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Evaluation of the Effectiveness of the International Index of Erectile Function (IIEF-5) (SHIM) Questionnaire on the Diagnosis and Treatment of Erectile Dysfunction

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**Evaluation of the Effectiveness of the International Index of Erectile Function (IIEF-5)
(SHIM) Questionnaire on the Diagnosis and Treatment of Erectile Dysfunction**

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**Doctoral Capstone Project submitted to the
School of Nursing
at West Virginia University
in partial fulfillment of the requirements
for the degree of**

Doctorate of Nursing Practice

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2013**

***Keywords:* erectile function, provider, prevalence, International Index of Erectile
Function–5 (IIEF-5), erectile dysfunction (ED)**

ABSTRACT

Evaluation of the Effectiveness of the International Index of Erectile Function (IIEF-5) (SHIM) Questionnaire on the Diagnosis and Treatment of Erectile Dysfunction

Evelyn Martin

Thirty million or 52% of males between 40 and 70 years of age in the United States have some degree of erectile dysfunction (ED) (Feldman et al., 1994; Hakim, Subit, Kandzari, & ZasLau, 2002; Tsertsvadze et al., 2009). The American Urology Association (AUA) outlines measures to slow the rate of, control, and treat ED. To decrease the prevalence, ED must be diagnosed, identified, and the major risk factors aggressively controlled. Utilization of clinical practice guidelines (CPGs) may improve identification and documentation of treatment, but questions remain about how to implement CPGs in practice. The purpose of this pilot project was to evaluate the effectiveness of the International Index of Erectile Function (IIEF-5) questionnaire on the diagnosis and treatment of ED in two primary care rural clinics in West Virginia. Through the use of Diffusion of Innovation Theory, the IIEF-5 questionnaire was utilized and implemented into the clinics. This study used a descriptive design with pre and post chart reviews and a convenience sample of 121 male patients 40-70 years old. Clinicians and staff were oriented to the use of a screening instrument before its implementation. The questionnaire was piloted for six-weeks. Data from chart reviews were collected from 50 randomly selected charts pre and 89 charts post implementation. Of the 89 post implementation charts, only 71 were eligible for the pilot project. The pre implementation prevalence was 5/50 (10%) and documentation for treatment of ED pre implementation was 2/5 (40%). Post implementation the prevalence of ED was 53/71 (75%) and documentation of treatment options in those completing

the questionnaire was 42/53 (79%). There were no significant differences in ages for males 50 to 70 years between the pre and post implementation group (0.6). However, there was a statistical significant difference between the pre and post implementation males ≤ 49 years of age. In Group 1 – 21/50 (42 %) of the men were ≤ 49 ; Group 2 – 4/71 (5.6%) were ≤ 49 years. Prevalence of ED in Group 1 - participants 50 - 70 years of age was 5/29 (17%), while prevalence of ED in Group 2 - participants 50 - 70 years of age was 50/66 (76%). There was one participant in the group with an unknown age. All 71 (100%) questionnaires were scanned into the patient's charts and a diagnosis of ED was added to the patients list of health care issues. The use of the IIEF-5 questionnaire in primary care clinics is an effective tool for evaluating the diagnosis and treatment of ED and can easily be incorporated into the patients' charts.

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Evaluation of the Effectiveness of the International Index of Erectile Function (IIEF-5) (SHIM) Questionnaire on the Diagnosis and Treatment of ED

ED (ED) is one of the most common diseases of male sexual dysfunction. For a male, it can also be a very distressing condition. ED is a health issue that affects the physical, mental, social well-being, and the interpersonal relationships of the afflicted patients (Canadian Guidelines Towards Optimized Practice [TOP], 2009; Feldman, Goldstein, Hatzichristou, Krane, & McKinlay, 1994; Hatzimouratidis et al., 2010; Hwang, Tsai, Lin, Chiang, & Chang, 2010; Jonas, 2001). The National Institutes of Health (NIH) Consensus Development Conference on Impotence (1993) definition of ED is a continual failure to attain or retain an erection adequate for satisfying sexual intercourse (Feldman et al., 1994; Yamada, Hara, Umematsu, Suzuki & Kadowaki, 2012). The designation ED is the preferred newly adopted term as opposed to the previously used term “impotence”. ED is more appropriate because a male may continue to have sexual desire and be able to have an orgasm with his ejaculate unimpaired regardless of the failure to get or keep an erection (Montague et al., 2009). ED can produce emotional and interpersonal relationship difficulties, and frequently leads to poor self-esteem, low self-confidence, and withdrawal from partners, thereby affecting the patient’s quality of life (Hwang et al., 2010).

Background and Significance

According to the Massachusetts Male Aging Study (MMAS), the best estimate for prevalence of ED is 52% or 30 million men in the United States between 40 and 70 years of age (Feldman et al., 1994; Hakim, Subit, Kandzari, & ZasLau, 2002; Tsertsvadze et al., 2009). A sample size of 1700 male participant’s ages 40-70 years were included in the MMAS study (Feldman et al., 1994). A later study by the United States Department of Health and Human

Services, Centers for Disease Control and Prevention, and the National Center for Health Statistics (2001-2002), the *National Health and Nutrition Examination Survey (NHANES 2001-2002)* looked at a group of 2126 male participants ≥ 20 years and found the incident rate to be lower: 427 (20.1%) male participants age 40-70 years with ED. One major factor in the prevalence of ED is age with the occurrence of ED growing from 5% among men age 40 to 15% among those 70 years of age. The MMAS also gives a conservative worldwide projection of 322 million cases by 2025 based upon age specific prevalence estimates (Aytac, McKinlay, & Krane, 1999; Tsertsvadze et al., 2009). The incidence of ED is higher in men with comorbidities such as: diabetes, hypertension, arterial insufficiency, high cholesterol levels, stress, mental health issues, and spinal cord injuries (Johannes, Araujo, Feldman, Derby, Kleinman, & McKinlay, 2000). As the population of the United States continues to age, ED is likely to become a more prevalent issue for men. Although there is a lot of information about the pathophysiology of ED, relatively little is known about how ED affects men's daily lives.

The financial cost of ED is extensive. According to Litwin, & Saigal (2007), in 2000 the estimated number of provider visits by men 18 and older living in the United States with a diagnosis of ED was 2.9 million. Pfizer reported the United States sales for Viagra, a phosphodiesterase-5 inhibitor (PDE-5) for the year 2008 were \$897 million with worldwide sales for the same year at \$1.9 billion (Pfizer, 2009). Similarly, the United States sales for Cialis, a second PDE-5 inhibitor, for the year 2009 were \$623.3 million, and worldwide sales totaled \$1.6 billion for the same year (Tolliver, personal conversation, Jan. 15, 2011). Likewise, the revenue for Levitra, the third PDE-5 inhibitor for 2009 totaled \$360 million (Bayer, 2009). Other revenue is generated through black market sales of these medications. Additionally, the annual cost for evaluation and treatment of ED was \$327 million (Tsertsvadze et al., 2009). In a region in

Southern West Virginia, the 2009 sales for Viagra, one of the three well-known PDE-5 inhibitors, totaled \$839, 000 (Bright, personal conversation Jan. 15, 2011).

While the healthcare burden of ED is not as significant as that of diabetes or cardiovascular disease, it is still a burden to the patient. Factors contributing to erectile dysfunction include those that are both psychological and physical in nature (Montague et al., 2009). Psychological factors include anxiety, stress depression, even the idea of failure causes performance anxiety (Montague et al., 2009). Physical factors contributing to the erectile dysfunction in men include diabetes, arterial and vascular disease, penile nerve damage, sacral nerve damage, hormone imbalance, Peyronie's disease. Social and lifestyle factors contributing to erectile dysfunction include heavy smoking, drinking or drug abuse, obesity, in addition to, high cholesterol. (Montague et al., 2009). Statistics of patients having both ED and specific comorbidities found in the United States are as follows: vascular (40%), diabetes mellitus (30%), ED after radical surgery (13%), spinal cord injuries and other traumas (8%), other endocrine problems (6%), and multiple sclerosis (3%) ("Statistic of erectile dysfunction in US," 2011).

Other considerations include: the related cost of office visits to providers, tests to rule out other factors, the diagnosis of ED, hormone therapy, intracavernous injections, vacuum erectile devices, penile implants, and implant surgery. As previously mentioned, according to Hwang et al. (2010) ED can produce emotional and interpersonal relationship difficulties, and frequently leads to poor self-esteem, low self-confidence, and withdrawal from partners, thereby affecting the patient's quality of life. With these psychological causes of ED, various factors can affect sexual emotions and affect or worsen ED including: anxiety, depression, or other mental health conditions, stress and the interrelationship issues created by stress (Cappelleri & Rosen, 2005; Hwang et al., 2010). Furthermore, the cost for depression and anxiety medications, in addition to

the clinical visits to providers for treatment, are also included in the financial burden of ED. Not included in the financial burden but a cost in itself is what ED does to the afflicted patient's self-esteem, self-confidence, and interpersonal relationships.

Internal medicine and/or family practice physicians and practitioners are frequently the initial provider with whom the patient has contact to talk about ED. According to a study by Rutchik et al. (2000), the prevalence of sexual diseases and issues in patients seen by primary care physicians and internist has been estimated to be as high as 34%. In southern West Virginia, an evaluation of the prevalence of ED complaints and the use of a validated questionnaire for the diagnostic assessment of ED had not been performed.

Theoretical Framework

The theoretical framework chosen to guide this pilot project was Rogers Diffusion of Innovations theory. Diffusion of Innovations illustrates ways to describe how a population would receive an innovation (Rogers, 2003). There are three important observations in the development of community change: traits that make an innovation flourish effectively, the significance of peer-to-peer dialogues and peer groups, and accepting the needs of a diverse population. Rogers designed the conceptual foundation in 1962 to describe why, how, and at what pace new concepts and technology would circulate throughout an organization. Contributions of diffusion research have been included into other disciplines including: communications, public relations, social psychology, consumer behavior, rural sociology, and public health (Rogers, 2003). As compared to most other theories of change, Diffusion of Innovations takes a different direction. Diffusion of Innovations' prime focus is concerned with the spread of innovations and behaviors to better support the needs of the population. In Diffusion of Innovations it is not the population that changes, but the innovations themselves (Rogers, 2003).

Relative advantage is the degree to which a specific population, such as a clinic, recognizes an innovation as better than the idea, product, or way of doing something it replaces. The better the apparent relative advantage of an innovation, the quicker the innovation's rate of adoption may be (Rogers, 2003).

According to Rogers (2003), there are four key elements in the Diffusion of Innovations theory. The key elements of diffusion are: (1) innovation, (2) communication channels, (3) time, and (4) social system. If the innovation is adopted, it extends by means of an assortment of communication channels. Throughout communication, innovations are seldom gauged from a scientific point of view; more accurately, individual opinions of the innovation sway diffusion. As the sites for this project were both relatively small clinics, the investigator tailored the project design to meet the clinic's needs.

Rogers (2003) describes an innovation as an idea, action, or entity that an audience perceives as new. As neither of the clinics chosen for this pilot project was using a measurement tool for identifying ED, this theory supported the implementation of a pilot practice change for assessing, identifying, and documentation of treatment options to patients with ED. The providers were trained on the use and scoring of the IIEF-5 questionnaire.

The second element, diffusion is a special type of communication where the information traded relates to the new idea. The second element, communication channels, is where the providers accept the idea of utilizing the measurement tool and pass the idea on to others (Rogers, 2003). In addition, during the communication channel the participants were informed of the project. Implementation of the project occurred for a six-week period in two clinics in southern West Virginia. A baseline chart review of 50 charts was completed at the beginning of the innovation. At the end of the implementation period, another 89 charts were reviewed and

assessed to determine whether the questionnaires were being used for diagnostic assessment and if so, was there documentation of treatment options. Communications relating to this project were in verbal and written form to present specific information to the providers. Communication was essential for the success of the pilot project. The investigator completed an educational meeting with the physicians one week prior to implementing the pilot project. During the six-week pilot project period, communication was principally initiated by the investigator. In addition, there were no issues or questions concerning the project voiced during follow-up communication. The physicians were both pleased at how well the project was going and the value of the project for their respective patients.

The third element, time, affected this project in that there was a six-week pilot period for the providers to become familiar with the IIEF-5 and begin using this tool with the clinics' patients. The diffusion process takes place over time (Rogers, 2003). As this was a pilot project, the short duration was vital as the limited time gave the providers an idea of how quickly the project could be implemented, and how quickly the project could become successful. Time starts with the knowledge of the new idea and goes through the final acceptance and implementation or rejection of the new idea. Time also encompasses the rate of adoption and is affected by five distinct groups of adopters, from innovators and early adopters through early and late majority to laggards (Rogers, 2003).

Rogers describes a social system that can be applied to the clinic environment. The social system as defined by Rogers is a set of interconnected parts that are joined in shared problem solving to achieve a common goal. The social system decides diffusion, norms on diffusion, the tasks of opinion leaders and change agents, varieties of innovation decisions, and innovation consequences. To utilize Rogers' model in a health care setting requires one to presume that the

innovation in classical diffusion theory is comparable with scientific research findings in the framework of practice, a supposition that has not been carefully tested (Rogers, 2003).

In addition to the five stages, Rogers (2003) also describes five adopter categories. The rate of innovation adoption is determined primarily by the adopter category. The adoption of an innovation follows an S curve when mapped out over a length of time. Rogers defines the five-adopter categories: innovators, early adopters, early majority, late majority, and laggards.

Innovators are those participants in a system who quickly adopt an innovation. This usually encompasses the first two and one-half percent. Innovators are described as those that are willing to take a risk, are adventurous, and have leadership attributes and qualities. The investigator in this project sought to gain favor with the providers at the clinics, as the providers appeared to be potential innovators. The provider in the clinic in Charleston, West Virginia has an interest in new ideas and tends to step outside the typical realm of a family practice provider. The other clinic provider is more established and was not looking for new ideas to help expand his practice, but was willing to try the pilot project to see if the use of a questionnaire would benefit his patients. Although this innovation was implemented as a pilot project, both providers were willing to take the risk to improve communication with the patients on such a sensitive subject.

Early adopters are the solid members of the communities. When the early adopter accepts an idea, this is usually the “stamp” of approval for others to adopt the idea. Early adopters follow the innovators and make up the next 13.5 percent of participants in a system to adopt an innovation. Because early adopters are considered to be leaders, they are sought after by change agents.

Early majorities are those that adopt new ideas before most in the community, but are never the leaders. They make up 34 percent of the members in the system and usually contemplate the idea for a while before moving to acceptance. The early majority typically adopts a new innovation or idea before the regular members of the organization, but only after careful reflection. Late majority members are the skeptics. They make up the next 34 percent of the members in the system and usually adopt for economic reasons or due to peer pressure. They approach new ideas with skepticism and caution, and do not usually adopt until almost everyone else in the system has adopted the idea.

Finally, laggards look to the past, identifying what has previously worked. They tend to be distrustful of new ideas and of change and hold out until the very end. Laggards want to be sure that the innovation will be worth their effort. They also see the adoption of specific innovations as a high risk and are afraid to move forward (Rogers, 2003). Laggards make up the last 16 percent of the individuals in a system to adopt an innovation.

Another concept of Rogers' model (2003) that needs to be explained and defined for this project is the innovation-decision process. An individual moves from first acquiring knowledge of an innovation to the formulation of a mindset toward the innovation, to making a decision to adopt or reject, to implementing the new idea, then to confirming this decision during that progression. Rogers' five-stage adoption progression consists of: 1) the knowledge or awareness step; 2) the persuasion step; 3) the decision or evaluation step; 4) the implementation or trial step; 5) the confirmation or adoption step.

The first step of this pilot project was the knowledge or awareness step, where the individuals were made aware of the innovation but needed more information (Rogers, 2003). The knowledge step included reviewing the guidelines for diagnosis and treatment of ED with the

providers, as well as providing information on the use of the IIEF-5 tools for diagnostic evaluation of the degree of ED and for detecting treatment related changes in patients with ED. During the knowledge step, the investigator discussed findings from the clinics' chart reviews. There are three types of knowledge concerning an innovation. The first is awareness-knowledge. This is information that an innovation exists. In this project, the investigator described the project to the providers at the clinics, defining what was needed and how the project was to be implemented. The next type is the how-to-knowledge. Throughout this type of knowledge, the investigator went over what was necessary to make the project work correctly and made sure the providers understood. The last type of knowledge is principles-knowledge. During this type of the knowledge, the investigator explained how the innovation worked. It was imperative that the providers knew the steps that it would take to make the project a success for the clinic, patients, and the investigator. The investigator took the time to explain the importance of the innovation and the importance of the role of the providers.

The second step is the persuasion step. This is where the individual becomes interested in the new idea and wants to find out more about the innovation (Rogers, 2003). In addition, those who come onboard earlier in the process can be used to help persuade those still not sure about adopting the innovation. During this step, the investigator took time and discussed the project with the providers, explaining why the project was so important and that by adopting the IIEF-5 their identification of new patients with ED would benefit the practice by potentially creating additional revenue with more office visits, potential new patients, and better satisfied patients overall. In addition, during this step the providers would decide that the project was either something they would adopt or that it was too time consuming, too costly, or just not a good fit for their clinics.

The third step is the decision or evaluation step. This is when the individual gathers more information and can think about applying the innovation to current and anticipated future circumstances. The decision step is another step where the individual or organization can choose whether to adopt or reject the innovation (Rogers, 2003). The decision step occurred when the providers scanned the IIEF-5 into the patient's chart. This step offered another chance to make necessary changes, to see who was onboard, and to take steps towards changing the minds of those not onboard. The investigator was prepared to "sell" the project even more during this step. Rogers suggests that although the innovation may be accepted or rejected at any time during the project, it is usually during this step that this happens. Rogers further defines adoption as the choice to make complete use of an innovation as the best route of action, and rejection as a choice not to adopt an innovation. If the organization chooses to adopt, then a decision is made on the best course of implementing the innovation. If the organization chooses to reject, then the decision is made not to adopt the innovation.

The fourth step is the implementation or trial stage. This is when the individual applies the new idea (Rogers, 2003). In addition, this was also when the provider's behavior changed with the actual implementation of the project (Rogers, 2003). Implementation occurred when the providers decided that the tool was useful to the clinic's practice. The providers decided to routinely use the tool with every male patient, scan the tool into the charts, and to schedule follow-up appointments for those with a diagnosis of ED as identified by the tool. The decision to use the IIEF-5 in these clinics was easy, but sometimes actually putting the innovation in place may cause unique problems. During this step, the investigator needed to be available to answer any issues not previously addressed.

The last step, the confirmation or adoption step is when the individual decides the new idea is of benefit and continues to use the innovation. The confirmation step occurred when the providers ascertained the benefits and incorporated the innovation into the system (Rogers, 2003). This step occurred when the project became protocol for men visiting the clinics. Rogers suggests that the confirmation step does not have to be the end step; that the providers may seek reinforcement and may have a change of mind about the decision. During this step, the concept of reinvention occurs. The project could have been changed and reintroduced back to the clinic if necessary through reinvention. With reinvention, the individual or organization may change or modify the innovation during the adoption or implementation process (Rogers, 2003). If the project is adopted and used after the diffusion project is terminated, then this is considered to be sustainability. Discontinuance is what happens when the providers adopt the idea but then decide not to continue using the innovation. Discontinuance has two types: 1) replacement discontinuance is the rejection of the idea in order to adopt a newer, better idea, or 2) disenchantment discontinuance is the rejection of the idea because the innovation was not what was wanted or expected, or there was dissatisfaction with the innovation's performance (Rogers, 2003). In the case of the two clinics in this pilot project, both providers were happy with the innovation and were pleased to adopt the use of the IIEF-5 questionnaire into their practice.

According to Rogers (2003), the rate of adoption is identified as the relative speed with which individuals in a social system adopt an innovation. The rate is typically measured by the amount of time needed for a specific percentage of the individuals in a social system to adopt an innovation. Rogers (2003) describes five attributes that affect the rate of adoption: 1) observability or the degree to which the results of a new idea are evident to potential adopters; 2) relative advantage or the degree to which the innovation is considered superior to current

practice; 3) compatibility or the degree to which the innovation is perceived to be consistent with socio-cultural values, previous ideas, and/or perceived needs; 4) trialability or the degree to which the innovation can be experienced on a limited basis; 5) complexity, the degree to which an innovation is difficult to use or understand its simplicity.

Observability of this project may prove measureable now that the providers have seen what the project entails and the results of the short pilot. With the implementation of the project, the providers may begin talking about it to their peers, and others may adopt this innovation for their practices. Relative advantage will be recognized once the patients and providers realize the gains from the innovation. Prior to the project, neither clinic utilized a measurement tool; therefore, the addition of the IIEF-5 questionnaire will be a valuable addition. Gathering baseline data from the clinics prior to the implementation of the project allowed the investigator to show how beneficial the IIEF-5 could be to the clinics. As the innovation produces not only revenue for the clinics, but potential new diagnoses and treatments of ED in patients, adoption may be welcomed. Relative advantage and compatibility of the project with one of the clinics was that the provider utilizes a similar questionnaire for menopausal problems in women coming into the practice; therefore, training was minimal. In addition, as the IIEF-5 measurement tool is one that the patients can answer themselves in the privacy of their examination room, while waiting for the providers. There will be minimal increased workload or time commitment involved.

Finally, the providers and patients made this project a success by working together to address this innovation. At any point during the pilot period, the providers were given the opportunity to voice their opinion on the project, suggest changes, discuss what they didn't like, and discuss whether or not this was a viable project for their clinics. The investigator met or spoke with the providers every other week to allow for feedback. The investigator also provided

phone numbers and email addresses to the providers for use if there were any questions or problems that arose prior to the meetings.

Although the Diffusion of Innovations theory is an appropriate model for presenting clinical guidelines or practice changes, there are potential issues in the use of the theory for this practice change. Even though the guidelines suggesting the use of the validated IIEF-5 questionnaires exist, to have them adopted in a clinical setting may take some time. As more research demonstrates the benefits of using the IIEF-5 for the providers and patients, the adoption may come more quickly. Expectation of a swift adoption and execution may cause problems in the system, which inevitably may cause the project to fail or be rejected.

The benefit of the Diffusion of Innovations theory has been realized in the medical, educational, organizational, community, and practice settings. Most of the new ideas whose diffusion has been analyzed are technological innovations. Frequently when using the Diffusion of Innovations theory, an organization will not get instant gratification; however, with this project utilization of the IIEF-5 demonstrated a quick method of acquiring results. The Diffusion of Innovations theory is an important theory that may serve providers, investigators, administrators, researchers, and change agents well.

Evidence-based practice dissemination and implementation efforts should concentrate on the attitudes of the providers and certain practice viewpoints. The expansion of knowledge depends not only on adaptive practices, but also on fostering positive physician attitudes, and having the knowledge about an organization that encourages communication and change.

Rogers' Diffusion of Innovations Theory Literature Review

Rogers' Diffusion of Innovations theory has been included by various disciplines from huge conglomerates to small private practices. A systematic review by Greenhalgh, Robert, Macfarlane, Bate, & Kyriakidou (2004) discusses the Diffusion of Innovations theory concerning the healthcare service area and additional service organizations. The authors identified 13 research areas that support the use of the Diffusion of Innovations in health service organizations. The authors found three main focal points: (1) an economical and evidence-based model regarding the Diffusion of Innovations in health service organizations; (2) a need to focus on further research on the Diffusion of Innovations in service organizations; and (3) a vigorous and convenient method for systematically reviewing multifaceted research evidence.

A study by Hader et al. (2007) focused on the views of physicians in utilizing clinical practice guidelines (CPG). The aim of this study was to evaluate why physicians did or did not employ innovations such as guidelines and to observe the degree to which these reasons fit a universal model of the innovation method. Forty-five physicians were interviewed regarding their opinions, attitudes, and behaviors towards CPGs for this qualitative study. The results of the study showed numerous major influences that the physicians saw as a necessity for them to adopt the innovations: (1) the physicians need to know that the guidelines exist; (2) the need for change must be apparent; (3) the need to know that the innovation has positive results and has no risk for their patients; (4) the patients and their families want the change; and (5) everyone involved supports the CPG and the physicians see positive patient outcomes with no augmented risk for continuation of the use of the CPG. While CPGs are developed to improve the health of patients, the physicians were critical of CPGs and reluctant to adopt the CPGs if they believed the health of their patients might be at risk. Strengths of the study were not mentioned, neither were any

weaknesses. One weakness of the study however, is that it is a qualitative study and not generalizable.

Chapter II: Literature Review and Synthesis

Search Strategy

Clinical practice guidelines and articles were searched from the following sites: National Guideline Clearinghouse, Science Direct, Cochrane Library, and Academic Search Complete, Cumulative Index to Nursing and Allied Health Literature (CINAHL), and PubMed. The following limits were set to include: articles published between 2005 and 2011, full text, in English, human subjects, randomized controlled trials (RCTs), and published in peer-reviewed journals. The search began with the keyword “ED” which yielded 9661 results. The addition of “erectile function” yielded 6738 results. Then adding “International Index of Erectile Function (IIEF-5)” narrowed the search to 1387 results. With the inclusion of the terms “diagnosis” and “treatment” the results were narrowed to 696. Again, the addition of the keywords “screening”, “evaluation”, “practice change”, “clinical setting”, and “provider behavior change” yielded 81 results. The author individually reviewed each of these 81 articles and retained only those relevant to this project. A hand search or “snowballing technique” was utilized which produced three more relevant clinical practice guidelines. Articles were excluded if they did not contain the key terms: ED, diagnosis, treatment, and IIEF-5 together in the study. A total of 15 relevant articles including: five clinical practice guidelines (CPGs) (Canadian Guidelines Towards Optimized Practice [TOP], 2010; Hatzimouratidis et al., 2010; Kimoto et al., 2008; Montague et al., 2009; Qaseem et al., 2009), four systematic reviews (Cappelleri & Rosen, 2005; Markou, Perimenis, Gyftopoulos, Athanasopoulos, & Barbalias, 2004; Ruiz-Aragon, Marquez-Pelaez, & Romero, 2010; Tsertsivadze et al., 2009), three RCTs (Azuri, Gelerenter, Dushinat, Friedman, & Kokia, 2009; Hwang et al., 2010; Shabsigh et al., 2010), two prospective cohort studies (Hakim

et al., 2002; Ponholzer et al., 2005), and one non-experimental descriptive study (Baldwin, Ginsberg, & Harkaway, 2003) were reviewed.

Review of Literature

A critical appraisal was completed on each of the 15 documents using the appropriate appraisal tool (Scottish Intercollegiate Guidelines, 2007; Appraisal of Guidelines Research & Evaluation Research Trust, 2006). The Canadian Towards Optimized Practice (TOP, 2010) program guideline focused on the management of ED in men. The TOP program ED clinical practice guideline (CPG) is a systematically produced publication and guideline established on evidence from scientific publications and medical journal articles. The guideline is meant to assist practitioner and patient decisions about healthcare for ED. To confirm clinical accuracy, the CPG is reviewed and validated regularly. The guideline was developed in 2001, reviewed in 2004, and revised in 2006 and 2010. To produce and revise the CPG, the Canadian TOP's Informed Practice team regularly reviewed the abridged publications of American College of Physicians (ACP) Journal Club, Evidence Based Medicine Journal, and Patient-Oriented Evidence that Matters (InfoPOEMS). These reviews examined a large base of the medical literature on ED, and the team used a systematic approach in choosing the most pertinent and the highest quality research. In addition, the condensed reviews were augmented with regular reviews of major journals, such as the British Medical Journal (BMJ), New England Journal of Medicine (NEJM), and The Journal of the American Medical Association (JAMA). Comprehensive searches of the published literature were performed on areas of significance, searching for the highest level of evidence (systematic reviews and randomized controlled trials). The Canadian Alberta (TOP) program funded the guideline. The goal of the guideline is plainly stated and represented early in the citations of the guideline. The target population and target

users of the guideline are well documented. Common causes, management, and available treatment options are well depicted. Moreover, documentation includes updating of the guideline. The authors do not mention whether any of the developers of the guideline were compensated for their contribution or list any conflicts of interest among the developing team. In the guideline, there was evidence that supported the use of a validated questionnaire for the diagnostic assessment of ED, along with physical examination and treatment options including: lifestyle changes, recommendations for initiating treatment with follow-up visits to evaluate progress and monitor therapy, and indications for referral. The guideline supported that the use of the Sexual Health Inventory for Men (SHIM) or IIEF-5 may be helpful in the clinical setting. Limitations associated with the guideline include the level/strength of evidence on which the guideline was established, how the guideline relates with the scientific evidence, and the potential cost of applying the recommendations. In addition, the developers do not specify whether the guideline was subjected to peer review and/or testing.

The European Association of Urology (EAU) guideline focused on the epidemiology, diagnosis and treatment of ED and premature ejaculation (PE) in men (Hatzimouratidis et al., 2010). The revision included an update on ED and as PE was a new addition to the guidelines, the authors included an evaluation of the highest quality scientific data, current research, and clinical practice, while taking their patient's personal situations, principles, and preferences into account. The EAU provided the funding for the development of the guideline.

In this guideline, the panel recommends the clinical use of a validated questionnaire for the diagnostic assessment of ED along with physical examination and treatment options including lifestyle changes, recommendations for initiating treatment with follow-up visits to evaluate progress and monitor therapy, and indications for referral. The goal of the guideline was

plainly stated and was represented early in the citations of the guideline. The developers conducted a systematic review of the literature in 2010 and seven revisions of the guideline from 2000 to 2009. The target patient population and target users of the guideline are well published. Common causes, management, and available treatment options are well depicted. Each of the recommendations in the guideline is clear, easy to follow and has a level and grade of evidence upon which the guideline is established and associated with the scientific evidence. The recommendations made are clinically relevant, practical, with measureable outcomes, that if followed will aid in appropriate care for patients with ED. The guideline has been peer reviewed and tested. The authors mention that none of the developers of the guideline were compensated for their contribution nor was there any conflict of interest listed. Limitations associated with the guideline include the shortage of data concerning the probable cost of utilizing the recommendations. In addition, although the authors mention the IIEF-5 numerous times, the IIEF-5 tool was not included in the guideline. Furthermore, the authors do not specifically mention suitable criteria for screening and review purposes.

The American Urological Association (AUA) Practice Guidelines Committee appointed an ED Guideline Update Panel (the Panel) in 2000 to update the existing guideline (Montague et al., 2009). The Panel's key focus was to use an evidence-based style to create a guideline for the new ED treatment modalities, which had become available in the United States after the 1996 Report was published. In addition, the Panel was to amend those sections that needed revising so that patients and physicians could have scientifically based information upon which to base their treatment and practice. There was strong evidence throughout the document that supported using the IIEF-5 as an outcome measure. The guideline objectives and clinical questions were plainly stated and clearly depicted early in the documentation. Databases utilized in the literature search

were clearly defined including several MEDLINE searches, with techniques that varied from very broad to very explicit. The systematic approach for evidence search was apparent and clearly documented with a sound relationship between recommendations and supporting evidence.

The authors specify and document the potential users and the potential patient population for whom the guideline was intended. Relevant treatment options and their associated risks and benefits along with side effects of the treatment options were well explained. In addition, the Panel also outlined proposals for future clinical research issues. The guideline supports use of the IIEF-5 questionnaire, which was designed to be utilized in the clinical setting. The guideline was outlined, evaluated by the Panel and by 80 peer reviewers, and ultimately accepted by the Practice Guidelines Committee and the Board of Directors of the AUA. The AUA guideline is not funded by business in any way; the association finances all costs related to guideline development. If appropriate, the AUA may collaborate with other institutes to develop guidelines. This organization can offer additional funding for guideline development and present a probable conduit to increase distribution of the guideline. All panel members were volunteers, and therefore, compensation was to further the field of urology. The AUA acknowledges that full involvement on a guideline panel is an educational endeavor; consequently, panel members were granted up to 15 Continuing Medical Education (CME) credits at the conclusion of the guideline. Limitations associated with the guideline include the shortage of data concerning the probable cost of utilizing the recommendations. Also noted in the literature was the inconsistency in the use of standardized outcome measures for ED. According to the literature, there were 354 different outcome measures (excluding the IIEF-5 tool) found. Additionally, the 15 questions of the IIEF-5 are divided into five domains and an overall score, however, questions 3 and 4 were

the most commonly reported while some studies reported using other domains and using multiple domains together.

The Japanese Society for Sexual Medicine (JSSM) introduced a guideline for ED concerning the diagnosis and treatment of ED appropriate for general physicians (Kimoto et al., 2008). The target readership in this case comprises most urologists whose practice does not concentrate on sexual dysfunction. Strong points of this clinical practice guideline consist of a well-depicted clinical question and solid documentation of systematic methods used to search for evidence. Funding for the guideline came exclusively from the JSSM with authorization of the Board of Directors. The authors conducted a literature search of PubMed as well as several specialty urology journals. The guideline was peer reviewed with levels of evidence cited in the guidelines and the recommendations graded. All of the members of the guideline preparation committee have received payments from various pharmaceutical companies during the past three years.

The guideline supports the use of the International Index of Erectile Function 5 (IIEF-5) tool and maintains that it is helpful in the clinic. The guideline also includes ED diagnostic and treatment flow charts. Limitations include patients' concerns or even involving the patients in the discussion for developing the guidelines were not included. In addition, the potential cost of the various treatment options was not addressed in the guideline.

A clinical practice guideline from the American College of Physicians (ACP) (Qaseem et al., 2009) focused on presenting the available evidence on the hormonal testing and pharmacologic management of ED. In this guideline, 130 RCTs demonstrated significant evidence for the clinical benefits with the use of phosphodiesterase-5 (PDE-5) for treatment of ED regardless of the cause (such as mental illness, diabetes, or prostate cancer) or baseline

seriousness of ED. The 15 RCTs supporting the efficacy of hormonal blood tests in distinguishing and influencing therapeutic outcomes for treatable causes of ED was inconclusive. The target audience for this guideline is all physicians, and the target population is all males with ED. The guideline objectives and clinical questions were plainly stated and depicted early in the guideline. In addition, documentation was included that discussed the method for updating the guideline and conflicts of interest among the developing authors. Funding for the guideline development was obtained solely from the ACP.

The systematic approach for evidence search was clear and well documented at the beginning of the guideline. Databases utilized for the literature search were acknowledged and included MEDLINE, AMBASE, Cochrane Central Register of Controlled Trials, and other databases. The guideline graded the evidence and recommendations utilizing the ACP clinical practice guidelines grading system. Various treatment modalities were described in the guideline along with their health benefits and side effects. Limitations include the patients' concerns or even involving the patients in the discussion for developing the guidelines were not included. In addition, the potential cost of the various treatment options was not addressed in the guideline. Furthermore, there was no mention of using a measurement tool of any type for the diagnostic assessment of ED. Another limitation mentioned in the guideline was that the quality of the studies needed improvement. Still another limitation mentioned was that the evidence concerning the occurrence of adverse events was inadequate and questionable, and more high-quality head-to-head trials are required to investigate disparities in adverse events.

Cappelleri and Rosen (2005) conducted a systematic review of 21 studies on the prevalence of ED, 23 intervention studies on the efficacy of ED, and eight other studies (mostly correlational). There were three main objectives of the study: (1) to provide a status report on the

SHIM and its effect on the management of ED, (2) to provide a comprehensive account of studies in which the SHIM was utilized, and (3) to provide a systematic framework to manage and evaluate the studies. The results of the study concluded that the magnitude of research and quality of studies on the SHIM give evidence to the questionnaire's positive effect on understanding and improving ED, and that this positive effect may remain significant in coming years. A sample size of 69,872 men from 52 studies was included in the review. A report on the methodology was clearly represented and thoroughly reviewed. The MEDLINE search of literature was meticulous and included pertinent, well-described studies that were comparable in style. The review incorporated studies that included prevalence, interventions, relationships, and that found the SHIM to be an integral measure of ED. Researchers and participants found the SHIM to be user-friendly, fast, economical, and simple to administer. Limitations of the study were: (1) some men answering the SHIM had not engaged in sexual activity either by choice or lack of opportunity, (2) there was some confusion between the elements of the SHIM and the full-scale IIEF or its Erectile Function (EF) domain, (3) there were slight problems that existed regarding the validation of the SHIM, and (4) the SHIM (IIEF-5) was not intended to diagnose the etiology of ED only the incidence and severity, as well as monitoring patient success with treatment.

Markou and colleagues (2004) conducted a systematic review and meta-analysis of ten randomized controlled trials to determine the efficacy and safety of vardenafil in the treatment of male ED. The results of the study concluded that vardenafil increased the EF domain of the IIEF-5 questionnaire by 6.18 units of weighted mean difference (WMD). Vardenafil also increased the percentage of erections firm enough to allow vaginal penetration (WMD: 26) and the percentage of sexual attempts that were successful per participant (WMD: 29.8). In conclusion, after a 12-

week period of treatment, the evidence showed that in the general population of men with ED, vardenafil safely and without fail improved all efficacy facets of EF, enhancing erections and contentment in men.

An account of the systematic methodology was plainly stated and thoroughly covered with detailed information on inclusion and exclusion criteria. A rigorous literature search was completed and included MEDLINE, Embase, CINAHL, Cochrane Library electronic databases and Current Contents. A manual search of the literature was performed, along with the European Agency for the appraisal of Medical Products and the records of the United States Food and Drug Administration advisory panel associated with pertinent approval applications. Included in the study were ten randomized controlled trials involving 6,809 men. Limitation of the study included heterogeneity ($P < 0.00001$) of outcomes of the two primary and one secondary result. When reviewed, this seemed to have been clinical in origin because the population characteristics of the studies (diabetics, healthy participants, broad population, and radical prostatectomy patients) may have influenced the response.

Ruiz-Aragon, Marquez-Pelaez and Romero (2010) conducted a systematic review of 10 observational studies and 29 case series studies. The objective of the systematic review was to assess the erectile function in participants with a diagnosis of prostate cancer who planned to have surgery by one of three methods including laparoscopic, radical, or robotic prostatectomies. The results of the study concluded that there was a lower percentage of ED after the intervention in the participants who underwent robotic surgery (3-51%). Laparoscopic and radical surgeries showed higher percentages of impotence (36-91%). In looking at the case series, there appeared to be lower percentages of ED in participants who underwent robotic surgery (22%) then laparoscopic surgery (40%) and finally open radical prostatectomy (41.4%).

Recognized strengths of the study included an appropriate and clearly focused question. An explanation of the methodology was clearly illustrated and appropriately covered. The literature search was meticulous and incorporated significant, well depicted studies that were comparable in nature. Databases searches included: MEDLINE, Embase, Hayes, Cochrane Library, Center for Review Dissemination, and ECRI as well as databases of the healthcare technology agencies. The authors also conducted a manual search in journals specializing in cancer, urology, and prostate issues. A limitation of the study was the low quality of the reports used in the study. Additionally, since scientific publications were identified in the literature searches, a publication bias cannot be ruled out. Furthermore, there were no randomized controlled trials or high quality studies in the systematic review. In both the observational and the case series, heterogeneity was the major bias. This occurred mainly in terms of participant selection, procedures completed, and the fact that the observational studies were often different.

Tsertsvadze et al. (2009) conducted a systematic review and meta-analysis of 222 randomized controlled trials (RCTs) of oral phosphodiesterase-5 inhibitors (PDE-5) and observational studies of hormonal treatments for ED in a sample of 17,468 men. The results of the review showed that the PDE-5 inhibitors were more effective than placebo in improving sexual intercourse (69% versus 35%). In four RCTs comparing the three different PDE-5 inhibitors, the adverse events were equal. Results from 15 of the RCTs evaluating hormonal treatment were inconsistent.

A detailed description of the methodology was included, clearly described, and thoroughly covered. The literature search was thorough and included pertinent, well-described studies that were alike in nature. Databases for the literature search included: MEDLINE, EMBASE, Cochrane Central Register of Controlled Trials, PsycINFO, AMED, and SCOPUS.

Included studies were evaluated for strength of evidence by using the appropriate methods and judged using accepted criteria and review protocols. The strength of the study was the large amount of high-grade evidence on therapeutic effects of PDE-5 inhibitors compared with placebos for men with ED. A limitation of the study was that numerous trials were received with limited methodological and reporting quality, predominantly those that directly compared PDE-5 inhibitors, and those that assessed hormonal therapies. Additionally, clinical or methodological heterogeneity and nonexistent information narrowed the amount of statistical data pooling. Furthermore, according to the authors, the small number and selective coverage of serious cardiovascular events were conflicting and incomplete and should be explained with concern. In addition, most of the RCTs presented only short-term efficacy and harms data and longer-term data was unavailable.

Hwang et al. (2010) conducted a randomized controlled trial with a second randomized booster to present current data on the prevalence of ED in Taiwanese men and to validate the erection hardness score (EHS) and Quality of Erection Questionnaire (QEQ) in this population. The results of the study concluded that the prevalence of ED, as defined by IIEF-5, was 27% among all participants and 29% among those 40 years of age or older. While prevalence of ED increased with age, men of all ages had a propensity to underestimate their ED. By utilizing the IIEF-5, the authors found that 25% of the men who identified that they did not have ED, in reality, had mild to moderate ED. The authors used the IIEF-5 as a comparison tool to validate the EHS and the QEQ for the assessment of ED.

Strengths associated with this study include the randomized controlled trial study design with the second randomized booster. Study methods were well detailed with information on inclusion and exclusion criteria. There were 1,009 men eligible to participate in the study during

the first randomization and the second random booster included another 51 men. A limitation of the study was the use of a telephone interview one time only to validate the EHS. In the telephone interview, numerous calls were necessary to make just one contact, privacy may have been inadequate, and participants who had health problems such as a knowledge deficit or hearing issues may have been at a disadvantage with this kind of survey.

Shabsigh et al. (2010) conducted a double blind randomized, placebo-controlled trial using a sildenafil flexible dose to identify previously unrecognized or undiagnosed ED so that it could be discussed as a medical condition. The prevalence of unrecognized ED with comorbidities commonly associated with ED was determined by analyzing the results of the study. Men eligible for the study were ≥ 30 years old with at least one risk factor. Risk factors include but were not limited to: smoking, cardiovascular disease, diabetes, controlled hypertension, metabolic syndrome, obesity, and depression, as well as no past or current diagnosis of ED. Conversely, men with these conditions may also have underlying ED. Criteria for admission into the study also included the use of the EF domain of the IIEF questionnaire. The EF question asks the participant whether or not they currently have ED. The participants that answered with a “no” or “unsure” were eligible for inclusion into the study.

In this study, 1,053 men responded to the Erection Function domain of the IIEF-5-EF questionnaire and received a score. In general, IIEF-5-EF diagnosis of ED were documented in 71% (744/1053) of males, of which 54% (399/744) had moderate or severe ED (IIEF-5-EF score ≤ 16), 23% (171/744) had mild-to-moderate ED (IIEF-5-EF score 17-21), and 23% (174/744) had mild ED (IIEF-5-EF score 22-25). A limitation of the trial design was that the basis for men’s explicit answers to the screening question was not investigated further. The authors found that while awareness of having ED was minimal, most of the participants with risk factors had a

IIEF-EF score indicating some degree of ED and recommend that patients with risk factors be evaluated.

Azuri, Gelerenter, Dushinat, Friedman, and Kokia (2009) used a randomized controlled trial to examine the outcome of increasing understanding of the diagnosis and treatment of ED in a community environment using physicians' education. A sample size of 1,959 men in two intervention groups and 1,903 men in the control group along with a random sample of 40 primary care physicians in both the intervention and control groups were the focus of this study. The results of the study showed that during the six-month timeframe prior to the intervention and the six-month timeframe after the implementation, there were no major differences in diagnosis of new ED participants, in PDE-5 inhibitor prescriptions or in referrals to urologists. The findings lead the authors to determine that periodic lectures and electronic patient records do not significantly influence the physician's actions. Limitations of the study included: (1) participants may not have had ED, even though they were chronic patients with long-standing risks, (2) participants may not have seen their provider during the six-month follow up timeframe, and (3) an extended follow up timeframe may improve the chances of diagnosis and treatment. Furthermore, even though the authors followed more than 3,000 patients, the study sample (20 physicians and 20 physician controls) was small.

A prospective study by Ponholzer et al. (2005) focused on examining erectile function with a validated study instrument in 2,869 men between the ages of 20 and 80 years with numerous possible risk factors taking part in a health investigation in a municipal area of Vienna. The objective of this study was to evaluate incidence and risk factors for ED by examining a large group of men taking part in a health investigation and by using the IIEF-5. As evidenced by the IIEF-5 score, 32.2% had no ED (IIEF-5 score greater than 22), 23.7% had mild ED (IIEF-5

score 17 to 21), 5.0% mild to moderate ED (IIEF-5 score 12 to 16), 2.2% moderate ED (IIEF-5 score 8 to 11) and 1.3% severe ED (IIEF-5 score 0 to 7). Risk factors for ED increased with age, diabetes, hyperlipidemia, lower urinary tract symptoms, hypertension, psychological stress, and low physical activity (all, $p < 0.05$).

Strengths of the study included the fact that all participants completed a thorough health examination with standardized assessment of medical history, physical examination, and a laboratory study. In addition, the authors used the IIEF-5 to measure prevalence and seriousness of ED. Furthermore, due to recruiting men participating in a health screening, the study had a good sample size with 2,869 participants. Limitations included that a sample bias could not be excluded, as the typical epidemiological model was not used to generate the study population. In addition, the majority of males over 60 years of age in Austria is retired and has more time for physical activity, which may cause selection bias in this age group.

A prospective study by Hakim, Subit, Kandzari and Zaslau (2002) appraised the screening patterns of primary care physicians with respect to ED. The study was conducted utilizing the SHIM questionnaire with men that came to a urology clinic. The study included 102 male patients that completed and returned the survey. Of the patients returning the SHIM questionnaire, 56% had a score of 21 or less, diagnostic of a degree of ED. Eighty-three percent had primary care physicians (PCP); 23% of participants with a PCP were screened for ED and of those, 58% initiated the discussion with their physician. The results of the study also demonstrated that participants leave the PCPs office without being screened for ED. This study found that a validated questionnaire such as the SHIM should be utilized with participants who have any identifiable risk factor. In addition, monitoring for ED is appropriate, as effective treatment of ED is obtainable. It was also noted that ED could be linked with undiagnosed

cardiac disease. Limitations of the study included the predominant use of elderly participants. In addition, selection bias may have occurred as participants included only those with ED.

Furthermore, the small sample size of 102 participants was a limitation of the study.

A non-experimental descriptive study by Baldwin, Ginsberg, and Harkaway (2003) assessed the under-reporting of ED among men with unrelated urologic issues. The aim of this study was to evaluate the occurrence of ED in men with unconnected urologic conditions and sought the rationale for why the men did not always report ED. There were 500 men enrolled in this non-experimental descriptive study. The results of the study suggested that the majority of men (82%) with some degree of ED who had not reported ED wished that the primary care physician had brought the topic up during a regular office visit. In addition, 74% of those suffering some degree of ED were self-conscious, and as a result, did not want to discuss ED with the urologist. The study also found that urologist had to ask specific questions to get the patients to discuss ED, while patients seemed at ease and ready to talk about ED with the primary-care physicians. The most common reason cited for the under-reporting of ED was embarrassment. The strength of the study was the availability of men in the urology clinic. A limitation to the study was that the patients were already seeing an urologist.

Synthesis

The evidence collected through the appraisal of 15 documents including: four clinical practice guidelines (Canadian Guidelines Towards Optimized Practice [TOP], 2010; Hatzimouratidis et al., 2010; Kimoto et al., 2008; Montague et al., 2009), four systematic reviews (Cappelleri & Rosen, 2005; Markou et al., 2004; Ruiz-Aragon et al. 2010; Tsertsvadze et al., 2009), two RCTs (Hwang et al., 2010; Shabsigh et al., 2010), and two prospective studies

(Hakim et al., 2002; Ponholzer et al., 2005) support the use of a validated questionnaire for the diagnostic assessment of ED.

Evidence from all five clinical practice guidelines (Canadian Guidelines Towards Optimized Practice [TOP], 2010; Hatzimouratidis et al., 2010; Kimoto et al., 2008; Montague et al., 2009; Qaseem et al., 2009), two systematic reviews (Markou et al., 2004; Tsertsivadze et al., 2009) and one RCT (Azuri et al., 2009) supports the use of the PDE-5 inhibitors for the treatment of ED, with the five clinical practice guidelines (Canadian Guidelines Towards Optimized Practice [TOP], 2010; Hatzimouratidis et al., 2010; Kimoto et al., 2008; Montague et al., 2009; Qaseem et al., 2009) supporting PDE-5 inhibitors as first line therapy.

Supported by the collective results of these studies, a validated questionnaire does promote ease of discussion and facilitates diagnostic assessment of ED in the clinic. Furthermore, PDE-5 inhibitors were supported as first line treatment for ED. Heterogeneity was found across some of the studies. Ruiz-Aragon et al. (2010) emphasized that in both observational studies and case series the major bias observed was heterogeneity, largely in relation to patient choice, procedures executed, and ways of comparing observational studies, which were not always alike. Markou et al. (2004) stated that the heterogeneity of outcomes between using vardenafil or placebo of the two primary and one secondary result when reviewed gave an impression of being clinical in origin, since the population traits of the study (diabetes, general patient population, healthy patients, and surgical patients, such as prostatectomy patients) may influence the results. The differences in the sample characteristics could cause discrepancies in outcomes across studies.

Gaps exist in the evidence about treatment specific agents and long-term consistency of the PDE-5 inhibitors over time. While four (Canadian Guidelines Towards Optimized Practice

[TOP], 2010; Hatzimouratidis et al., 2010; Kimoto et al., 2008; Montague et al., 2009) of the clinical practice guidelines support the use of a validated questionnaire, they may need to be upgraded to specify one in particular and make the use of the questionnaire a recommendation. The majority of the studies reviewed provide strong evidence to support the use of a validated questionnaire in the clinic for the diagnostic assessment of ED and the use of the PDE-5 inhibitors as a treatment option for ED. Support of the need for a protocol change is included in the body of evidence, which includes the utilization of a validated questionnaire that assists in changing provider behavior, and improves provider observance of the suggestions in the clinical guidelines for ED. Based on the review of the literature the following PICO question was developed: Does provider education and the use of the International Index of Erectile Function – 5 (IIEF-5) questionnaire increase diagnosis of ED and documentation of treatment options in two clinics in Southern West Virginia?

Project's Congruence of Organizations Strategic Plan

The settings for this pilot project were two private practice primary care clinics in southern West Virginia. This pilot practice change was supported by the missions of both clinics. The overall mission of both clinics is to provide quality professional healthcare, to promote health, prevent illness, and to empower patients to manage their health. Both clinics are dedicated to improving the quality of health care and health outcomes through providing timely, innovative, and compassionate care. Chronic medical conditions found at both clinics include: Types 1 diabetes, Type 2 diabetes, hypertension, cardiovascular disease, psychological problems, hyperlipidemia, obesity, smoking, and alcohol abuse. The main goal of the pilot project was to evaluate the incorporation of the IIEF-5 questionnaire into the patient's chart to increase the

diagnosis and documentation of treatment options for ED when indicated by the score on the questionnaire. The main goal of the pilot project and the goals of the clinics are congruent.

Project

This pilot project was comprised of an educational session on the use and scoring of the IIEF-5 questionnaire followed by an evaluation of provider behavior change in the assessment, detection, and documentation of treatment options for patients with ED. The IIEF-5 questionnaire was utilized in two clinics in southern West Virginia over a six-week period. Information and education on ED and the use of the IIEF-5 questionnaire was given to both providers separately during a single meeting prior to the implementation. The investigator completed a pre implementation (n=50) random chart review and a post implementation chart audit on the (n=89) completed questionnaires to evaluate the use of the questionnaire in assessing, detecting, and documenting plans of care and follow-up for patients with ED. The proposed pilot project was completed with delivery of outcomes to the stakeholders.

Goals and Objectives

The main goal of the project was to evaluate a pilot project to incorporate the IIEF-5 questionnaire into the patient's chart, to increase the diagnosis and documentation of treatment options for ED as indicated by the score on the questionnaire. This innovation was implemented to improve the health status of the patient population. Understanding the significance of ED has augmented the importance of early detection and increased quality of life. The hypotheses for the capstone project are: a) the use of the IIEF-5 questionnaire in the clinical practice will increase the diagnosis of ED; b) the use of the IIEF-5 questionnaire in the clinical setting will increase the documentation of the discussion of treatment options for men with ED when indicated by their score.

Subsequently, the five objectives for this capstone project were:

1. To increase provider awareness relating to the use of the IIEF-5 questionnaire for ED.
2. To increase the number of patients who are screened for ED.
3. To increase the number of patients with a diagnosis of ED.
4. To increase the number of patients diagnosed with ED receiving treatment options as documented in the charts.
5. To increase the number of patient charts with documentation of ED.

Chapter III: Methodology

Project Design

This pilot project was submitted to the West Virginia University Institutional Review Board (IRB). It was reviewed by the IRB, approved, and determined to be expedited. The project used a descriptive design to address the objectives.

This capstone project was designed to incorporate the use of the IIEF-5 questionnaire into the patient's chart to increase the diagnosis and documentation of treatment options for ED when indicated by the score on the questionnaire (Appendix A). The providers at both clinics granted permission to include the use of the IIEF-5 questionnaire into their perspective clinic (Appendices B & C). The capstone project was designed based upon national guidelines and evidence-based research.

The capstone project was conducted over a six-week period, with weekly phone discussions and bi-weekly visits to the sites to answer any questions and keep supplies of the questionnaires and pens on hand. The IIEF-5 questionnaire was given to all male patients between the ages of 40 to 70 years visiting the clinics during the six-week study period who agreed to participate in the study. Attached to the IIEF-5 questionnaire was a demographic sheet seeking information such as age, marital status, race, and co-morbidities such as diabetes, cardiovascular disease, hypertension, kidney disease, depression, etc. as found on the Demographics/Cover page (Appendix D). This capstone project also included a Data Collection Form for the providers to complete and scan into the patient's chart, which served as a reminder during the patient's next visit of the patient's erectile function status (Appendix E). This capstone project provided an IIEF-5 questionnaire for the providers to use to assist in the assessment, diagnosis, and discussion for treatment options of ED as identified by the patient's

score. According to the scoring of the IIEF-5, severity of ED is classified with the following scale: a score of 0-7 equates with severe ED, a score of 8-11 equates with moderate ED, a score of 12-16 equates with mild to moderate ED, a score of 17-21 equates with mild ED, and a score of 22-25 equates with normal/no ED (Table 1).

Table 1 Assessment of ED – IIEF-5

Normal Erectile Function	Score	22 - 25
Mild ED	Score	17 - 21
Mild to Moderate ED	Score	12 - 16
Moderate ED	Score	8 - 11
Severe ED	Score	0 - 7

The investigator discussed the use of the IIEF-5 questionnaire with the key stakeholders during a face-to-face one-on-one conversation with both clinic providers to evaluate the probability of the proposed pilot project.

Resources

To complete the pilot practice project, the following resources were required: providers or key stakeholders, IIEF-5 questionnaires with permission to use, educational materials, demographics/cover sheet tool, data collection tool, timeline for the project, and a budget plan. The primary resource for championing implementation of the pilot project was the providers or key stakeholders at each clinic. Involvement in this pilot project did not alter the day to day duties of normal patient care. The investigator discussed each phase of the pilot project with the providers prior to its design in order to elicit their input and gain their acceptance of the pilot project.

Other resources necessary to implement the pilot project included items such as copies of the questionnaire (Appendix A), the pre-numbered log sheet (Appendix H), the demographics/cover page (Appendix D), pens, and gasoline for trips to the sites. The investigator compiled and presented an educational program (Appendix J) to the providers at both clinics.

Procedure

Instruction in the use and scoring of the IIEF-5 was necessary as neither provider had heard of the questionnaire. A formal teaching session was held with both providers individually during after clinical hours to explain the questionnaire and how to score the tool. One of the objectives of the pilot project was to improve provider awareness relating to the use of the IIEF-5 questionnaire for ED. The instructional focus incorporated (a) the use of the IIEF-5 questionnaire in the clinical practice, (b) scoring the completed questionnaire, (c) patient population to be included in the pilot project, (d) importance of follow-up with patients whose score were indicative of diagnosis of ED, (e) the documentation of erectile dysfunction into the patients charts, and (f) treatment options offered to the patients.

Evidence from research studies and ED guidelines were discussed with the providers in hopes of garnering their support for the pilot project. Each of the providers discussed the pilot project with their respective nurse and decided what part the nurse would take in the pilot project. The nurses at both clinics gave the pre-numbered questionnaire to the patients who agreed to participate after writing the patient's name on the corresponding pre-numbered log sheet; the nurse scored the questionnaire and placed the questionnaire in the exam room with the patient. The provider then discussed the score of the questionnaire with the patient during the patient's visit. The log sheet was kept in the provider's possession at all times, when the investigator was not obtaining necessary information for the pilot project. Both clinics utilize an

electronic medical record (EMR) for patient charts and as such, the providers had the nurse scan the scored questionnaire into the patients' chart.

The provider completed the data collection form during the patient's visit. The data collected included patient questionnaire, IIEF-5 score, age, and whether the patient had a pre-existing diagnosis of or was being treated for ED. The data collection tool (Appendix E) was used to collect specific objective data on measures supported by the guidelines. The tool was based on the American Urological Association guidelines (Montague et al., 2009) and supporting evidence from the literature with emphasis on risk factors and early detection of ED. In addition the Data Collection form also included areas for the provider to mark whether or not there was: follow-up appointments scheduled to evaluate treatment and whether or not the patient was satisfied with his current treatment (Appendix E). The providers kept the list identifying the patient name with the corresponding numbered questionnaire locked in their offices when they were not using the list. When the providers were using the list, either the providers or their nurse kept them at their workplace in the clinic at all times. Some of the charts did not hold all the information needed to fill out the tool; therefore, the investigator designed the Data Collection form to reflect this. Information not found in the charts, but included on the Data Collection form included: whether the patient had undergone specific laboratory test, whether the patient had a follow-up to evaluate treatment of ED once diagnosed, whether the patient was satisfied with his current treatment, etc. (Appendix E).

Budget

The investigator developed a budget plan to project and control cost of the pilot project (Appendix G). The cost of space at the clinics, provider and staff participation and time, the use of the IIEF-5 questionnaire, and the nurse practitioners time were all donated. Other costs

included the investigator's time to put together the questionnaires, educate the providers, travel expenses, office supplies, Christmas baskets in lieu of pre implementation lunch, and post pilot project disclosure lunches for the clinics. The total cost of the pilot project was \$541.02, of which \$500.00 was grant money. The most significant cost was that of the copies of the questionnaires for the clinics.

Evidence of Key Site Support

The sites for the implementation of the capstone project were two primary care clinics in southern West Virginia, at which the investigator had been in ongoing discussion since early 2010, when the investigator was conducting a needs assessment. The practice owners were supportive of the investigator's project. There had been multiple discussions between the clinic providers and the investigator regarding the project and the questionnaire, along with the potential benefits to the clinics and patient. Signed letters of support were obtained that allowed implementation of the pilot project at the sites (Appendices B, C).

Chapter IV: Results

Characteristics of the Sample

The sample for this pilot project were patients of two primary care doctors in two clinics in southern West Virginia. One of the medical providers is an Internal Medicine Doctor (MD) and female, while the other is a Family Practice Medical Doctor (MD) and male. This pilot project consisted of two samples: the baseline sample and the post implementation sample. Criteria for the randomly selected patients from the clinics were that of male patients, 40 to 70 years of age, with or without an ICD-9 code of 607.84 and 302.72. The post implementation sample consisted of all male patient 40 – 70 years of age that completed the IIEF-5 questionnaire during their visit with the providers. The baseline sample (n=50) had a mean age of 53.1 with a standard deviation of 8.3 years, with the minimum age of 40 years and the maximum age was 70 years. The number of male patient charts that were included in the post implementation pilot project was (n=71) and had a mean age of 59.7 years with a standard deviation of 6.6 years and included one patient with an unknown age (Table 2). In both the pre and post implementation sample race/ethnicity was 90.9% (n=110) Caucasian and 1.7% (n=2) African Americans, which is fairly consistent with the racial/ethnicity statistics of Raleigh and Kanawha Counties in West Virginia. Race/ethnicity was found to be unknown in 7.4% (n=9) of the total charts reviewed. Another factor in the pre/post combined data sets that was reviewed was marital status, which included a sample of 78.5% (n=95) married, 9.1% (n=11) divorced, 1.7% (n=2) unknown, 7.4% (n=9) single and 3.3% (n=4) are cohabitating (Table 2).

Table 2 Pre and Post Implementation Demographic Data

Demographics	Pre Implementation Chart review (n=50) n (%)	Post Implementation Chart review (n=71) n (%)	All patients (n=121) n (%)
Age (years)			
40-50 years	23 (46)	5 (7)	28 (23)
51-60 years	15 (30)	31 (44)	46 (38)
61-70 years	12 (24)	34 (68)	46 (38)
Unknown	0	1	1
Mean (SD)	53 (8.3)	60 (7)	57 (9)
Minimum-maximum	40-70	40-70	40-70
Race, n (%)			
White	46 (92)	64 (90)	110 (90.0%)
African American	1 (2)	1(1.4)	2 (1.7%)
Asian	0	0	0
Unknown	3 (6)	6 (8)	9 (7.4%)
Marital Status			
Married	36 (72)	59 (83)	95 (78.5%)
Divorced	5 (10)	6 (8)	11 (9.1%)
Unknown	1 (2)	1 (1.4)	2 (1.7%)
Single	6 (12)	3 (4)	9 (7.4%)
Cohabiting	2	2	4 (3.3%)

Note: The pre implementation sample was randomized, whereas the post implementation sample was a convenience sample. An Independent sample t-test was conducted to compare the age differences between the pre and post implementation groups.

Co-morbidities were addressed and collected on the Data Collection form (Table 3).

Table 3 Pre and Post implementation Co-Morbidities

Co-Morbidities	Pre Implementation Chart review (n=50) n (%)	Post Implementation Chart review (n=71) n (%)	Frequency Total Number of patients with Comorbidity
Smoking/Tobacco	23 (46)	14 (20)	37 (31)
Alcohol	23 (46)	16 (23)	39 (32)
Diabetes	9 (18)	22 (31)	31 (26)
Heart Disease	7 (14)	23 (32)	30 (25)
Hypertension	28 (56)	30 (41)	58 (48)
Kidney Disease	2 (4)	5 (7)	7 (6)
Peripheral Vascular	0	5 (7)	5 (4)
Thyroid Problems	4 (8)	10 (14)	14 (12)
Depression	22 (44)	12 (17)	34 (28)
Decreased sex drive	0	21 (30)	21 (17)
Prostate surgery	1 (2)	5 (7)	6 (5)
Multiple sclerosis	0	0	0
Current treatment of			
Nitrates	1 (2)	1 (1.4)	2 (2)
Spina bifida	0	2 (3)	2 (2)
Prostate problems	10 (2)	9 (13)	19 (16)
Spinal cord injury	2 (4)	1 (1.4)	3 (2)
Penile trauma	0	0	0
Hyperlipidemia	22 (44)	3 (4)	25 (21)

Project Results

Provider objectives. Informed consent forms from both providers were obtained prior to the start of the pilot project, as well as the investigator signing a HIPAA form at both clinics. Both providers articulated understanding of the proposed pilot project and their involvement in the pilot project.

The first objective was to increase provider awareness relating to the use of the IIEF-5 questionnaire for ED as measured by utilization of the IIEF-5 in the clinic. This objective was

met when the investigator discussed and introduced the IIEF-5 questionnaire to the two primary care providers.

The post implementation chart audit (n=71) revealed an increase in patient charts in that 53 or 75% of the patients answering the questionnaire had a new documented diagnosis of ED. The providers voiced their satisfaction in the ease of using the questionnaire and the results they were seeing in their patient's questionnaire scores. Chi-square analysis demonstrated a statistically significant rise in the total of patients diagnosed post implementation ($p<0.00$). Post implementation chart review showed 100% of the patients that received a diagnosis of ED had documentation of ED in their charts.

Patient objectives. The second objective was to increase the number of patients who were screened for ED as measured at the beginning and at the termination of the pilot project by the number of IIEF-5 questionnaires that were completed. This objective was met in that there were 89/250 (36%) questionnaires completed, of which 71 (80%) were eligible for this pilot project. Patients with a current or previous diagnosis of ED or currently receiving treatment for ED, as well as those <40 or >70 years of age were excluded.

Utilization of the IIEF-5 questionnaire by the providers in the clinic during the six-week pilot project provided evidence of an increase in identification of ED in patient's charts. Data gathered on the data collection form consisted of specific questions including: (a) was the IIEF-5 questionnaire discussed with the patient (n=71): the providers discussed the questionnaire with 71 patients, (b) was the patient's score (n=71) discussed: the providers documented that the patient's score was discussed with 71 patients (100%).

The third objective was to increase the number of patients with a diagnosis of ED as measured using the IIEF-5 questionnaires. Beginning measurements during the pre

implementation period via chart review revealed five of 50 patients (10%) had a diagnosis of ED. Data utilizing the IIEF-5 questionnaire scores from the post implementation group assessment showed a diagnosis of ED in various degrees in (n=53/71) or 75% of the male patients 40 to 70 years of age (Table 4). Chi-square analysis demonstrated a statistically significant rise in the total of patients diagnosed post implementation ($p<0.00$).

Table 4 Pre and Post Implementation Diagnosis ED

Diagnosis	Pre Implementation (n=50) n (%)	Post Implementation (n=71) n (%)	Combined Total (n=121) n (%)
Erectile Dysfunction	5 (10)	53 (75)	58 (48)

Table 5 Pre and Post Implementation Diagnosis ED – Age 40 - 49 and 50 - 70 years

Demographics	Pre Implementation Chart review (n=50) with ED n (%)	Post Implementation Chart review (n=70) with ED n (%)	All Patients Chart review (n=120) n (%)
Age (years)			
40-49	0/21(0)	3/4(75)	3/25(12)
50-70	5/29(17)	50/66(76)	55/95(58)

There were no significant differences in ages for males 50 to 70 years between the pre and post implementation group (0.6). However, there was a statistical significant difference between the pre and post implementation males ≤ 49 years of age. In Group 1 – 21/50 (42 %) of the men were ≤ 49 ; Group 2 – 4/71(5.6%) were ≤ 49 years. Prevalence of ED in Group 1 of

participants 50 - 70 years of age was 5/29 (17%), while prevalence of ED in Group 2 - participants 50 - 70 years of age was 50/66 (76%). There was one participant in the group with an unknown age. Chi-square analysis demonstrated a statistically significant rise in the total of patients diagnosed post implementation ($p < 0.00$) (Table 5).

According to the scoring on the IIEF-5, a patient score of less than 22 is indicative of a degree of ED. Severity and prevalence of ED via scoring on the IIEF-5 questionnaire for this pilot project is as follows: normal erectile function was 18/71(25.4%); mild ED was 16/71 (22.5%); mild to moderate ED was 15/71 (21.1%) moderate ED was 6/71 (8.5%) and severe ED was 16/71 (22.5%) (Table 6).

Table 6 Severity and Prevalence of ED

Assessment	Post Chart Review (n=71)	%
Normal Erectile Function	18	25.4
Mild ED	16	22.5
Mild to Moderate ED	15	21.1
Moderate ED	6	8.5
Severe ED	16	22.5

The fourth objective was to increase the number of patients diagnosed with ED receiving treatment options as documented in the charts. Of the eligible 71 completed questionnaires, discussion of ED was found on 71(100%) of the patients charts. Patient scores were found in 71 of the 71 (100%) completed questionnaires, with 53/71 having a score < 22 , indicating a degree of ED. Success of the project was in large, due to the two primary care providers commitment to their patients. Both providers were willing to listen to the Project Leader's presentation on ED, evidence-based practice, and the use of the IIEF-5 in the clinical setting. Success of the project was also due to the Project Leader's passion for wanting to assist patients with ED and her ability to promote how using this questionnaire could benefit not only the patient, the patient's

interpersonal relationship, the potential benefits to the patient's health, but the providers communication and rapport with the patients, as well as, the clinics bottom line.

Utilizing a question on the data collection form: were treatment options offered to the patients whose scores indicated a degree of ED (n=53) resulted in 42 patients offered treatment (79%), 11 patients were not offered treatment (21%). Of the 11 patients not offered treatment, five had heart disease, four scheduled follow-up visits to discuss options, one patient was not interested, and one admitted that he was not sexually active. On the pre implementation chart review 2/5 patients that had a documented diagnosis of ED had a documented treatment option (40%). Chi-square analysis demonstrated a statistically significant in the total of patients offered treatment for ED ($p < 0.00$).

The fifth objective was to increase the number of patient charts with documentation of ED. This was measured by the IIEF-5 questionnaire found scanned in the patients EMRs. There were 89 patients (100%) found to have a questionnaire scanned in their charts, whether or not the patients were eligible for the pilot project. Pre implementation chart review found five of 50 patient charts with a documentation of ED, whereas post implementation found 53 of 71 patient's charts with a documented diagnosis of ED.

Chapter V: Summary, Discussion, Implications

Congruence with Theoretical Framework

This pilot project demonstrated congruence with Rogers' Diffusion of Innovation theoretical framework. Rogers defines innovation, the first of his four main elements of diffusion as: "An innovation is an idea, practice, or project that is perceived as new by an individual or other unit of adoption" (Rogers 2003, p.12). An innovation may not be new, as in the IIEF-5, but to the providers, the IIEF-5 questionnaire was new to them and their clinics, as neither had heard about the IIEF-5 prior to the investigator approaching them for permission to do the pilot project in their clinic, therefore their perception was that it is a new innovation. According to Rogers (2003) consequences are deviations that happen to an entity or a social system, as an outcome of the acceptance or dismissal of an innovation. The innovation for this pilot project involved a practice change to incorporate the IIEF-5 questionnaire into the clinics for diagnosis and documentation of treatment options offered in two clinics in southern West Virginia. The providers chose to accept this innovation and adopt it for their clinics. To diminish the ambiguity of accepting the innovation, entities should be well-versed about its benefits and weaknesses to make them cognizant of the consequences. The providers found over the six-week pilot project period, that the innovation to incorporate the IIEF-5 questionnaire into the clinics for diagnosis of ED was of great benefit to their patients. Moreover, the providers discovered that the addition of the IIEF-5 questionnaire into the patients EMR was worth the extra time, for accurate documentation of a diagnosis and discussion of ED as indicated by the score on the questionnaire, and of the treatment options offered. Communication is the second element and is the practice where the members generate and communicate evidence amongst the group to reach a collaborative understanding. This communication transpires via channels amid

sources. According to Rogers (2003), a source is an entity or an organization that creates a communication, whereas, a channel is the method by which a communication moves from the source to the beneficiary. Effectively communicating the new innovation to the providers or key stakeholders was vital to the success of this pilot project. Meeting one-on-one with the providers to inform them of what the pilot project entailed, their part in the pilot project, and answer any questions or concerns regarding the pilot project and following up with visits, phone calls, and educational materials helped to further ensure the success of the pilot project. The third element of the diffusion on innovation theory is time. A new innovation spreads across the social system over time. According to Rogers (2003) time is encompassed in diffusion in the innovation-decision process, the innovativeness of an entity or other measure of adoption, and an innovation's rate of adoption in a specified time period. Social system is the last element in the diffusion process. According to Rogers (2003) the social system is a group of interconnected components involved in shared problem solving to achieve a mutual goal.

Discussion

The goal of this pilot project was to evaluate the effectiveness of the International Index of Erectile Function (IIEF-5) questionnaire on the diagnosis and treatment of ED in southern West Virginia. This pilot project was an initial evaluation of a practice change at both clinics. Both physicians were receptive to the pilot project and excited about the end results that there were no challenges or issues. Providers from both clinics voice satisfaction in the use of and the results of the pilot project and have determined that they will continue to use the questionnaire for their patients. This pilot project will function as the underpinning for future projects in both clinics.

Utilization of the validated, internationally recognized IIEF-5 questionnaire in this pilot project gives evidence to the value of the tool in the clinic setting to measure prevalence and severity of ED. One of the objectives of this pilot project was that provider awareness relating to the use of the IIEF-5 questionnaire for ED would improve. Erectile function in this pilot project was determined on the patients' score to the IIEF-5 questionnaire given by the providers in two clinics in southern West Virginia. Providers at both of the clinics have found the IIEF-5 questionnaire to be a valuable, sensitive, and specific tool in the clinic. After using the questionnaire during the pilot project period and seeing the results, the providers believe that this tool will be an asset to their clinics and that their patients will benefit greatly from its use. The questionnaire was found to be a simple and easy method for assessing and measuring ED. The ease at which the severity of ED could be established using the IIEF-5, helped support the use of the questionnaire.

The evidence collected in this pilot project supports the use of a validated questionnaire for the diagnostic assessment of ED. Evidence collected in the four clinical practice guidelines (Canadian Guidelines Towards Optimized Practice [TOP], 2010; Hatzimouratidis et al., 2010; Kimoto et al., 2008; Montague et al., 2009), four systematic reviews (Cappelleri & Rosen, 2005; Markou et al., 2004; Ruiz-Aragon et al. 2010; Tsertsvadze et al., 2009), two RCTs (Hwang et al., 2010; Shabsigh et al., 2010), and the two prospective studies (Hakim et al., 2002; Ponholzer et al., 2005) also supported the use of a validated questionnaire for the diagnostic assessment of ED.

According to a study completed by Hader et al. (2007) there were numerous major influences that the physicians saw as a necessity for them to adopt an innovation. First, the physicians needed to know that the guidelines exist. Second, the need for change must be

apparent. Third, the physicians needed to know that the innovation would have positive results and have no risk for their patients. Finally, the patients and their families must want the change. During this pilot project, once the providers realized the IIEF-5 questionnaire existed, they were willing to use it in their clinics. The providers supported the use of the validated IIEF-5 questionnaire and saw positive patient outcomes with no augmented risk for continuation of the use of the IIEF-5 questionnaire. Lastly, with 89 of the 250 patients seen during the pilot project period completing the questionnaire, the providers realize that their patients are accepting of change. This pilot project supports provider practice change as found in the literature with the necessities physicians are seeking in order to adopt an innovation.

Barriers to the project. ED in its self is a potential barrier - simply because of the embarrassment of the topic. According to Baldwin et al. (2003) the most common reason cited for the under-reporting of ED was embarrassment. Patients do not want to bring up the topic and wish that their primary care physician would and eliminate the need for them to do so (Baldwin et al., 2003). Another barrier could be that the patients just do not want to fill out another form or just do not want to complete the questionnaire. Other than the patients willingness to participate in the pilot project, another barrier could be the providers not wanting to take the time to implement the questionnaire and then to follow-up with the results or treatment options associated with ED. A potential barrier to the project might be if the providers allow their nurse to present and explain the IIEF-5 to the patients. If the patient feels this is an embarrassing subject, they may not want to discuss it with anyone but the provider. Obtaining IRB approval was a potential barrier, as patient consent was required.

Limitations of the project. The sample size (n=71) was a limitation to this pilot project. Another limitation was the study time frame. Expanding the implementation period from six-

weeks to three to six months would give the Project Leader time to evaluate the treatment options offered to the patients. The additional time would also allow the investigator to evaluate whether the physicians were going to adopt the practice change. Another limitation to this pilot project is that the national guidelines only support the use of a validated questionnaire, instead of making the use of the questionnaire a recommendation. Adding the use of a validated questionnaire to the recommendations of the guidelines would help to ensure the success of future endeavors. An additional limitation was that the post implementation patients were not randomly selected. Finally, a limitation to the project was that the pre and post implementation age groups were skewed. In the pre implementation group, there were 23/50 (46%) patients 40 - 50 years of age, while the post implementation group had 5/71(7%) patients 40 – 50 years of age with a diagnosis of ED.

Implications for Practice. The overall mission of both clinics is to provide quality professional healthcare, to promote health, prevent illness, and to empower patients to manage their health. Both clinics are dedicated to improving the quality of health care and health outcomes through providing timely, innovative, and compassionate care. With the prevalence of ED, utilization of the IIEF-5 in the clinic would open the door to men specifically pursuing help for ED. In addition, because of what ED does to the interpersonal relationships having an avenue to get help for ED could potentially help the couple's relationship, thereby reducing stress, and depression. The use of the IIEF-5 questionnaire for all initial new patients' visits, as well as current male patient's yearly exam would help to ensure that the providers are covering all aspect of the health exam. This may let the providers discover other issues such as early cardiovascular disease.

This pilot project functioned to improve assessment, diagnosis, and documentation of treatment plans for patients with ED. The pilot project utilized established evidence-based clinical guidelines and the validated IIEF-5 questionnaire to diagnose ED to enable healthcare providers to acknowledge the significance of diagnosing and treating ED in patients for earlier recognition and prevention, not only for ED but for potential cardiovascular disease. Informing and educating the providers on the IIEF-5 and the use of the questionnaire has increased awareness in ED, of the sensitivity of the subject, as well as an increase in awareness of ED among their patients.

ED and potential cardiovascular disease may be reduced by utilizing the IIEF-5 questionnaire as part of the clinics health maintenance routine. Educating the afflicted patient with information on lifestyle changes can potentially reduce health care issues and provide a better quality of life.

Implication for Doctorate of Nursing Practice (DNP). This pilot project incorporated the DNP essentials, utilized scientific underpinning, and evidence-based practice to promote and augment health care. While increasing the providers understanding and awareness of ED, this pilot project helped to reduce the inefficiency in under diagnosing, reporting, and treating patients afflicted with this condition. Utilizing the IIEF-5 questionnaire in the clinics will allow the providers to identify patients with ED, document a diagnosis of ED, and offer treatment options based on evidence-based research and clinical practice guidelines. Establishing a provider practice change was the core of this pilot project. Increasing concerted relationships with the providers will garner continual sponsorship in resolving this healthcare problem. Following the evidence-based research and clinical practice guidelines will promote healthy

outcomes and prevention of chronic illnesses, thus in direct correlation future financial impact will be diminished.

Recommendations

Continuing education on the clinical practice guidelines and evidence-based research on ED may help prevent cardiovascular disease. This pilot project opens the door to future endeavors in the area of ED in southern West Virginia and elsewhere in the country. One recommendation would be to extend the project out for a three, six, or twelve month period. In the clinic it would be prudent to use the IIEF-5 questionnaire during the male patient's yearly health exam and increase the age range to screen males 30 to 80 years of age, regardless of a previous diagnosis. With the possible correlation between ED and cardiovascular disease, a recommendation is to longitudinally follow all the patients in this pilot study with a diagnosis of ED, to evaluate their future cardiovascular disorders. Using the IIEF-5 questionnaire as follow-up for the evaluation of treatment is another recommendation for the clinics. With the use of the EMR systems it would be fairly easy to run a data search categorizing: male patient, 30 to 80 years of age, and with an ICD-9 code for ED, therefore, a recommendation would be to search the clinics complete database instead of a random selection.

Conclusion

In conclusion, this pilot project provides estimates on the prevalence of ED utilizing the IIEF-5 questionnaire in two clinics in southern West Virginia. As previously discussed in this paper, the IIEF-5 questionnaire had been found to be effective in improving diagnosis, documentation, and treatment of ED (Feldman et al., 1994) but was not previously used in primary care clinics. Consequently, this intervention was utilized to evaluate the effectiveness of the IIEF-5 questionnaire on the diagnosis and treatment of ED in these clinics. The objectives

were clearly stated and the instruments used to gauge the objectives are described in the literature as valid and reliable.

The findings from this pilot project support provider behavior change for the improved assessment and diagnosing of ED, as well as the documentation of treatment options offered. Assessment for ED, using the IIEF-5, should be completed on all male patients, 40 to 70 years of age with specific co-morbidities. Primary care providers should be screening their patients as effective treatment for ED is obtainable and because ED has been related to cardiovascular disease. This pilot project has built a foundation for future research on evaluation of provider behavior change and utilization of the validated IIEF-5 questionnaire for assessment of ED and documentation of treatment option. ED is a preventable health issue in males which is presently under estimated and under reported by patients, as well as under diagnosed and treated by providers.

References

Appraisal of Guidelines Research & Evaluation Research Trust (2006). *AGREE Appraisal Tool*.

Published 2006. Retrieved from [http://www.agreetrust.org/docs/AGREE Instrument English.pdf/](http://www.agreetrust.org/docs/AGREE_Instrument_English.pdf/)

Aytac, I. A., McKinlay, J. B., & Krane, R. J. (1999). The likely worldwide increase in erectile dysfunction between 1995 and 2025 and some possible policy consequences. *British Journal of Urology*, 84(1): 50-56. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/10444124>

Azuri, J., Gelerenter, R., Dushinat, M., Friedman, N., & Kokia, E. (2009). Raising awareness for the diagnosis and treatment of erectile dysfunction in patients with high risk to develop ED. *International Journal of Impotence Research*, 21, 249-252. Retrieved from www.nature.com

Baldwin, K., Ginsberg, P., & Harkaway, R.C. (2003). Under reporting of erectile dysfunction among men with unrelated urologic conditions. *International Journal of Impotence Research*, 15, 87-89. Retrieved from www.nature.com

Bayer Pharmaceuticals (2009). Annual report 2009: Management report-performance by subgroup, segment, and region. Bayer HealthCare. Retrieved from <http://www.annualreport2009.bayer.com/en/Bayer-Annual-Report-2009.pdf>

Canadian Guidelines Towards Optimized Practice [TOP]. (2010). *Guideline for the investigation and management of erectile dysfunction*. Revised Feb. 2010. Retrieved from www.topalbertadoctors.org/

- Cappelleri, J.C., & Rosen, R.C. (2005). The Sexual Health Inventory for Men (SHIM): a 5-year review of research and clinical experience. *International Journal of Impotence Research*, 17, 307–319. Retrieved from <http://www.nature.com/doifinder/10.1038/sj.ijir/17, 307-319>.
- Feldman, H.A., Goldstein, I., Hatzichristou, D.G., Krane, R.J., & McKinlay, J.B. (1994). Impotence and its medical and psychosocial correlates: Results of the Massachusetts Male Aging Study. *The Journal of Urology*, 151, 54-61.
- Greenhalgh, T., Robert, G., Macfarlane, F., Bate, P., & Kyriakidou, O. (2004). Diffusion of innovations in service organizations: Systematic review and recommendations. *The Milbank Quarterly*, 82(4), 581-629.
- Hader, J.M., White, R., Lewis, S., Foreman, J.L.B., McDonald, P.W., & Thompson, L.G. (2007). Doctors' views of clinical practice guidelines: A qualitative exploration using innovation theory. *Journal of Evaluation in Clinical Practice*, 13, 601-606.
- Hakim, J., Subit, M., Kandzari, S., & Zaslau, S. (2002). Quality control in the screening of erectile dysfunction - Results of a survey. *Urology*, 60(1), 125-129. Retrieved from <http://web.ebscohost.com/www.libproxy.wvu.edu/ehost/>
- Hatzimouratidis, K., Amar, E., Eardley, I., Giuliano, F., Hatzichristou, D., Montorsi, F., ... Wespes, E. (2010). Guidelines on male sexual dysfunction: Erectile dysfunction and premature ejaculation. Available: <http://www.europeanurology.com/>
- Hwang, T., Tsai, T., Lin, Y., Chiang, H., & Chang, L.S. (2010). A survey of erectile dysfunction in Taiwan: Use of the erection hardness score and quality of erection questionnaire. *Journal of Sexual Medicine*, 7, 2817–2824. Retrieved <http://web.ebscohost.com/ehost/pdfviewer/>

- Johannes, C.B., Araujo, A.B., Feldman, H.A., Derby, C.A., Kleinman, K.P., & McKinlay, J.B. (2000): Incidence of erectile dysfunction in men 40 to 69 years old: Longitudinal results from the Massachusetts Male Aging Study. *Journal of Urology*, 163: 460.
- Jonas, U. (2001). The history of erectile dysfunction management. *International Journal of Impotence Research*, 13(3), S3–S7. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/>
- Kimoto, Y., Nagao, K., Sasaki, H., Marumo, K., Takahashi, Y., Nishi, S., ... Futamatsu, M. (2008). JSSM Guidelines for ED. *International Journal of Urology*, 15, 564-576. doi10.1111/j.1442-2042.2008.02060.x
- Litwin, M.S., & Saigal, C.S. (2007). Introduction in: Litwin, M.S., Saigal, C.S. *Urologic Diseases in America*, HS, PHS, NIH, NIDDK. Washington, D.C.: GPO; 2007. NIH publication 07–5512:3–7. Retrieved from <http://health.nih.gov/>
- MacDiarmid, S.A., Talmage, T.C., Holmes, T.M., Robert, P.R., & Doyle, R.B. (1998). An assessment of the comprehension of the American Urological Association symptom index. *The Journal of Urology*, 159(3), 873-874.
- Markou, S., Perimenis, P., Gyftopoulos, K., Athanasopoulos, A., & Barbalias, G. (2004). Vardenafil (Levitra) for ED: A systematic review and meta-analysis of clinical trial reports. *International Journal of Impotence Research*, 16, 470-478. Retrieved from www.nature.com
- Men's Health (2011, Jan 15). Re: Statistics of erectile dysfunction in US [Web log comment]. Retrieved from <http://www.medexpressrx.com>

Montague, D.K., Jarow, J.P., Broderick, G.A., Dmochowski, R.R., Heaton, J.P., Lue, T.F., ...

Aquino, K.H. (2009). *The management of ED*. Retrieved from

<http://www.auanet.org/content/guidelines/>

National Institute of Health. (1993). NIH consensus conference. Impotence. NIH consensus development panel on impotence. *JAMA*, 270 (1), 83-90. Retrieved from

<http://www.ncbi.nlm.nih.gov/pubmed/8510302>

Pfizer (2009). Pfizer reports fourth quarter and full-year 2008 results and 2009 financial guidance. Retrieved from <http://media.pfizer.com/files/investors/presentations/>

Ponholzer, A., Temml, C., Mock, K., Marszalek, M., Obermayr, R., & Madersbacher, S. (2005).

Prevalence and risk factors for erectile dysfunction in 2,869 men using a validated questionnaire. *European Urology*, 47, 80-86. Retrieved from

<http://www.sciencedirect.com.www.libproxy.wvu.edu/>

Qaseem, A., Snow, V., Denberg, T., Casey, D., Jr., Forciea, M. A., Owens, D., & Shekelle, P.

(2009). Hormonal testing and pharmacological treatment of erectile dysfunction: A clinical practice guideline from the American College of Physicians. *Annals of Internal Medicine*, 151, 639-649. Retrieved from <http://www.annals.org>

Ramanathan, R., Mulhall, J., Rao, S., Leung, R., Martinez Salamanca, J. I., Mandhani, A., &

Tewari, A. (2007). Predictive correlation between the International Index of Erectile Function (IIEF-5) and Sexual Health Inventory for Men (SHIM): Implications for calculating a derived SHIM for clinical use. *Journal of Sexual Medicine*, 4, 1336-1344.

Rogers, E. M. (2003). *Diffusion of Innovations*. 5th edition. New York: Free press; 2003.

- Rosen, R., Cappelleri, J., & Gendrano, N. (2002). The International Index of Erectile Function (IIEF-5): a state-of-the-science review. *International Journal of Impotence Research*, 14, 226-244.
- Ruiz-Aragon, J., Marquez-Pelaez, S., & Romero, L.G. (2010). Erectile dysfunction in patients with prostate cancer who have undergone surgery: Systematic review of literature. *Actas Urologicas Espanolas*, 34(8), 677-685. Retrieved from www.elsevier.es/actasuro
- Rutchik, S.D., Baudiere, M., Wade, M., Sullivan, G., Rayford, W., & Goodman, J. (2000). Practice patterns in the diagnosis and treatment of erectile dysfunction among family practice physicians. *Urology*, 57, 146-150.
- Scottish Intercollegiate Guidelines Network (2008). *SIGN 50: A guideline developer's handbook*. Retrieved from: www.sign.ac.uk/methodology/checklist.html/
- Shabsigh, R., Kaufman, J., Magee, M., Creanga, D., Russell, D., & Budhwani, M. (2010). Lack of awareness of erectile dysfunction in many men with risk factors for ED. *BMC Urology*, 10, 18. Retrieved from <http://www.biomedcentral.com/1471-2490/10/18>
- Tsertsvadze, A., Fink, H., Yazdi, F., MacDonald, R., Bella, A., Ansari, M., ... Wilt, T. (2009). Oral phosphodiesterase-5 inhibitors and hormonal treatments for ED: A systematic review and meta-analysis. *Annals of Internal Medicine*, 15, 650-661. Retrieved from <http://www.annals.org>
- United States Department of Health and Human Services, Centers for Disease Control and Prevention, and National Center for Health Statistics (2001-2002). *National Health and Nutrition Examination Survey (NHANES) (2001-2002)*. Retrieved from http://www.cdc.gov/nchs/data/nhanes/nhanes_01_02/

Yamada, T., Hara, K., Umematsu, H., Suzuki, R., & Kadowaki, T. (2012). Erectile dysfunction and cardiovascular events in diabetic men: A meta-analysis of observational studies.

Public Library of Science ONE. 7(9), e43673. doi: 10.1371/journal.pone.0043673

Figure 1

Five Stages in the Decision Innovation Process

Source of information: Rogers (2003)

Appendix A: IIEF-5

No. _____

International Index of Erectile Function 5 (IIEF-5)/ SHIM

Each question has several possible responses. Circle the number of the response that best describes your own situation. Please be sure that you select one and only one for each question.

OVER THE PAST 6 MONTHS:

1. How do you rate your **confidence** that you could get and keep an **erection**?

None	Very Low	Low	Low Moderate	High	Very High
0	1	2	3	4	5

2. When you had **erections** with sexual stimulation, **how often** were your **erections** hard enough for penetration (entering your partner)?

No sexual activity	Almost never or never	A few times (much less than 1/2 the time)	Sometimes (about 1/2 the time)	Most times (much more than 1/2 the time)	Almost always or always
0	1	2	3	4	5

3. During sexual intercourse, **how often** were you able to maintain your **erection** after you had penetrated (entered) your partner?

Did not attempt intercourse	Almost never or never	A few times (much less than 1/2 the time)	Sometimes (about 1/2 the time)	Most times (much more than 1/2 the time)	Almost always or always
0	1	2	3	4	5

4. During sexual intercourse, **how difficult** was it to maintain your **erection** to completion of intercourse?

Did not attempt intercourse	Almost always or always	Most times (much more than 1/2 the time)	Sometimes (about 1/2 the time)	A few times (much less than 1/2 the time)	Almost never or never
0	1	2	3	4	5

5. When you attempted sexual intercourse, **how often** was it satisfactory for you?

Did not attempt intercourse	Almost never or never	A few times (much less than 1/2 the time)	Sometimes (about 1/2 the time)	Most times (much more than 1/2 the time)	Almost always or always
0	1	2	3	4	5

Appendix A: cont.

SHIM Questionnaire (Sexual Health Inventory for Men) or IIEF-5 Date: _____

IIEF-5 Questionnaire Number _____

Patient Score: _____

The Sexual Health Inventory for Men further classifies Erectile Dysfunction (ED) severity with the following:

0-7 Severe ED

8-11 Moderate ED

12-16 Mild to Moderate ED

17-21 Mild ED

22-25 Normal

***Was the IIEF-5 discussed with the patient?** ☐ YES ☐ NO

Was the score discussed with the patient? ☐ YES ☐ NO

Were treatment options offered? ☐ YES ☐ NO

Was a follow-up appointment scheduled? ☐ YES ☐ NO

With Permission - Source: Rosen RC, Riley A, Wagner G, Osterloh IH, Kirkpatrick J, Mishra A. The international index of erectile function (IIEF) a multidimensional scale for assessment of ED. Urology. 1997 Jun; 49(6):822-30. Copyright 1997 by Elsevier Science, Inc.

Appendix B: Letter of Approval

4/9/2012 3:56 PM FROM: BITS TO: +1 (304) 3471346 PAGE: 002 OF 002

04/09/2012 11:31 34/1346

NURSING

PAGE 02

March 28, 2012

Susan McCrone, PhD
WVU School of Nursing
PO Box 9630
Morgantown, WV 26506

Re: Capstone project for Evelyn Martin, DNP Candidate

Dear Dr. McCrone,

This letter is to support Evelyn Martin's Capstone project for her DNP degree. I have agreed to let Evelyn Martin, MSN, FNP-BC conduct her Capstone project (The evaluation of a pilot project utilizing the International Index of Erectile Function (IIEF) questionnaire into the patient's chart, to increase the diagnosis and documentation of treatment options for ED when indicated by the score on the questionnaire) at our clinic. We will be happy to assist Mrs. Martin and will provide the support necessary to accomplish this project.

Sincerely,

Kelly Pisenbarger, MD

Appendix B: Letter of Approval cont.

4/9/2012 3:56 PM FROM: FITS TO: +1 (304) 3471346 PAGE: 001 OF 002

confidential
fax

Kelly M Pittsenbarger M.D.

314 George St.
Beckley Wv 25801
304-255-2426 (Office)
304-253-3715 (Fax)

To: ATTN: Evelyn Martin
Fax Number: +1 (304) 3471346

From: Diana Walker
Fax Number:
Business Phone:
Home Phone:

Pages: 2
Date/Time: 4/9/2012 3:56:30 PM
Subject: RE: Capstone project For Evelyn Martin, DNP Candidate

Appendix C: Letter of Approval

Elizabeth L. Brown, M.D.
INTERNAL MEDICINE

401 DIVISION STREET
SUITE 302
SOUTH CHARLESTON, WV 25309
TELEPHONE: (304) 414-2140
FAX: (304) 414-2149

March 28, 2012

Susan McCrone, PhD
WVU School of Nursing
PO Box 9630
Morgantown, WV 26506

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Sincerely,

A handwritten signature in black ink, appearing to read "EL Brown".

Elizabeth L. Brown, MD

Appendix D: Demographics/Cover page

No. _____

This is a project to look at adding a questionnaire to this practice to see if it will help you and your doctor find out if you have ED. This will also let you discuss the different treatment choices with your doctor, if you want to. I appreciate your time in filling out the following questions. In completing this project, I hope that you and your doctor will be able to better meet your needs. The information collected here will remain private. Please **DO NOT** put your name on any part of the questionnaire.

- Age: ☐ <30 yrs. ☐ 31 – 40yrs. ☐ 41 – 50 yrs.
 ☐ 51 – 60 yrs. ☐ 61 – 70 yrs. ☐ 71 – 80 yrs.
- Race: ☐ White ☐ Asian ☐ African American
- Marital status: ☐ married ☐ divorced ☐ unmarried living alone
 ☐ unmarried and living with someone

Place an X in the box if your doctor told you that you have any of the following - Please check all that apply.

Diabetes	☐	Thyroid problems	☐	Multiple sclerosis	☐
Heart disease	☐	Depression	☐	Currently on nitrates	☐
Hypertension	☐	Decreased sex drive	☐	Spina bifida	☐
Hyperlipidemia	☐	Prostate surgery	☐	Prostate problems	☐
Kidney Disease	☐	Smoking/Tobacco	☐	Spinal cord injury	☐
Peripheral vascular	☐	Alcohol	☐	Penile trauma	☐

Appendix E: Data Collection Form

Patient number: _____

Age: _____

Medications: _____

Co-morbidities and Risk Factors: _____

Does the patient have a documented diagnosis of ED: Yes No Unknown

Diagnostic laboratory tests for the diagnosis of ED (mark with X when completed):

Liver hepatic function panel Lipid profile Thyroid function study

Urine analysis Creatinine Glucose level

Prostate specific antigen (PSA) Complete blood count

Serum testosterone hormone level (free or total)

To assess pituitary function when the serum testosterone level is low:

Gonadotropin follicle stimulating hormone Gonadotropin luteinizing Serum prolactin

Are they on or do they use a treatment for ED:

If yes, what type of treatment: _____

If yes, what are the results: satisfactory unsatisfactory Unknown

Is there follow-up to evaluate treatment: Yes No

If yes, is it in an appropriate timeframe - 3 months: Yes No

If no, is there a documented reason why: Yes No

Did patient do recommended follow-up: Yes No Unknown

Is the patient satisfied with their current treatment? Yes No Unsure

Appendix F: Timeline

Appendix G: Budget

Financial		Cost
IIEF-5 questionnaire	(\$1.33423 = 1€) 300€ (\$400.27) to 600€ (\$800.54) per study with 50€ (\$66.71) to 250€ (\$333.56) per language	\$ 00.00
Physicians time	\$ 00.00	\$ 00.00
Power point for lunch and learn	\$ 55.00 NP time ½ hour each x 2	\$ 00.00
Space at clinics	\$ 00.00	\$ 00.00
Lunch for Education program	\$ 100.00	\$ 100.00
Christmas Baskets for clinic sites post implementation		\$ 42.29
Copies of Questionnaire	\$ 143.73 @ \$0.09 per page 500 copies 1 one-sided and 2 two-sided pages, pens, staples, staples, and labels from Staples	\$ 143.73
Gas for 4 trips to clinics – 696 miles @ 3.75 gallon	\$ 255.00	\$ 255.00
Medical assistant/nurse	\$ 93.30 (donated by the clinics)	\$ 00.00

Total Pilot Project Cost \$541.02

Faculty Grant in the amount of \$500.00 was obtained for this DNP project, therefore total cost to the investigator was: \$ 41.02

Appendix H: Log Sheet

	NAME	DOB	IIEF-5 NO.
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	NAME	DOB	IIEF-5 NO.
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Appendix I: Content Outline

Summary of Education Training for the Providers on the Evaluation of the Effectiveness of the

International Index of Erectile Function (IIEF-5) Questionnaire

ED

Also known as “impotency”

Defined as the failure to reach and/or maintain an erection for satisfactory sexual performance

Most common sexual disorder in men

Anxiety, low self-esteem, low self-confidence, and difficulty with interpersonal relationships

Significance of Problem

ED affects 52% or approximately 30 million men in the United States between 40 and 70 years of age

ED is growing from 5% among men age 40 to 15% among those 70 years of age

Conservative worldwide projection of ED is 322 million cases by 2025

Relevant databases

National Guideline Clearinghouse (NGC)

Cochrane Library

Cumulative Index of Nursing and Allied Health Literature (CINAHL)

PubMed

Science Direct

Appendix I: Content Outline

Academic Search Complete

Google Scholar

Literature search

Key words: Erectile function, International Index of Erectile Function (IIEF-5), erectile dysfunction, diagnosis, treatment, practice change, screening, evaluation, clinical setting, and provider behavior change

Search Strategy

Narrowed articles:

- Recent < 7 years old
- Human studies
- Peer reviewed journals
- Available in English

15 studies were reviewed for this project

Relevant Literature

Five clinical practice guidelines

Four systematic reviews

Three randomized controlled trials

Two prospective studies

Non-experimental descriptive study

National Benchmarks for ED

There have been no specific benchmarks developed for ED

Appendix I: Content Outline

Synthesis of the Literature

Evidence collected through the review of the 15 articles supports the use of a validated questionnaire for the diagnosis of ED

Evidence from all five clinical practice guidelines, two systematic reviews, and one RCT support the use of the PDE-5 inhibitors for the treatment of ED as first line therapy

Synthesis of the Literature - Gaps

Gaps exist in the evidence about treatment specific agents and long-term consistency of the PDE-5 inhibitors over time

While four of the clinical practice guidelines support the use of a validated questionnaire, only one includes a validated questionnaire as a recommendation

Main Goal of the Project

To evaluate a pilot project to incorporate the IIEF-5 questionnaire into the patient's chart to increase the diagnosis and documentation of treatment options for ED when indicated by the score on the questionnaire

PICOT

Does provider education and the use of the IIEF-5 questionnaire increase diagnosis of ED and documentation of treatment options, in southern West Virginia?

Hypotheses

The use of the IIEF-5 questionnaire in the clinical practice will increase the diagnosis of ED

Appendix I: Content Outline

The use of the IIEF-5 questionnaire in the clinical setting will increase the documentation of the discussion of treatment options for men with ED

To orient the physicians and staff at two sites on the use of the IIEF-5 questionnaire between October 15, 2012 and November 1, 2012

To evaluate a baseline number of patients with a diagnosis of ED in each clinic by doing a pre intervention chart review of 50 randomly selected male patient charts between October 15, 2012 and November 1, 2012

Objectives

To determine the number of patients with ED in post intervention randomized samples by September 30, 2012

To evaluate the inclusion of the IIEF-5 questionnaire in the medical record for every male patient > 18 years of age during the eight-week pilot project

To have an increase in documentation of discussion and treatment options offered to patients with ED from baseline to post incorporation of the questionnaire by 10%

Clinical Site

Dr. Elizabeth L. Brown – General Internist

Private practice in Charleston, West Virginia

Dr. Kelly Pitsenbarger – Family Practice

Private practice in Beckley, West Virginia

References Provided on Request

Appendix K: PowerPoint Presentation (available as a separate download, in full)