CM1 tends to be worse with activity, coughing or changes in body position (Chalaupka 2000; Ertsey & Jelencsik, 2000; Greenlee, Donovan, Hasan, & Menezes, 2002; Sun, Harrop, & Sutton, 2001).

Case Study

Mrs. Anderson* is a 32 year old Caucasian female who presents to the clinic complaining of occipital headaches that have been persistent for years. Despite having been to many sessions with chiropractors, massage therapists and physical therapists in the past for what practitioners believed to be cervical neck pain induced headaches, her symptoms continued to worsen over the last two years. She now complains of worsening headaches, dizziness causing near syncopal episodes. Her symptoms are starting to strain her relationship with her husband and her family. She is finding household chores increasingly difficult to complete and has recently given up driving because she is scared of “passing out”. Her extended family has been helping her out the last couple of months but she is having less support the longer her symptoms continue.

Her past medical history is significant for a history of headaches which started in college. She does have prescription medication for her headaches. She is currently on relpax and reports having tried at least three or four other medications in the last couple of years. Otherwise, she does not take prescription or over the counter medications. Mrs. Anderson is married with 2 children. Her husband had a vasectomy after their last child. She has no surgical history. She has been seen for her symptoms in the past and has had x-ray and an MRI more than five years ago which she reports were normal. She had not had laboratory evaluation at the time of initial consultation.

Due to the worsening of her symptoms, another MRI was ordered. The results showed her cerebellar tonsils were herniated through the foramen magnum by approximately 12 mm, which is consistent with a significant CM1. Laboratory workup was unremarkable, her inflammatory markers were normal as were her antinuclear antibodies, thyroid function tests, complete blood cell count and complete metabolic panel.

Analysis

Treatment options for CM1 generally involve either observation or surgical intervention. A number of studies have shown spontaneous regression of cerebellar herniation over time (Greenlee, Donovan, Hasan, & Menezes, 2002; Sun, Harrop, & Sutton, 2001). However the literature is generally confined to pediatric cases and incidentally found cases. Often times as the spinal column elongates with natural growth, the length of herniation improves (Greenlee, Donovan, Hasan, & Menezes, 2002). With symptomatic CM, surgical intervention with a posterior fossa crainiectomy and upper cervical laminectomy of the first and second cervical vertebrae with or without dural graft patching is the primary treatment option (Alden, Ojemann, & Parks, 2001; Taylor & Larkins, 2002). In a retrospective case review of 27 patients with CM1 who underwent surgical intervention, Dones, De Jesus, Colen, Toledo & Delgado (2003), found the main benefit of surgery to stop the progression of symptoms. Of the subjects who presented with headaches only 13% showed improvement after surgical intervention but the remaining subjects did not decline postoperatively. Vertigo improved in 50% of the subjects postoperatively. The study did not include longitudinal postoperative follow up to assess for delayed improvement.

There is some evidence of pharmacological interventions to improve CM1. Indomethasin, an anti-inflammatory medication is thought to decrease cerebral blood flow and reduce

intracranial pressure with daily use (Ertsey & Jelencsik, 2000). Chalaupka (2000) showed that use of acetazolamide, a diuretic medication, may improve CM1 manifestations due to decreased intracranial pressure and depression of neuronal excitability. These treatment options are fairly benign without significant adverse effects and some believe they should be attempted prior to surgical intervention (Chalaupka, 2000; Ertsey & Jelencsik, 2000).

Mrs. Anderson's has gone without diagnosis for the last five years. In the last year, her decline in overall health has been causing significant strain on her daily life and her family life. She is no longer driving and was requiring assistance from her extended family for many of her and her families daily activities. Due to her age, the severity and duration or her symptoms, and the significant cerebellar herniation, prompt referral for neurosurgical consult is recommended and was facilitated for the patient in order to decrease the risk of disease progression and in hopes to provide symptom relief. Consequences of not treating Mrs. Anderson go beyond the physical symptoms as her disease and symptoms are putting significant stain on relationships in her life. Providing symptom improvement would improve those relationships which could be worsened otherwise.

Recommendations

After review of her clinical information and diagnostic information it was recommended that she be evaluated by a neurosurgeon for possible surgical intervention. Additionally, I recommended that Mrs. Anderson, her husband, sister and mother-in-law come into the office to discuss her diagnosis, treatments options and expected clinical course. A visit with all involved parties would provide them an opportunity to have their questions and concerns addressed.

It is expected that Mrs. Anderson will have surgery and this will improve her vertigo. It is hoped that her headaches will improve as well but surgical intervention should at least keep her

symptoms from worsening. She has lived with the headaches for the past five years but in the last year with the addition of the vertigo she has had concerns about caring for her family. If her vertigo alone improves she will consider the intervention successful.

Evaluation

Mrs. Anderson underwent surgical decompression with a suboccipital crainiectomy and cervical laminectomy. She has experienced improvement in her headaches since the surgery. She wears a brace as needed but 6 weeks post operatively she is back to driving and making her families dinners again. She is still not able to lift more than five to ten pounds, but feels significantly better. She reports her family relationship have improved since time of diagnosis.

The DNP has a pivot role in the care of the patient with CM1. The DNP can assure early diagnosis and facilitate referral to appropriate teams for treatment. Patients may present with a wide array of clinical manifestations, chronic headaches and vertigo being common complaints. Thus, knowledge about CM1 can lead to prompt diagnosis and earlier treatment.

Reflection

Mrs. Anderson's case presented not only a complicated differential but additionally presented with family relationship strain caused by her symptoms. The personal and professional skills needed to intervene in this case included clinical knowledge as well as communication and interpersonal skills. Clinical knowledge is important to formulate a differential for common concerns of headaches and vertigo which should include CM1.

Communication and interpersonal skills are needed to connect with patients, their families, and specialist is an area of leadership that I feel is fairly well developed. From early on in my career, communication has been an area that has been emphasized. In this case study, listening to the patients concerns and not dismissing her symptoms which could result in misdiagnosis for

another couple of years was the first step in developing a working relationship with the patient. Identifying her individual needs, including assisting her and her family in understanding Chiari malformations made significant improvements in the family dynamic issues that were present due to her symptoms.

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Running head: VITAMIN D DEFICIENCY

Vitamin D Deficiency Induced Pain

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Vitamin D Deficiency Induced Pain

Vitamin D deficiency has become an increasingly common health concern nationally and globally and in recent years has been recognized as a pandemic (Holick & Chen, 2008). Deficiency is associated with many health concerns including hypertension, obesity, diabetes, autoimmune diseases, colon, breast and prostate cancer (Cannell, Hollis, Zasloff & Heaney, 2008; Holick, 2004) as well as skeletal defects, bone pain and myalgia (Brinkley, Krueger, & Drenzer, 2008; Holick, 2007; Mascarenhas & Mobarhen, 2004). The clinical case studied in this report examines the role that vitamin D deficiency plays as a cause of persistent arthralgia and myalgia in a young woman.

Vitamin D is normally synthesized in the skin after exposure to sunlight, ingested from fish or plant sources or from dietary supplementation (Holick, 2007; National Institutes of Health [NIH], 2008). Vitamin D is hydroxylated in the liver to 25-hydroxyvitamin D [25(OH)D], which is the major circulating form of vitamin D and the best measure of vitamin D status. 25(OH)D is hydroxylated in the kidney to 1, 25-dihydroxyvitamin D, which is the most active form. Vitamin D deficiency can occur as a result from reduced sun exposure, decreased intake or absorption, increased hepatic catabolism, or decreased endogenous synthesis (Holick, 2007; NIH, 2008).

The measurement of serum 25(OH)D is the gold standard for determining the vitamin D status of a patient (Cannell, Hollis, Zasloff, & Heaney; Holick, 2005). Over the last two decades, the definition of vitamin D deficiency has varied. Although there is no consensus on the optimal 25(OH)D concentration, most experts agree that serum level less than 20 ng/ml indicates deficiency and 21-29 ng/ml is considered insufficiency (Cannell, Hollis, Zasloff, & Heaney; Holick, 2005). The optimal range of serum 25(OH)D level is still the subject of debate but is assumed to be 32-50 ng/ml or higher (Holick, 2007).

Although the use of vitamin supplementation and fortification of foods with vitamin D has greatly reduced the incidence of osteomalacia, it remains a considerable health concern, estimated to affect over one billion people worldwide (Holick, 2007). According to one study, vitamin D deficiency was reported in approximately 36 percent of otherwise healthy young adults and up to 57 percent of general medicine inpatients in the United States (Holick, 2006). Among 150 subjects in inner city Minneapolis with persistent, nonspecific musculoskeletal pain, 93 percent were found to be deficient in vitamin D status. Twenty-eight percent of those subjects suffered from severe deficiency (Plotnikoff & Quigley, 2003). Another study found that 93 percent of persons aged 10-65 years of age who were admitted to a hospital emergency room with muscle aches and bone pain were deficient in vitamin D (Holick, 2007).

Case Study

Ashley*, a 23 year old female presented to my office complaining of generalized myalgia, arthralgia and fatigue that has been ongoing for the last couple of years. She first became concerned with these symptoms a couple of years ago. She was evaluated by a provider at her student health center on her college campus within the last year. She reports that her blood work came back normal and was told to take a multivitamin and get more rest. Now home for vacation, she presents with her mother for second opinion of her symptoms. Her mother requests that she be tested for autoimmune disorders and fibromyalgia, reporting that Ashley's grandmother had rheumatoid arthritis, a distant aunt recently diagnosed with lupus and she was told she had fibromyalgia a couple of years ago, although currently is doing well.

Ashley's past medical history is significant only for seasonal allergies for which she takes antihistamines and nasal steroids during the summer and fall months. She lives a couple hours away while going to school and comes back some weekends and on vacations. She works at a

retail store and is getting her masters degree. She does smoke socially, less than 1 pack per week and drinks alcohol almost every weekend. At the recommendations from the health care provider she saw earlier, she is taking a multivitamin and getting at least seven hours of sleep most nights. On exam, Ashley is overweight at 63 inches and 160 pounds (body mass index of 27.5) with central adiposity. She is fair skinned with light brown hair. Her cardiovascular and respiratory assessments are normal. She brings her lab work obtained earlier in the year with her for review. It reveals a normal complete blood count, thyroid function testing and complete metabolic panel. After history and physical examination additional lab work was ordered including a 25(OH)D level and Antinuclear Antibody (ANA). Her ANA was normal but her vitamin D level came back at 12 ng/ml; indicating vitamin D insufficiency.

Analysis

Vitamin D deficiency can cause generalized or isolated throbbing bone pain which is often misdiagnosed as other pain syndromes. Deficiency is associated with decreased absorption of dietary calcium and phosphorus which causes an elevation of PTH to respond to calcium deficiency. The secondary hyperparathyroidism causes wasting of the skeleton and poor bone mineralization of the bone matrix leading to osteomalacia (Heaney, Dowell, Hale, & Bendich, 2003; Holick, 2005). The relationship between vitamin D and calcium is thought to contribute to perceived muscle pain and weakness as well as. Deficiency of vitamin D leads to alterations of intracellular calcium status which affects muscle functioning (Heaney, Dowell, Hale, & Bendich, 2003). Additionally, vitamin D receptors are present in human muscle tissue (Holick, 2004).

Several factors are present that complicate vitamin D deficiency treatment. First, as discussed previously, the diagnosis of vitamin D deficiency is not well established (Cannell, Hollis, Zasloff, & Heaney; Holick, 2005). Equally as ambivalent are the recommendations for

prevention and treatment of deficiency (Cannell, Hollis, Zasloff, & Heaney). The current recommended daily allowance for vitamin D in the United States is 200 IU per day for children and adults up to age 50 years, 400 IU per day for age 51-70 and 600 IU per day over the age of 70 (National Institute of Health, 2008). Studies indicate these levels are not sufficient (Holick, 2005; Holick, 2007). In the absence of sun exposure, doses between 1000 and 2000 IU daily for adults are likely needed to maintain levels between 30-50 ng/ml of 25(OH)D (Holick, 2005; Holick & Chen, 2008).

Recent studies offer some information on how much vitamin D may be required to improve vitamin D status. Holick et al., (2005) showed that serum levels of 25(OH)D increase by 1 ng/ml for every 100 IU vitamin D3. Similarly, Cannel, et al. (2008), found that 1000 IU/day of vitamin D3 will usually result in about a 10 ng/ml elevation of 25(OH)D when given over three to four months (Cannell, Hollis, Zasloff, & Heaney, 2008). Conversely, a light skinned person wearing a bathing suit can absorb 20,000 IU after five minutes of unprotected sun exposure (Boyles, 2003).

Recommendations:

Evidence has shown an increase in females of childbearing age with severe vitamin D deficiency leading to pain syndromes (Boyles, 2003). Based on resent research, Ashley should be treated with supplementation to improve her symptoms and to prevent possible complications that can occur as a result of hypovitaminosis D. After discussing treatment options with Ashley and her mother, it was decided to start her on vitamin D3 available over the counter. She was started on 3000 IU daily for a month and then will reduce to 1000 IU daily for an additional three to four months at which time her labs will be redrawn. The expected is to have improvement of her arthralgia and myalgia symptoms over the next six months. Although unprotected sun exposure

can be very beneficial in improving vitamin D status, it remains controversial and given her fair complexion type I have advised her to continue to wear sun protection when out in the sun for prolonged periods of time.

Evaluation

Ashley's case presents many interesting and complex diagnostic concerns. Vitamin D deficiency as an etiology of pain has become more apparent in the literature. However the definition and best treatment remains under debate. Her case requires one to not only wade through the multitude of conflicting literature, but make sound choices based on that literature and in the context of the individual case. Vitamin D deficiency is well known in the literature but clinical diagnosis and evaluation has lagged behind. As clinicians, it is important to stay abreast literature to ensure patients are getting quality clinical care. Although treatment recommendations may differ depending on the individual patient, the clinician needs to be aware of the variety of options for treatment in order to transfer knowledge and experience gained for the individual patient to the broad population of patients one will see with similar symptoms.

Ashley has been on therapy for one month at the time this paper was compiled, her vitamin D levels have not yet been retested and she does not have improvement in her pain thus far. She is encouraged to supplement her diet with vitamin D and she will return in two months time to repeat laboratory values and follow up on her condition. She is expected to have improvement in her symptoms over the next three to six months.

Self Reflection

Ashley's case is one that I have become increasingly aware of over the last couple of years. The increasing rate of vitamin D deficiency in clinical practice, especially in this region makes her case important to evaluate in order to improve patient care among the population I see.

Vitamin D deficiency has become an important differential to consider when evaluating patients with persistent pain and other nonspecific findings. Family practitioners need to be aware of the literature, diagnosis and treatment for vitamin insufficiency. Prior to this case presentation I was not up to date with the clinical concerns that hypovitiminosis D and the health consequences. Increasing my awareness to newer information is one area that I need to continue to develop. While in school it is hard at times to find time to read medical journals or go through the vast amount of medical updates that I get through email. However, it is a responsibility that I have to the patient to stay abreast the literature.

Ashley's case is complex because she has lived with pain for years and has been without diagnosis. When presenting her with the possibility of a vitamin deficiency as the source of her pain, I found it challenging to create patient by in that supplementation available over the counter could potentially improve her symptoms. To continue to encourage her to take this for months before she may see improvement in her symptoms is another challenge, one that requires good communication and relationship development with the patient and her family.

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Running head: DEPRESSION IN AN ELDERLY DIABETIC

Depression in an Elderly Diabetic:

Loss of Control of Blood Sugars after Losing a Loved One

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Depression in an Elderly Diabetic:

Loss of Control of Blood Sugars after Losing a Loved One

The rate of diabetes has been increasing at alarming rates in the last decade (Cowie, Rust, Byrd-Holt, Eberhardt, Flegal, & Engelgau, et al., 2006). It is estimated there are approximately 20.5 million people in the United States living with diabetes and another 50 million more with prediabetes (American Diabetes Association, 2007). There are more than 340,000 diabetics living in Washington State (Washington State Department of Health, 2008), including 8,800 people in Benton and Franklin counties (Washington State Department of Health, 2007).

Each year more than 220,000 people will die from diabetes related complications; a number that most think is grossly underestimated. It is the fifth leading cause of death by disease in the United States and a leading cause of morbidity; associated with an increased risk of heart disease, kidney disease and blindness (American Diabetes Association, 2007). Expenses are not limited to morbidity and mortality of the disease, the economical burden of this condition is estimated at over 132 billion dollars per year (American Diabetes Association, 2008a).

Depression is a common co-morbidity associated with diabetes and other chronic diseases (Anderson, Freedland, Clouse and Lustman, 2001). A metanalysis of 42 studies, evaluating the prevalence of depression among diabetic patients, found that depression was twice as common in a person suffering from diabetes then in the general population (Anderson, Freedland, Clouse and Lustman, 2001). Specifically, those with type 2 diabetes are at higher risk then those with type 1 diabetes (Albanesi de Nasetta & Morales de Barbenza, 2006). It is estimated that over 32% of all diabetics suffer from depression (Noh et al, 2005).

Literature demonstrates diabetic patient with comorbid depression have an increase in morbidity and mortality. Black and Markides (1999), studied depression and diabetes in a

Mexican American population. The results of their work demonstrate that clients with diabetes and concomitant depression are three times more likely to die then diabetics without high levels of depressive symptoms. A more recent study published data from the Prevention of Suicide in Primary Care Elderly: Collaborative Trial (PROSPECT) illustrates that diabetic patients with untreated depression have an increased risk of mortality then those with treated depression (Bogner, Morales, Post, and Bruce, 2007).

Case Study

R.P. is a 73 year old Caucasian male presenting for follow up of his blood sugars to the clinic he has been receiving care at for the last six years. He was diagnosed with type 2 diabetes 18 years ago and has been in fair control until recently. Four months ago testing showed his glycosylated hemoglobin level to be stable at 7.2%. Today's test demonstrates an increase of 2 points, to 9.2%. Mr. P is currently on metformin ER 1000mg twice daily and glimepiride 4 mg each morning. He is testing his blood sugars intermittently and reports they are generally "normal". He does experience some hypoglycemic episodes but finds these are easily managed and he has not required assistance from others while being hypoglycemic. Past medical history is significant for hypertension, atrial fibrillation, spinal stenosis and benign prostatic enlargement. In addition to his diabetes medications, he reports taking hydrochlorothiazide, lisinopril, digoxin, tamsulosin, dutasteride and extra strength Tylenol as needed for back pain.

On physical exam, Mr.P is a well developed, six foot tall male, dressed in his usual slacks, collared shirt and suspenders. He is pleasant, but does not greet the nurses and practitioners with the same joy that he did on previous encounters. His vitals are stable other than a four pound decrease in is weight. Ophthalmic, cardiac, respiratory, musculoskeletal and neurologic exams are unchanged. His affect is depressed, he does not smile or tell stories like he has previously. He is

teary in the office when asked about his diet and reports he has not had much of appetite recently and when he does eat, it is generally something higher in carbohydrates that his family or friends bring over. He maintains that he is taking him medication “more than half of the time”. He complains of feeling poorly if he takes it without eating. His recent and remote memory is intact. Depression screening with the Patient Health Questionnaire-9 (PHQ-9) is significant for high likelihood of depression.

Mr. P was married for 50 years last fall. His wife passed away three months ago unexpectantly. He has been alone in his home other than occasional visits from his children, all of which live in other cities. He has a neighbor and a friend from church that call every once in awhile. Mr. P is Catholic but has not gone to church regularly since his children have been grown. He is living independently in the house he and his wife bough 18 years ago.

Analysis

Diabetes is a complex disease that requires expert care. When coupled with depression, the disease is even more challenging to manage. The number of American’s living with this condition makes it a significant health concern. Depression is a commonly found in people with chronic diseases, even more so in those with type 2 diabetes. The rising rate of these conditions warrants expert care to manage chronic illness, screen for coexhisting conditions and treat accordingly in order to limit complications.

Mr. P is at high risk for developing depression. He is elderly (Black & Markides, 1999; Bogner, Morales, Post & Bruce, 2007), diabetic (Anderson, Freedland, Clouse & Lustman, 2001; Bogner, Morales, Post & Bruce, 2007), and has recently gone through a major life adjustment (Anderson et al., 2002; Bogner, Morales, Post & Bruce, 2007). The current guidelines by the American Diabetes Association recommend routine screening for depression in diabetic patients

(2008b). Mr. P was given the PHQ-9 tool to fill out which has been validated for use in primary care settings (Kroenke, Spitzer & Williams, 2001). It can be used as a diagnostic tool and a management tool. Repeating the PHQ-9 during treatment provides the clinician with an objective measure of treatment response (Kroenke, Spitzer & Williams, 2001). The PHQ-9 confirmed the suspicion of depression from history and physical exam findings.

Depression and other psycho-social problems can impair the individual's ability to carry out diabetes related tasks thus compromising their health status (Anderson et al., 2002). It is associated with treatment nonadheraence (Gonzalez et al., 2008), and if left untreated, increases morbidity and mortality in the diabetic patient (Black & Markides, 1999).

Recommendations

Mr. P was started on 10mg of fluoxetine once daily. Fluoextine is a selective serotonin reuptake inhibitor that is used for depression and anxiety. In patients with comorbid diabetes and depression, fluoxetine, along with sertraline, are the two antidepressants supported by the literature (Goodnick, 2001). In addition to medication management, Mr. P was referred to a widow/widower grief support group held at the community center twice a week. He was encouraged to start light exercise to improve his depression and diabetes control (Warburton, Nicol & Bredin, 2006).

After reviewing Mr. P's medication and testing, it is evident the current medication is not suitable for his current situation. Metformin can be effective in reducing blood glucose but can be irritating to the gastrointestinal system if not taken with food (Ripsin, Kang & Urban, 2009). Mr. P's meal situation is drastically different then it was when his wife was alive and long acting peak-less insulin will work better to control his basal glucose without risking hypoglycemia or gastrointestinal issues (Ripsin, Kang & Urban, 2009). Glimiperide, the sulfonyleurea that Mr. P is

on, will be stopped as it is causing hypoglycemia, a common side effect made worse by his sporadic food intake. R.P. has been to diabetic education classes years ago but will be sent back for education on insulin management and meal planning. Evidence shows improvement in glycemic control in patients who undergo diabetic education classes (ADA, 2008b).

Evaluation

Mr.P's fluoxetine was titrated up slowly to 40mg daily. He has been on the medication for the last six months and is tolerating it fine without adverse side effects. His PHQ-9 scores have improved since treatment was initiated and he reports he is feeling better. He is still tearful many days out of the week but the time he spends being tearful has reduced significantly. Expert consensus guidelines recommend treating single episodes of depression in the elderly for one year (Alexopoulos, Katz, Reynolds, Carpenter & Docherty, 2001). Mr. P will continue the medication for another couple of months, after which time he will be titrated off slowly. If his symptoms return or are not manageable, he will be started back on antidepressant therapy for a period of two-three years (Alexopoulos, Katz, Reynolds, Carpenter & Docherty, 2001).

Basal insulin was started and titrated up from 10 units at night to his current dose of 30 units each night. He was taken off all of his oral medications and at the next office visit he was started on bolus insulin prior to meals based on amount of carbohydrate counting. Over the next six months his glycosylated hemoglobin level dropped from 9.2% to 7.0%. He has completed diabetic education, feels comfortable in carbohydrate counting and self management of his insulin. He denies episodes of hypoglycemia.

The doctorate in nursing practice (DNP) plays a vital role in diabetes management, including depression screening and management of comorbid conditions. Depression is common amongst patients with diabetes and often it goes untreated (Newman & Hassan, 1999). When left

untreated, depression increases morbidity and mortality (Bogner, Morales, Post, and Bruce, 2007). The DNP needs to be aware of the need to assess psychosocial status and do so in a timely and efficient manner so that referral for appropriate services can be accomplished.

Reflection

R.P. is a patient that I have been seeing over the last couple of years at the clinic. I had the opportunity to care for both him and his wife, up until she passed away. The change in Mr. P's demeanor was pretty drastic after his wife's passing and was not hard for myself and the office staff to recognize the symptoms of depression. The symptoms are not always going to be that loud or apparent and recognizing subtle signs and screening is important to improve diabetes care. Medical judgment in the clinical arena is an area I feel comfortable in. Making the diagnosis of depression and treating Mr. P for this is something that comes without much thought.

Although I have cited communication and interpersonal relationships as many of my strong areas in past case studies, in this particular case study, communicating about depression and emotional issues was challenging. I became a nurse practitioner to help patients through prescribing medications and making appropriate referrals to other specialist. As a nurse I learned the importance of communication to build relationships but never felt comfortable with therapeutic communication. This case study brought up some of those struggles and forced me to become aware of them, further developing and rounding out my clinical skills.

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Chronic Fatigue Syndrome Case Study

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Chronic Fatigue Syndrome Case Study

Chronic Fatigue Syndrome (CFS) is an increasingly common clinical concern seen among primary care practitioners. According to the centers for disease control, the disease affects a large number of Americans, between 800,000 to 4 million (CFIDS, 2008; Griffith & Zarrouf, 2008; Reynolds, Vernon, Bouchery & Reeves, 2004). Although the number diagnosed with the condition is varied in the literature, most agree that it is grossly under diagnosed. According to the CDC (2008), only 20% of those living with CFS have been diagnosed. The condition is most prevalent in women aged 40-59 but can occur across the lifespan. CFS is more common in women, among all socioeconomic classes and ethnicities (CFIDS, 2008; Griffith & Zarrouf, 2008).

Chronic Fatigue Syndrome is characterized by severe, debilitating fatigue lasting at least six months duration and results in significant reduction in activities (CDC, 2008; Griffith & Zarrouf, 2008). The fatigue associated with CFS is not improved by rest and many times is worsened by physical activity and mental activities. Associated symptoms include troubles with concentration, sleep disorder, muscle or joint pain, headaches, tender cervical or axillary lymph nodes, and recurrent sore throat. The clinical course and symptom severity varies among patients and unpredictable relapse and remission is common. The hallmark of the illness is a dramatic decline in activity level and stamina. As of yet, there are no laboratory markers for CNS and little is known about the pathophysiology of the disease (CFIDS, 2008; Griffith & Zarrouf, 2008; Reynolds, Vernon, Bouchery & Reeves, 2004).

There is abundant literature about the treatment options for CFS. Cognitive behavioral therapy (CBT) and graded exercise have been shown to have significant benefit on clinical symptoms (Prins, van der Meer & Bleijenberg, 2006; Rimes & Chalder, 2005; Whiting, Bagnall,

Sowden, Cornell, Murlow, Ramirez, 2001). In a 2008 meta-analysis, cognitive behavioral therapy (CBT) was shown to improve function and symptom management in patients with CFS (Malouff, Thorsteinsson, Rooke, Bhullar & Schutte, 2008). The analysis included 1371 patients. Five of the studies evaluated reported clinical and statistical improvement of CFS related fatigue. On average, 50% of the patients evaluated achieved clinical resolution of their symptoms (Malouff, Thorsteinsson, Rooke, Bhullar & Schutte, 2008), a number far better than found in other studies.

Cognitive behavior therapy, as with other chronic disease therapies, works best in conjunction with other treatment modalities (Griffith & Zarrouf, 2006), such as exercise. Graded exercise programs have been shown to be more beneficial then flexibility programs and strenuous exercise.; and patients who were put on these programs generally had better symptom control (Powell, Bentall, Nye & Edwards, 2001; Rimes & Chalder, 2005). The patient may be resistant to such programs at first and may feel worse temporarily, but the importance of exercise has been well documented and should be encouraged (Whiting et al., 2001).

The use of medications in CFS show varied results in the literature (Rimes & Chalder, 2005; Whiting et al., 2001). Although many medications have been tried and are used occasionally, few have clinical research supporting their use. Medication management varies among patient symptoms and treatment needs to be tailored to individual patient needs. The role of antidepressants, such as selective serotonin reuptake inhibitors and tricyclic antidepressants, is known to improve patient mood, sleep and pain perception.

Other medications that have limited evidence for use include methylphenidate and corticosteroids. Methylphenidate was found to improve symptoms of concentration and fatigue in 22% and 17 % respectively (Blockmans, Persons, Van Houdenhove & Bobbaers, 2006) but is

a controlled substance that can have issues of dependency. Corticosteroid use for CFS is also controversial. A dose of 25 to 35 mg/day of oral hydrocortisone for 12 weeks showed modest benefit in 70 patients but caused adrenal suppression (Whiting et al., 2001).

Chronic fatigue syndrome is a complex disease that requires expert care. The number of Americans living with this condition makes it a significant health concern. The estimated number of those yet to be diagnosed supports the need for increased awareness among practitioners. Literature suggests that practitioners are hesitant about diagnosing CFS, and their hesitation negatively impacts the identity of the patient suffering from the diseasae (Larun & Malterud, 2007). The lack of confirmatory diagnostic testing makes diagnosis difficult. Care is needed to ensure patients are diagnosed and treatment is initiated to promote patient recovery (Larun & Malterud, 2007). Finally, the substantial economic impact of CFS, estimated at 9.1 billion (Reynolds, Vernon, Bouchery & Reeves, 2004), may be reduced with diagnosis and treatment.

Case Study

Mrs. S is a 33 year old Caucasian woman who presents to the office with concerns about ongoing severe fatigue. She complains of associated symptoms of cognitive impairment, generalized aches and problems sleeping at night. Her symptoms started just over a year ago after testing positive for mononucleosis. She presented acutely to the clinic 13 months ago with sore throat and lymphadenopathy. Rapid streptococcus testing and throat culture were normal and her serum blood tests revealed a normal CBC but positive mono spot test. Her sore throat, lymphadenopathy and fatigue improved slightly after subsequent weeks but never resolved completely.

In the last year she has had a number of laboratory tests including complete blood cell with differential, complete metabolic panel, antinuclear antibodies screen, sedimentation rate,

vitamin D, B12, lymes disease testing and Epstein bar virus titers, all of which were normal. Additionally, her urinalysis was normal, as were her echocardiogram and electrocardiogram. Screening for depression is negative, although she does report feeling frustrated and helpless due to her fatigue. Her physical exam findings are noncontributory; she has normal ear, nose, throat, cardiac, respiratory, neurologic and musculoskeletal findings.

Mrs. S. has been working as a bank teller for the last 10 years. She use to exercise daily, enjoyed running two mornings a week with her neighbor and was active with her family on the weekends. In the last 13 months she has not been able to work as much and has cut back to half time. She no longer runs and finds it hard to walk the dog with her children on the weekends. She is married with one child. Her husband is an accountant and works from home, assisting with their 5 year old daughter. Mrs. S is well supported, she has numerous friends in the area, and her sister and mother also live very close.

Analysis

Mrs. S's case represents a common clinical picture of chronic fatigue syndrome. Her history of being previously fit and active, accompanied by a dramatic decline in energy level, are common findings in CFS. The duration of her complaints of fatigue have persisted over six months time and she has key history findings including concentration impairment, sore throat, lymphadenopathy, muscular pain and sleep disorder. Furthermore her fatigue is not associated with other medical conditions, diseases processes or causes as ruled out by laboratory data which has lead to her diagnosis of chronic fatigue syndrome.

There is relatively little known about long-term outcomes of CFS, and many times the course is characterized by periods of remission and exacerbation. Full recovery from CFS is uncommon and only occurs in about 5% of patients (Cairns & Hotopf, 2005). Symptom

improvement with treatment intervention carries a better prognosis. Reports in the literature range from 8 to 63% (Cairns & Hotopf, 2005).

Recommendations

The best outcomes in patient symptoms occur when treatment modalities are used in combination (Griffith & Zarrouf, 2006). Mrs. S's treatment recommendations include low impact graded exercise. This has been shown to be very effective and should help to change lifestyle habits, improve stamina, and self confidence (Powell, Bentall, Nye & Edwards, 2001; Rimes & Chalder, 2005). Mrs. S was encouraged to start walking, stationary biking, swimming or stretching. I recommended she start with three to five minutes of activity at a time, three times per day. She should gradually increase her exercise as tolerated to maximize symptom improvement (Whiting et al., 2001).

I also referred Mrs. S to a mental health professional proficient in cognitive behavior therapy. It is expected that she will learn coping mechanisms to help manage her symptoms and modify her thought process which may be exacerbating symptoms. Finally, Mrs. S was started on amitriptyline, a tricyclic antidepressant to help with mood dysregulation, improve sleep and improve pain.

Evaluation

Mrs. S gradually increased her graded exercise program. At last follow up she was working up 15 minutes twice a day. Her symptoms were still apparent however she had returned to full time work and was walking her dog again. She was still not able to run but is optimistic that she might try it one day. The amitriptyline medication has been titrated up from 5mg to 20mg nightly. She notes improvements in her sleep and thinks this has positively affected her concentration during the day.

Chronic fatigue syndrome has been challenging for practitioners to diagnosis for a number of reasons, including a lack of confirmatory tests, case defining characteristics that are common in multiple disease states, and variability of patient symptoms (Larun & Malterud, 2007). As a result of this complexity, the diagnosis rate is low, estimated to be about 20% (CDC, 2008). It is these challenges and complexity that implicate the doctorally prepared nurse (DNP) in patient care. Literature shows obtaining a diagnosis and feeling supported and justified in their symptoms is very important for patients (Larun & Malterud, 2007). The DNP role includes not only expert clinical diagnostic skills but additionally calls on the holistic patient centered care common to nursing practice.

Reflection

Communication is the primary personal and professional skill that was used throughout this case. People with CFS are often sensitive to others perception of their illness and establishing a caring and trusting relationship with the patient is very important. I have developed my intrapersonal skills through the years and I feel that this is one area that is developed through the nursing curriculum and sets the DNP apart from other doctorally prepared health care professionals.

The clinical expertise needed to feel comfortable with diagnostic tests to rule out other pathology and make the accurate diagnosis can be challenging. This is one area that I am further developing expertise. I am comfortable developing the plan, implementing and ordering tests and treatments, but to commit to a diagnosis is at times intimidating.

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Running head: NURSING LEADERSHIP

Nursing Leadership

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Case Presentation

The free clinic serving Benton and Franklin County has been in existence since 2002 and has been growing significantly in the last couple of years. Approximately 300 patients were seen in the first year of operation. In 2007 over 3,400 visits were recorded. The growth has prompted the clinic to move from the two room church basement that it started in, into a large 10,000 square foot building. With the building expansion came expanded clinic hours. The clinic tripled its hours of operation, from one day per week to three days per week, dramatically increasing the number of patients that were served.

As with most free clinic, the focus was on acute health care needs for the uninsured. With the expanded hours, the clinic was seeing a large proportion of patients with chronic health conditions and a group of providers were concerned with quality of chronic disease management. These concerns prompted the development of a diabetic management team in the fall of 2007.

I have volunteered at the clinic since 2004 and have been a part of the diabetic management team since its initiation in the fall of 2007. The team was made up of the medical director and clinic director, a registered dietician, nurse practitioner specializing in diabetes management, retired internal medicine physician, a masters prepared nurse and me, a family practice nurse practitioner. Together, we brainstormed ways to improve the care of the diabetic population that we were seeing in the clinic and intervened in a number of different ways.

Case significance

Type 2 diabetes is a prevalent condition affecting approximately 17.5 million people nationally (ADA, 2008), including more than 340,000 in Washington State (Washington State Department of Health, 2008), and 8,800 people in Benton and Franklin counties (Washington

State Department of Health, 2007). The rate of diabetes has been increasing at alarming rates in the last decade (Cowie, Rust, Byrd-Holt, Eberhardt, Flegal, & Engelgau, et al., 2006). The Center for Disease Control lists diabetes as the fifth leading cause of death by disease in the United States (National Center for Health Statistics, 2006).

A growing number of people with type 2 diabetes are without health insurance, leaving the burden of chronic illness management to safety net clinics and free clinics which traditionally have been designed to treat acute illnesses. The uninsured are disproportionately more likely to develop diabetes (Cowie et al, 2006; Rabi, Edwards, Southern, Svenseon, Sargious, & Norton et al., 2006). Nationwide the prevalence of uninsured patients with diabetes is estimated at over 1.4 million (Wilper, Woolhandler, Lasser, McCormick, Bor, & Himmelstein, 2008).

The issues I chose to address in this case report are that of access to care and quality of health care for the uninsured. As previously stated, chronic illness in uninsured individuals is a significant problem without an end in sight. I, along with a group of other clinicians, have taken initiative to improve the situation for people in our communities.

Discussion

The stakeholders in this situation are the clinic, board members and on a broader spectrum, the community clinics and emergency rooms. The goals of the team were to find ways to manage type 2 diabetes to improve quality of care and hopefully decease burden on emergency departments. According to an in house questionnaire, 40% of patients report that if not for the clinic, they would have sought care at the emergency room. Another 40% reported they would have gone to the community clinics and 20% would have elected to not get treatment.

The locus of authority was done through the group. We would discuss items until we came to a decision. At times this led to tabling of discussions and postponement of decisions. In general, all the members were involved with decision making and their thoughts and ideas weighed. Ideas were discussed in relation to scientific evidence and standards of care and what has been shown to work in other free clinic settings. It never came down to a vote or to one person having to make decision. There were many criteria for decision making. The decisions had to be plausible for the free clinic setting. We could not feasibly have each patient test their blood sugars four times per day even if they really should be testing that often. Costs played a pretty large role in decision making. Evidence based guidelines and professional organization standards of practice were also part of the decision making criteria.

The DMT met each month at least once. Meetings with all medical providers occurred every couple of months and emails were sent out biweekly. Changes discussed and interventions developed in the DMT were assimilated into practice through these communications strategies. Furthermore, the DMT members were active volunteers which helped assimilate the programs into patient care.

The diabetic management team used evidence based guidelines at rational for intervention decisions and treatment algorithms. These were used to address the problem. Standards of care from the American Diabetes Association were founding documents that we built upon. Evidence based practices from endocrinology conferences and literature were used. Flow sheets were implemented after literature review of the best options for managing chronic care. Although electronic records and data import programs have been shown to be effective (Usla & Stausberg, 2008) the flow sheet was also effective (Hahn, Ferrante, Crosson, Hudson, & Crabtree, 2008) and more feasible in this challenging setting.

Evaluation

I see myself as a transformational leader. Transformational leadership was first described by James MacGregor Buns in 1978 during his descriptive research of political leaders (Judge & Piccolo, 2004). It has been developed into leadership theory and empirical model through the years and is used throughout a number of disciplines. The leadership style focuses on the larger fundamental needs and interaction with others is positive and encouraging. It has been widely used among professions and its validity seems to generalize across many situations (Judge & Piccolo, 2004). The use of transformational leadership in a team setting has been shown to be successful in clinical research (Kearney & Gebert, 2009; Schaubroeck, Lam, & Cha, 2007).

Current transformational leadership theories present four dimensions: charisma, inspirational motivation, intellectual stimulation and individualized consideration (Jugde & Piccolo, 2004). This leadership model really depicts our group. We all worked together, inspiring each other, challenging each other and working towards something we are all passionate about. My personal strengths are the interpersonal relationships which transformational leadership is founded in. A strong clinical knowledge base coupled with a positive and encouraging perspective add to my repertoire of strengths.

Self Reflection

Leadership style

My leadership style mimics my personal strengths and attitudes in life. I feel that this leadership style has worked well in the group setting that it has been applied to. The team has been more successful then initially imagined and has worked very well together to accomplish goals well beyond what we as individuals could have done independently.

Impact of leadership

My leadership influenced the care of the entire population of diabetic patients that were seen at the clinic. Individually, I saw and care for patients in the clinic, improving care for that one individual, but I also built systems to help the population of people suffering from diabetes mellitus. I helped make it easier for other providers to care for these people, ensuring that more of the patients were getting quality diabetes care that they otherwise would not get. Furthermore, my leadership helped the success of the diabetic management team, fostering a positive environment where we could challenge ideas and develop comprehensive tools for practice improvement.

Feedback

I received a lot of informal feedback about my presence and work on the diabetes management team. As a whole, we were all good about encouraging and supporting each other. With a team made of volunteers, all of us very busy in our person and professional lives, morale was very important. The clinic director, a family practice physician, on many occasions complemented my performance in this project. I remember one email she sent me that she encouraged me to go back to medical school because she thought I would make a great doctor. It was an odd complement but I know she meant it without any ill regarding to nursing profession.

Leadership Growth

As a young nurse, passionate about the profession and wanting to help wherever I could, I feel I developed leadership skills early on. Over the last two years my leadership strengths have grown in leaps and bounds. I started the DMT because I saw a need and an opportunity to help. I contributed to meetings when asked but was hesitant to volunteer many thoughts or ideas. Through the DNP program I have seen my interactions during the meetings and the way I connect with the team change dramatically. I wasn't a background voice or a meeting attendee; I

was a crucial member of that team. I provided expert clinical care to the individual patients during the day and then afterhours helped develop and implement interventions which would change the care to the population of people affected with diabetes. Arguably the most useful skill I learned through the completion of this project was team development, and how to work within a group to achieve results that far outreach any individual efforts possible.

Looking back, I was not at first comfortable contributing to the group because I was intimidated. I was not in a room full of nurses, people with similar experiences and education, but in a room of people with massively different educational backgrounds, all of which had more clinical experience then I had. I recognize now the value of my education and experiences and in the last couple of years feel comfortable contributing to conversations with even the most respected medical doctors, nurse practitioners, nurses and other allied health professionals.

Future

I see my role as a future Doctor of Nursing Practice provider to be diverse. One aspect of this new role is to provide expert clinical care to the individual patients. A second part of my view of the DNP role is to improve the care to populations of people. Specifically, my passion surrounds low income, uninsured diabetic patients. It is important for DNPs to collaborate to improve care and improve translation of knowledge. Finally, I will also serve as a local and political advocate for this population.

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Chronic Beryllium Disease: Not Gone but Forgotten

Abstract

Purpose: Chronic Beryllium Disease is a chronic and progressive pulmonary and systemic granulomatous disease caused by exposure to beryllium dust or fumes. CBD can be latent for decades after initial exposure making its recognition by primary care providers important.

Data Sources: Data sources included articles from medical journal database PUBMED as well as Hanford Site online information from the Department of Energy.

Conclusion: The Hanford Site contamination is a serious public health concern. The affected workforce is unknown but estimated in the thousands.

Implications for practice: Nurse Practitioners need to consider environmental and occupational exposure etiologies.

Keywords: Beryllium, Chronic Beryllium Disease, Hanford

Chronic Beryllium Disease: Not Gone but Forgotten

Case study

Mr. S, a 65 year old male comes into the clinic as a new patient. His long time primary care provider recently retired and he is searching for a replacement. He is married with three grown children and is a retired engineer. He has concerns about his asthma exacerbations. In the last 10 years he has been treated with a polypharmacy regimen including short and long acting bronchodilators and inhaled corticosteroids. In addition he reports being treated with oral steroids and antibiotics at least 2 times per year during his exacerbations. His medical history is significant for hypertension and benign prostatic enlargement. In addition to his inhaled medications, he reports taking hydrochlorothiazide 50mg daily, lisinopril 20mg daily, tamsulosin 0.4mg daily and dutasteride 0.5mg daily. Mr. S employment history is significant for working at the nuclear plant from 1972 until 2 years ago when he retired. He has been told he was exposed to a number of occupational toxins. He has had worsening paroxysmal nocturnal cough and shortness of breath with exertion in the last 5 years. He is in for evaluation of his deteriorating asthma symptoms.

Introduction

Beryllium is a relatively rare metallic element primarily used as a hardening agent in alloys, the most common being beryllium copper. It has many applications due to its strength, lightweight, relatively high melting point, corrosion resistance, thermal conductivity and machinability. It is used in a number of industries including aerospace, telecommunication, biomedical, defense and automotive (Weston et al., 2005), and can be found in a variety of objects such as electrical, machine and aircraft parts, nuclear weapons, hammers, golf clubs,

camera shutters, mirrors and dental prostheses (Lang, 1994). Beryllium and beryllium compounds are known carcinogens in animals and humans (Kuschner, 1981).

The Hanford site is a 586 square mile area of land along the Columbia River in southeastern Washington State used as a plutonium producing plant during the cold war. It housed the B-reactor, the first full-scale plutonium production reactor in the world (Hanford Site, 2008a). The project expanded to include nine nuclear reactors and five plutonium processing facilities, which were responsible for producing most of the nuclear arsenal for the US government (Hanford Site, 2008b). Beryllium was used in these nuclear reactors between 1960 and 1986. There are currently no active beryllium operations at Hanford. However, the risk of exposure still exists as there are 12 known facilities on site evaluated as contaminated or possibly contaminated with beryllium (Hanford Beryllium, 2008a). The Department of Energy has taken over the Hanford site and is currently engaged in the world's largest environmental cleanup project to remove more than 53 million gallons of radioactive waste, 2,300 tons of spent nuclear fuel, 9 tons of plutonium and 80 miles of contaminated groundwater (HanfordSite, 2007a).

Exposure to beryllium fumes or dust can cause sensitization to the element which can lead to Chronic Beryllium Disease (CBD). CBD is a pulmonary and systemic granulomatous disease that can occur years or even decades after exposure to beryllium. The number of workers who were exposed to beryllium during the plutonium production is unknown but estimated in the thousands. Today, the Hanford cleanup project employs 10,000 local workers (Hanford Site, 2008b). The Hanford site contamination is a serious public health concern and the environmental risks associated with it are enormous. The political, economical and ethical dimensions related to the Hanford project will be discussed in-depth in the body of the paper.

Epidemiology

Chronic Beryllium Disease is caused by inhalation of beryllium fumes or dust into the lungs. Sensitization occurs after exposure to beryllium as the body mounts an immune reaction to the beryllium compound. The mode of transmission is most commonly through inhalation into the lungs, however some research has linked beryllium splinters to sensitization (National Institute for Occupational Safety and Health [NIOSH], 2005). Once sensitized, the latency to CBD can range from a few months up to 30 or more years (Lang, 1994). The number of people with occupational exposure to beryllium in the United States is unknown but it is estimated to be around one million (Fontenot & Maier, 2005).

The prevalence of sensitization to beryllium is unknown and varies across different industries. In 2000, the National Institution for Occupational Safety and Health (NIOSH) surveyed employees at a copper-beryllium alloy strip and wire finishing plant. In this population 7% tested positive for sensitization and 4% were found to have CBD (NIOSH, 2005). A large study of three Department of Energy nuclear facilities, including Hanford, revealed a sensitization rate of 2.2 % (Welch et al., 2004). Another study in a beryllium processing facility in Pennsylvania reported 7.6% of the sample had CBD and another 7% were sensitized without CBD (Rosenman et al., 2005). Beryllium machinists seem to have the greatest risk of occupational exposure and have the highest rates of beryllium sensitization and CBD, although research has shown sensitization in individuals with incidental exposure indicating the amount and duration of exposure is not necessarily a predicator of disease susceptibility (Newman, Mroz, Balkissoon, & Maier, 2005). At Hanford the groups at risk are those who worked at the site between 1960-1986 when beryllium was used and stored and those workers who are actively involved with the Hanford site cleanup.

There does not appear to be any differences in disease susceptibility between age, sex, race, or ethnicity (Newman, Mroz, Balkissoon & Maier, 2005). Individual genetic differences do however play a central role in the pathogenesis of CBD. Disease susceptibility has been associated with Human leukocyte antigen (HLA) genes. HLA-DPβ1*0201 is associated with the development of CBD whereas HLA-DPβ1*0401 appears to be protective. Eighty-five percent of patients with CBD have an HLA-DPβ1 allele variant with a glutamic acid for lysine substitution at position 69 (Newman, 1996). A large portion of people with CBD who do not express the glutamic acid containing HLA-DPβ1 allele show a similar glutamic acid variation at the 71 position of the HLA-DRβ1.Other MHC genes, such as tumor necrosis factor (TNF) have also been associated with CBD susceptibly, disease severity and could potentially influence progression from beryllium sensitization to disease (Fontenot & Maier, 2005).

Although genetic testing to screen for exposure risk is not yet available, there are other ways to reduce exposure and risk of sensitization. Limiting the amount of exposure has been at the forefront of occupational safety. Prior to the Occupational Safety and Health Administrations (OSHA) guidelines for industrial exposure limit, it was not uncommon for beryllium air concentration levels to be greater than 1000 $\mu g/m^3$ (Lang, 1994). In contrast, the current OSHA exposure limit for airborne beryllium is $2\mu g/m^3$ based on a eight hour time weighted average (OSHA, 2008). Research has shown that even at this level individuals are not protected (Rosenman et al., 2005). To further reduce exposure risk some have recommended initiating administrative controls limiting the number of workers allowed into contaminated areas, improving ventilation systems to reduce dust and providing personal protective equipment when exposure cannot not be controlled (Cummings et al., 2007). To minimize contact exposure one

facility has initiated double gloving policies and gloving prior to disrobing in order to reduce the risk of sensitization and CBD (NIOSH, 2005).

Discussion

There are a number of ethical, economic and political considerations related to beryllium exposure at Hanford. Ethical concerns have historical context dating back to the 1930's when the United States failed to react to foreign published data linking beryllium inhalation and lung disease (Lang, 1994). Additional historical ethical concerns include the secrecy of the plutonium producing facilities. More than ninety-nine percent of individuals working at Hanford during the plutonium producing years were unaware of the true nature of the project and exposure risks (Hanford Cultural Resources Program, 2002). More recently, the identification of genetic polymorphisms increasing the risk of sensitization to beryllium have raised ethical concerns surrounding screening practices and the potential consequence the dissemination of that information could have on the individual's ability to obtain health insurance and disability insurance (Lang, 1994).

Enormous individual economic losses are realized with chronic beryllium disease, including loss of productivity from time missed, disability, and continual medical expenses. In addition to multi-individual losses, the federal expenses related to the concentrated efforts to decontaminate Hanford are enormous. As the largest environmental cleanup project in the world, the Department of Energy spends 1.8 billion dollars annually (Hanford Site, 2007a).

The other major governmental agency interface associated with beryllium exposure is the Occupational Safety and Health Administration branch of the U.S. Department of Labor. Historically government efforts to limit exposure have not been encouraging, despite the role government nuclear sites and plutonium producing facilities had in exposing thousands of

workers. The current OSHA exposure limit of 2µg/m^3 of workroom air for an 8 hour work shift was adopted in 1949, years after beryllium associated deaths were first reported and more than a decade after research linking beryllium exposure and lung disease was published (Lang, 1994). Despite abundance of evidence suggesting this level is not protective, OSHA has failed to adjust the recommendation putting more workers at risk for beryllium sensitization and CBD. Other organizations have recommended or implemented more stringent guidelines. The Department of Energy has established independent limits of 0.2µg/m^3. The American Conference of Governmental Industrial Hygienists, an independent organization of experts in the field of occupational health, has proposed a threshold limit value of 0.05µg/m^3, 40 times lower than the current OSHA limit (Rosenman et al, 2005). Recent governmental efforts have been more promising. In 2001 Congress passed the Energy Employees Occupational Illness Compensation Program Act which provides compensation for workers in government nuclear sites with chronic beryllium disease (Hanford Site, 2007b).

Recommendations

In past years Chronic Beryllium Disease has become a large health concern, especially in nuclear sites such as Hanford as well as in other industries utilizing beryllium metal. Employers are actively educating employees about the risks and taking measures to decrease exposure and screen for sensitization. The efforts are largely confined to the industry's occupational health providers and often primary care providers are not as educated about beryllium disease. Because CBD can be latent for decades after exposure, it is important to increase awareness to primary care providers who will be treating a large proportion of the retired workforce. Nurse Practitioners need to consider environmental and occupational etiologies and be aware of the possibly of CBD when seeing patients with previous exposures

like Mr. S in the opening case study. Early diagnosis is important to limit disease progression and to get patients enrolled in employer based assistance programs that may provide compensation for their medical care.

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Free Medical Clinics: Past, Present and Future

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October 2, 2008

Free Medical Clinics: Past, Present and Future

Case Study 1

Jenny* is a 24 year old graduate student nearing the completion of studies. She lives off student loans and earns about $300 per month working part time at a retail store. She has had an earache for the last week which is getting much worse and Jenny is now not able to hear well. Not wanting to spend a lot of money on an office visit, she decides not to go in to see her primary care provider. The next day her fever and ear pain worsen until she hears a “pop” in her ear followed by improvement in her pain. Over the next couple of days she notices hearing changes, ear discharge and has intermittent pain in her right ear. She eventually is seen at an urgent care clinic and is told she has a very large perforated ear drum that will likely require surgery to fix. She is started on antibiotics and referred to an otolaryngologist.

Case Study 2

Bill*, age 50, owns and operates a small farm with the help of his two sons. He has been unable to pay the high private health insurance premiums and is not able to get on his wife’s insurance plan. A few years ago he started experiencing chest pain that occurred while lifting equipment on the farm. He went into his primary care provider’s office for evaluation. After an exam, electrocardiogram, and laboratory testing, he was told he had coronary artery disease and was given prescriptions for cholesterol lowering medication and nitroglycerin for angina. His bill for the visit and lab work was over $400. At his request the medications prescribed were generic and able to be filled at a local pharmacy at reduced rates. After taking the medication for a year, his primary care provider would not authorize refills until he was seen for follow up and lab work. He had

been off the medication for over two years at the time of a massive coronary infarct that resulted in ambulance transfer to the emergency room, angioplasty and over $30,000 in medical expenses.

Chances are we all know someone like Jenny or Bill, who does not have health insurance or the finances to pay for medical care. According to recent data, more than 15% of people in this country do not have insurance and this number continues to increase at alarming rates. In 2006 more than 47 million people were without health insurance in the United States (US), representing an increase of more than 2 million from 2005(U.S. Census Bureau, 2007). The US remains the only industrialized country without a national health care plan (Blankenau, 2001) despite three decades of public support (Navarro, 1995). To combat this problem, some communities have established free medical clinics aimed to help the uninsured population.

The Historical Free Clinic

The Haight-Ashbury free medical clinic opened in the summer of 1967 in San Francisco, it is credited as being the first free medical clinic in the country. That same year four other clinics opened in Cincinnati, Detroit, Seattle and Vancouver BC. By 1969 there were 59 free medical clinics in 19 states and the District of Columbia. Schwartz (1971) conducted the first national survey in 1970 based on information from these 59 clinics. Data was gathered largely via telephone surveys and site visits of 24 clinics. The largest populations served were minorities and white, “middle class hippies”, the most common ages serves at these clinics were 19-24 years old. All of the free clinics in the study provided acute sick visit care and a number provided additional services. Sixty percent provided well care to infants and children, including immunizations. More than

92% of clinics provided prescription medications, although the supply was generally an assortment of denotations and did not have medial formularies. Sixty-three percent of clinics provided individual mental health and drug counseling and 39% provided legal services. The most common diagnoses seen in the clinic were venereal diseases, contraception management, urinary tract infections, upper respiratory infections, hepatitis and drug-related problems.

The emergence of free clinics in the 1960's has made a significant impact in quality and access to medical care in the uninsured. Evidence has shown that safety net clinics decrease the inappropriate use of emergency rooms and hospitals (Hadley & Cunningham, 2005) and improves patient morbidity and mortality rates (Nadkarni & Philbrick, 2005). The first free medical clinics were designed to treat acute health concerns, representing the need at the time. In the years since there has been a growing need for chronic disease management (Nadkarni & Philbrick, 2003). Free clinics are now part of a permanent, integrated health safety net. As such, services are also shifting from predominantly acute medical management toward disease prevention and health promotion (Scariati & Williams, 2007).

Free clinics are non-profit, community based organizations that provide a variety of medical care, including primary care, mental health counseling, pharmaceutical and dental services, at little or no cost to low-income, uninsured people (National Association of Free Clinics, 2007). The majorities of free clinics operate with only one or two paid workers, and rely heavily on volunteer practitioners to provide care. Free clinics are just one of the safety net clinics available for the uninsured. Others clinics include federally qualified health centers (FQHC), public hospitals, local health departments, and academic

medical centers (Hadley & Cunningham, 2004; Nadkarni & Philbrick, 2005). Together these establishments share the responsibility of providing care to those with no or limited insurance, at little or no charge.

Free Clinics in the Present

The number of free clinics is not well documented in the literature for a couple of reasons. First, many free clinics are small and informally operated and do not register in the voluntary national databases. Second, the financial instability of clinics leads to new clinics being opened and closed often. It is estimated there were more than 1,700 clinics in operation in 2003 (Isaacs & Jellinek, 2007). However the most recent directory from the National Free Clinic Foundation of America lists only 350 clinics (Nadkarni & Philbrick, 2005). The volatile nature of free clinics is well known. A survey of free clinics in the Mideast found that more than 75% of clinics surveys had been in operation less than 10 years (Geller, Taylor & Scott, 2004). Other research has attempted to contact clinics supposedly in operation, only to find that they have closed abruptly (Nadkarni & Philbrick, 2005).

The common characteristic found in free clinic contributing to their unpredictable existence is the financial instability (Isaacs & Jellinek, 2007, Soto, Bazyler, O'Toole, Brownson & Pezzullo, 2007). Free clinics operate off a very small budget, on average about $500,000 annually (Nadkarni & Philbrick, 2005). Most of the budget is exhausted on operating costs and patient care services, leaving only a modest amount to go toward a paid staff. Consequently, the clinics rely heavily on volunteer licensed independent practitioners to provide health services, including acute and chronic primary care, preventative care, prescription medications, mental health counseling and dentistry. Many

clinics can arrange for their patients to receive additional services, including laboratory, radiology and specialty care (Geller, Taylor & Scott, 2004).

Free clinics are traditionally used to treat acute health needs. There are many challenges to providing chronic disease management in this setting. For instance, the physicians, nurse practitioners and physician assistants providing care are volunteers who on average volunteer only once or twice per month (Nadkarni & Philbrick,2005). The lack of consistency in providers interrupts continuity of care and patients are often lost to follow up. Specialty care referrals and consultations needed to comprehensively treat chronic conditions are limited and inconsistent. And finally, there are language and cultural barriers to providing care to a number of people utilizing the FCs.

Despite these obstacles, the need for chronic care management in FCs is significant and the rate of people seeking treatment for chronic diseases is increasing. The Charlottesville Free Clinic reported patient visits for chronic diseases increased steadily over the first five years of operation and at year five, 16% of all visits were for diabetes and hypertension (Nadkarni & Philbrick, 2003). A descriptive study of the Morgantown Health Right Free Clinic reported 76% of patients seen had chronic health conditions, fourteen percent of which were diagnosed with diabetes (Smago & Costante, 1996). Similar reports are found at the Bradley Free Clinic in Virginia in which 81% of patient visits are for chronic illnesses (Bradley Free Clinic, 2008).

The Future of Free Clinics

There are nearly 1800 free clinics serving 2.5 million uninsured people per year nationwide (Isaacs & Jellinek, 2005) accomplished mostly through philanthropic donations of time and services and without government assistance. In order to facilitate

new clinic development and expand existing sites to, FCs need recognition and support from policy makers and health care leaders. The rising demands of chronic illness care, as well as the rising number of uninsured, present additional challenges to FCs as they strive to improve continuity of care needed to treat chronic conditions.

If Jenny and Bill, introduced in the opening cases, had received medical attention for their acute and chronic illnesses, they could have avoided complications and the added costs associated with delayed treatment. Advance practice nurses need to be aware of community resources and make appropriate referrals to FCs. Additionally, there is a tremendous need for volunteers to provide care in these clinics in order to expand the number of patients being seen. The nation's rate of uninsured people is growing rapidly without a solution in sight. As leaders in health care, advance practice nurses need to be aware of this problem and actively involved in solution seeking. The privilege of being a care provider comes with the responsibility and societal obligation to provide health care to everyone, regardless of ability to pay. FCs are at the forefront of this movement and offer a means for advance practice nurses to get involved.

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OREGON HEALTH & SCIENCE UNIVERSITY
SCHOOL OF NURSING
Ashland Klamath Falls La Grande Portland

DNP Clinical Inquiry Project Report & DNP Portfolio Approval

Student Name: Jessica Johnson

Degree: Doctor of Nursing Practice

Title of Study:

Program Evaluation: Multidisciplinary Disease Management and Improved Diabetes Care in a Free Medical Clinic

APPROVED:

Committee Chair: Gary Laustsen, PhD, APRN-CNP, RN (name and credentials) Signature: Gary Laustsen

Committee Member: Muriel Shaul, PhD, ANP, RN (name and credentials) Signature: Muriel Shaul

Committee Member: _____ (name and credentials) Signature: _____

Michael R. Bleich, PhD, RN, MPH, FAAN
Dean, School of Nursing Signature: Michael R. Bleich

Date: 6/5/09

Submit completed original form to the Graduate Program office.

Revised 4/2009