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**UTILIZATION OF SIMULATION TO TEACH PELVIC EXAMINATION  
SKILLS TO MEDICAL STUDENTS: IMPLICATIONS FOR MEDICAL  
EDUCATION**

A dissertation submitted in partial fulfillment of the requirements for the degree of Ph.D.  
at Virginia Commonwealth University.

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## Abstract

### **UTILIZATION OF SIMULATON TO TEACH PELVIC EXAMINATON SKILLS TO MEDICAL STUDENTS: IMPLICATIONS FOR MEDICAL EDUCATION**

By Brenda Lynn Seago, PhD

A Dissertation submitted in partial fulfillment of the requirements for the degree of PhD at  
Virginia Commonwealth University.

Virginia Commonwealth University, 2010

Major Director: Carl F. Ameringer, PhD, JD

Professor, L. Douglas Wilder School of Government and Public Affairs

Medical education is changing. Physicians have less time for teaching clinical skills and for direct observation of medical students, due to sicker patients in the hospital, shorter hospital stays, competing demands of research and patient care, and implementation of the eighty hour work week for residents. The consumer movement increased awareness of medical errors, patient safety and quality of healthcare.

Teaching the pelvic examination is ethically complex. Questions have arisen about medical students learning to conduct the pelvic examination on real patients. This study utilizes the pelvic examination simulator and genital teaching associates (GTAs) to teach pelvic exam skills to optimize limited resources, as well as address safety and ethical concerns.

The purpose of the study was to provide medical students with more practice in pelvic examination skills, to test a pelvic examination simulator, and to explore a new model for teaching pelvic examination skills to second year medical students.

After IRB approval, one hundred sixty eight second year medical students at Virginia Commonwealth University School of Medicine participated in the study. A two-armed trial design provided all medical students with pelvic exam training on the pelvic exam simulator and genital teaching associate. Data were gathered via an experience and demographic questionnaire, blood pressure readings, the *Fear of Pelvic Examination Scale* scores and performance scores after the training. Data analysis consisted of descriptive statistics, paired and independent sample *t*-tests and the linear mixed model. Statistical tests determined the relationship between fear, blood pressure and performance.

The findings revealed that the GTA training group had significantly more fear than the pelvic exam simulator group and significantly higher performance scores than the simulator group. The gender analysis indicated that males had significantly more fear than females. Prior experience with pelvic exam simulators did not appear to reduce anxiety among medical students when first conducting pelvic exams with humans. Completion of

pelvic exam training with a GTA may reduce fear substantially and make later training with the pelvic exam simulator the optimal first experience. Use of simulation in medical education reduces ethical concerns, optimizes limited resources and reduces patient safety issues.

## CHAPTER 1: Introduction

### Background

Simulations have become an integral part of medical education at all levels (Issenberg et al., 1999, Gaba, 2000). At least five factors contribute to the increasing use of simulations in medical education: a. the inadequacy of traditional teaching methods; b. the emergence of new technologies for diagnosis and management; c. the need to measure professional competence; d. the need to prevent medical errors, promote patient safety, and facilitate team training; and e. the need for deliberate practice.<sup>1</sup>

Although simulators have been used for many years in a variety of settings, data on their efficacy are still emerging. Research indicates there is potential for simulation technologies to improve physician training and assessment, with a resultant positive impact on patient safety and health care outcomes. The *Agency for Healthcare Research and Quality Evidence Report* suggests that simulation training is effective, especially for psychomotor and communication skills, but that the strength of the evidence is low “due to the small number of appropriate studies and scarcity of quantitative data.” (AHRQ, 2001) Many studies contain a narrow focus on a single medical specialty or a single simulation method to quantify clinical competence, a persistent problem in medical education

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<sup>1</sup> **Deliberate practice** refers to a form of training that consists of focused, grueling, repetitive practice in which the subject continuously monitors his or her performance, and subsequently corrects, experiments, and reacts to immediate and constant feedback, with the aim of steady and consistent improvement. It is generally accepted that this form of training calls for approximately 10,000 hours of concentrated effort if one is to achieve the optimum level of expertise.

research. In another review, the Best Evidence Medical Education (BEME) collaboration supported the use of simulation technology, focusing on high-fidelity medical simulations under specific conditions. The BEME review called for increased rigor in original simulation-based medical education research and improved journal reporting conventions (Issenberg et al., 2005). A more recent report discussed the “scope of simulation-based healthcare education,” pointing out that the best simulation-based medical education cumulatively utilizes simulation technology, teachers prepared to use the technology to maximum educational advantage and curriculum integration. The report argued that the major flaws in current simulation-based medical education stem from a lack of prepared teachers and curriculum isolation, not from technological problems or deficits (Issenberg, 2006).

#### Problem and Study Significance

The practice of teaching pelvic examinations to medical students in the clinical setting is ethically complex and controversial. Patients may be vulnerable and obtaining informed consent can be difficult. Coldicott et al. (2003), in a discussion of the ethics of intimate examinations, argue that it is not easy to balance ethical duties and educational requirements; students must learn, but patients must be protected. Setting aside the question of ethics, there are educational limitations to teaching the pelvic exam with actual patients. While patients can give feedback on their own experience (such as discomfort, pain) they have not been trained to give feedback on technique. Even an instructor observing a student conducting a pelvic examination does not know what internal

structures have been palpated during the bimanual part of the exam. Given the ethical dilemmas and teaching limitations, other approaches to instruction will be explored, including standardized patients (in this case, genital teaching associates) and simulators. Using simulation to teach the pelvic exam has the potential to optimize limited resources, address ethical concerns, and reduce anxiety and provide valuable feedback to the student.

The current research builds on prior work by focusing on psychomotor skills, utilizing two simulation methods and integrating simulation into the curriculum. Also, it focuses on the utilization of simulation in pelvic examination skill development with both a mid-fidelity pelvic examination simulator and a genital teaching associate (GTA) integrated into the medical school curriculum. This research will add to the growing quantitative data in the field that seeks to evaluate the impact of simulation on quality and healthcare outcomes.

### Purpose of the Study

Before 2008, second year students in the School of Medicine at Virginia Commonwealth University had only one opportunity to learn and practice the pelvic examination with GTAs during the Foundations of Clinical Medicine (FCM) course. Although more extensive training occurs in the third year Obstetrics and Gynecology clerkship, many students are assigned to clerkships, such as Family Medicine and Internal Medicine, where pelvic examinations are conducted prior to receiving additional training. Thus, there was a desire for students to have more practice with pelvic examination before performing the exam on actual patients in their third year of medical school. This



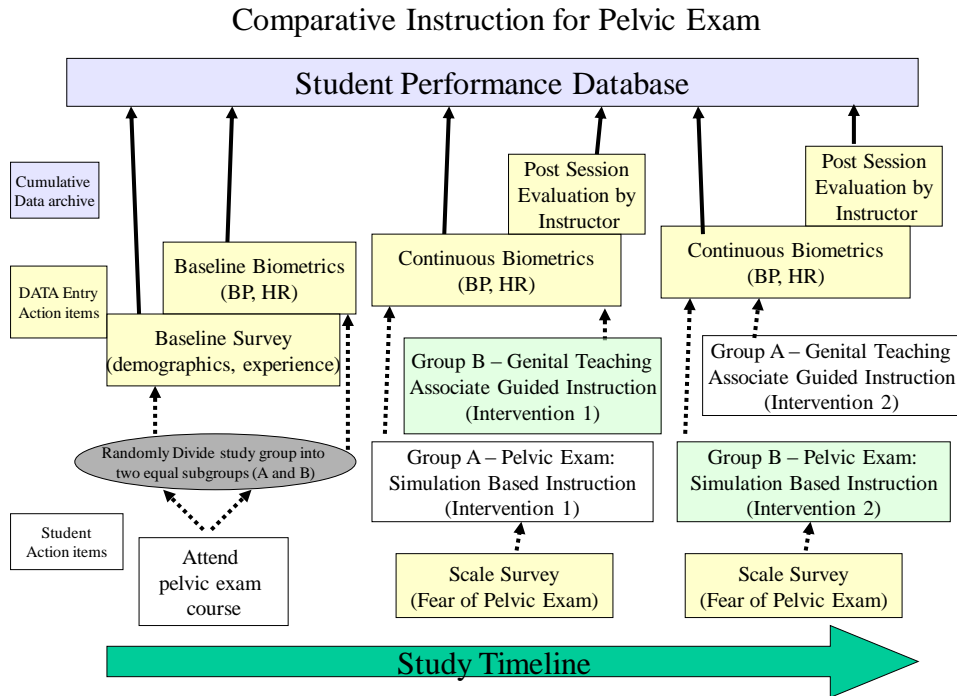
curricular need coincided with the availability of a new and previously untested pelvic examination simulator.

One of the goals of this study was to understand how combining a mechanical simulator workshop with the genital teaching associate workshop would address the need for additional practice. In addition, for many students the first pelvic examination workshop is a “rite of passage,” a first experience with female genitalia for some, as well as a new professional role for almost all students. This is a big transition for students and it is important to understand how the pelvic exam simulator would help the students either prepare for, or follow up on that experience.

FCM faculty discussed the advantages and disadvantages of pelvic exam simulator instruction vs. GTA instruction. Was one a better method of teaching the pelvic examination to medical students? Should the class be divided so that half of the students were taught using one method and the other half using the second method? The effectiveness of the GTA method of teaching the pelvic examination was documented (Holzman, 1977, Siwe, 2007, Livingstone, 1978, Muggah, 1988, Wanggren, 2005), but little was known about the effectiveness of teaching the pelvic examination to medical students using the pelvic exam simulator. Rather than utilize an unproven method with half the students, it was decided that all medical students would be exposed to both methods of teaching the pelvic examination. The medical students would benefit by learning the pelvic examination utilizing both methods because it would give them an additional opportunity to learn and practice the skill. This study therefore utilizes two

simulation methods: the standardized patient (in this case, a genital teaching associate (GTA)) and the pelvic exam simulator (SIM), in randomly assigned order, to teach the pelvic examination.

Currently, all medical students learn the pelvic examination on the pelvic exam simulator (SIM) and with the genital teaching associate (GTA) as a curriculum requirement for M2 Foundations of Clinical Medicine (FCM) course. The M2 class was randomized into two groups by computer. This was a two-armed trial design where one group received pelvic examination instruction on the simulator before receiving pelvic exam instruction from the genital teaching associate. The second group received pelvic exam instruction from the genital teaching associate before receiving pelvic exam instruction on the simulator. Students participating in the study completed the *Fear of Pelvic Examination Scale* before each instruction. An arrival blood pressure was taken before the study commenced, and additional blood pressure readings were taken during the pelvic exam instruction on the simulator and GTA. Students were evaluated on their performance as workshop participants. See conceptual model below.



**FIGURE 1: Comparative Instruction for Pelvic Examination**

A GTA, a specialized standardized patient, teaches the student how to conduct the exam on her. This study adds the pelvic exam simulator to the teaching and seeks to determine whether the order of performance (genital teaching associate, then simulator / simulator, then genital teaching associate) affects anxiety in, or readiness for performing a pelvic examination. In addition, the study will assess the student’s readiness to perform a pelvic examination before the actual workshop with the genital teaching associate. The research attempts to determine if measuring anxiety using blood pressure corresponds with student’s written assessment of their own fear of conducting the pelvic examination.

Identifying areas of anxiety, along with the additional teaching and practice of pelvic examination skills, may lead to safer and better outcomes for patients.

### Conceptual Framework

Outcomes objectives relate to potential outcome, or effects, of a curriculum beyond those delineated for learners. Outcomes might include health outcomes of patients. It is unrealistic to expect medical curricula to have easily measurable effects on quality of care and patient outcomes. Medical students, for example, may not have responsibility for patients until years after completion of a curriculum. However, medical curricula should be designed to have positive effects on quality of care and patient outcomes (Kern, 1998). Even if outcomes will be difficult or impossible to measure, the inclusion of outcome objectives in a curriculum will emphasize the ultimate aims of the curriculum and may influence the choice of curricular content and educational methods.

Figure 3 presents an outcomes framework (Moore et al., 2009) adapted for medical education that includes seven levels. The four levels of assessment developed by Miller (Miller, 1990) are embedded in the framework. Miller's Pyramid (Figure 2) depicts the ideal stages of development of a physician's clinical skills. The first three apply to medical students as well. First, a physician must *know* what to do (base of the pyramid) acquiring facts and interpreting them. At level two, the physician *knows how* to do something and describes it but may not be able to actually do it. At the next level, *shows how*, physicians are expected to demonstrate what they learned, usually under controlled conditions or in an educational setting. The final level in Miller's Pyramid is *does*, which

refers to practicing physicians actually using the acquired competence during encounters with their patients. This behavior is referred to as performance.

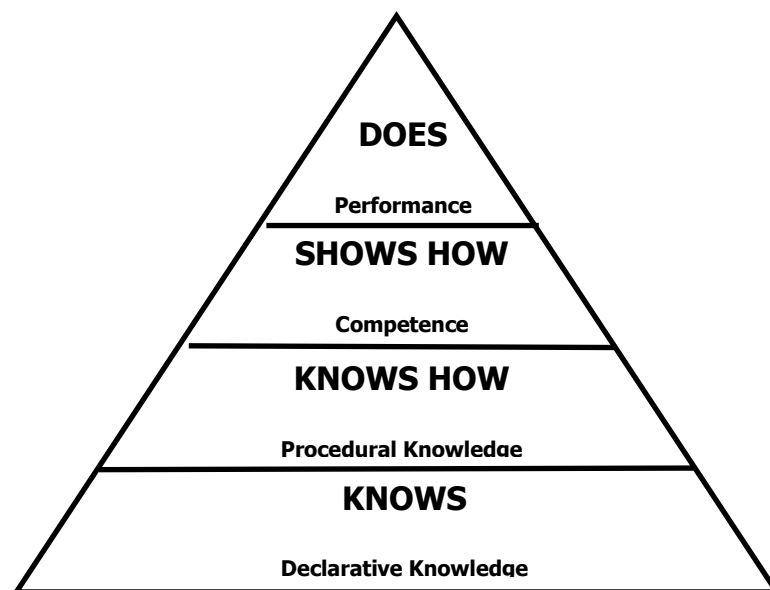


FIGURE 2: Miller's Pyramid (Miller, 1990)

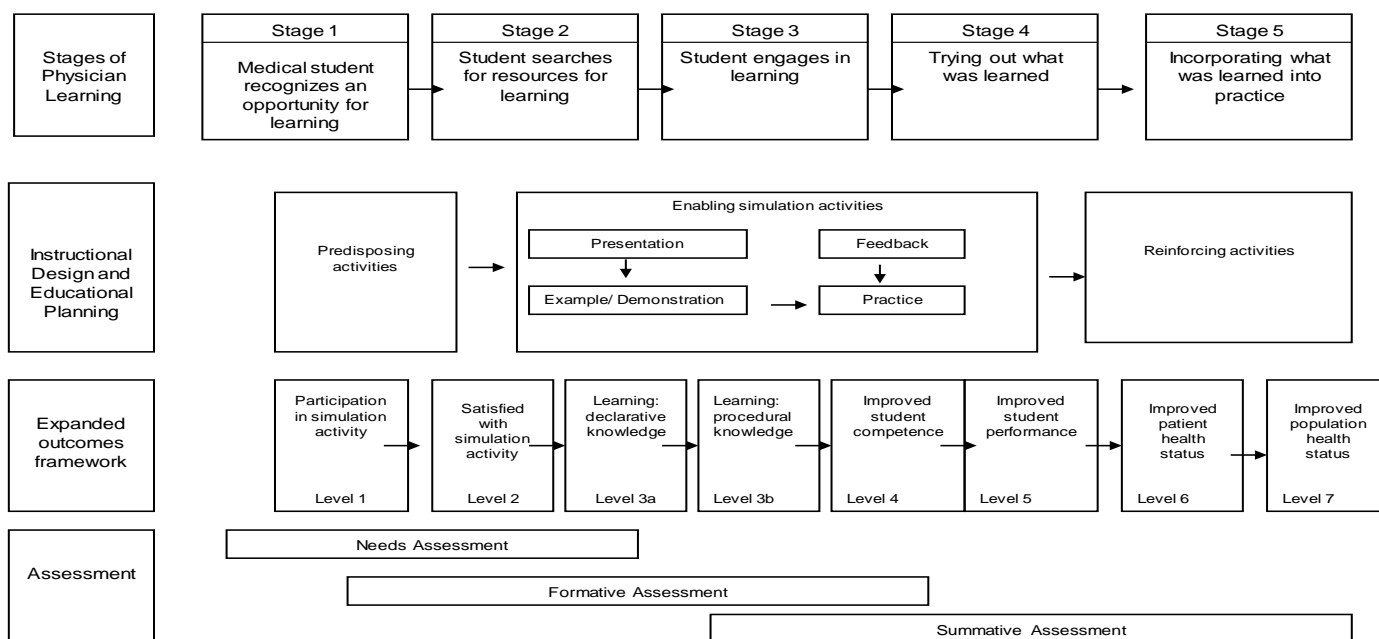
In the Seven Level Outcomes Framework (Figure 3 below), competence reflects what a physician is capable of doing; application in practice is performance. The current study addresses learning at levels 3A, 3B, and 4 as formative assessments, requiring ongoing feedback to trainees and faculty regarding their effectiveness as they proceed through instruction that leads to performance, the degree to which participants do what is intended of them in practice.

Outcomes Framework	Miller's Framework	Description	Source of Data
Participation LEVEL 1		The number of learners who participated in the educational activity	Attendance Records
Satisfaction LEVEL 2		The degree to which expectations of the participants were met regarding the setting and delivery of the educational activity were met	Questionnaires completed by attendees after an educational activity
Learning: Declarative Knowledge LEVEL 3A	Knows	The degree to which participants state <i>what</i> the educational activity intended them to know	Objective: Pre- and post-tests of knowledge Subjective: Self-report of knowledge gain
Learning: Procedural Knowledge LEVEL 3B	Knows how	The degree to which participants state <i>how</i> to do what the educational activity intended them to know how to do	Objective: Pre- and post-tests of knowledge Subjective: Self-report of knowledge gain
Competence LEVEL 4	Shows how	The degree to which participants <i>show</i> in an educational setting <i>how</i> to do what the educational activity intended them to be able to do	Objective: Observation in educational setting Subjective: Self-report of competence; intention to change
Performance LEVEL 5	Does	The degree to which participants <i>do</i> what the educational activity intended them to be able to do in their practices	Objective: Observation of performance in patient care setting; patient charts; administrative databases Subjective: Self-report of performance
Patient health LEVEL 6		The degree to which the health status of patients improves due to changes in the practice behavior of participants	Objective: Health status measures recorded in patient charts or administrative databases Subjective: Patient self-report of health status
Community health		The degree to which the health status of a community of	Objective: Epidemiological data and reports

LEVEL 7		patients changes due to changes in the practice behavior of participants	Subjective: Community self-report
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**FIGURE 3: Outcomes Framework for Assessing Learners and Evaluating Instructional Activities (Moore et al., 2009)**

Figure 4 represents a conceptual framework of an approach adapted for medical education for continuous planning and assessment focused on achieving desired outcomes (Moore et al., 2009). The framework is designed to show potential interfaces among all the components. The four horizontal layers in the conceptual framework are meant to be cyclical and interact vertically as well.



**FIGURE 4. Conceptual Framework of an Approach to Continuous Planning and Assessment (Moore et al., 2009).**

The 5 stages of physician learning (Moore, 2008) at the top of the figure were adapted for medical student learning. Students recognize the opportunity for learning by attending medical school and actively participating in learning activities designed for them. They do not necessarily seek out resources for learning, but may need to select between different resources to learn the same content. Next, the student actively engages in learning. The student may then have an opportunity to try out what was learned in a



clinical setting. In the last stage, as an intern or resident, he/she may incorporate what was learned into practice.

The next layer of the figure uses the predisposing-enabling-reinforcing instructional framework (Green and Kreuter, 1991) in planning an educational intervention to achieve desired results. This framework can be used to organize learning activities that are congruent with the 5-stage learning model. Examples of predisposing activities might include presentation of data describing current performance or even presentation of guidelines or standards of care. The enabling activities include *Presentation*, which provides a detailed step by step of a procedure, for example, and leads to a level 3A outcome (declarative knowledge: Miller's "what"), *Example/Demonstration*, which provides a hands-on demonstration of procedural technique and leads to a level 3B outcome (procedural knowledge: Miller's "how to"), *Practice*, such as psychomotor skills development for surgical and procedural development which leads to a level 4 outcome (competence: Miller's "shows how"), and *Feedback*, based on observation of practice, which also leads to a level 4 outcome (competence: Miller's "shows how"). Reinforcing activities for medical students might include assessments such as an Objective Structured Clinical Exam (OSCE).

Planning and assessment are continuously integrated and apply not only to participant learning throughout the learning activity, but to planning decisions throughout the implementation of a learning activity as well. A needs assessment should be completed so that learning activities are presented at the right level. Formative assessments measure

the progress of learners toward the goal of the learning activity. Summative assessments determine if desired results were achieved.

### Research Question

The study aim is to find out if there is a relationship between fear, performance, and blood pressure in simulation-based pelvic examination training in second year medical students. The research question then becomes, “How can knowledge of fear, performance, and blood pressure during simulation-based pelvic examination training reduce anxiety and increase student performance in order to help reduce medical errors and improve medical education?”

### Rationale and Significance

This research will further the understanding of pelvic examination skill development using simulation to improve quality and patient safety. The study will be useful to a wider audience interested in understanding anxiety for students who conduct pelvic exams. It will also provide valuable information regarding the order of performance (genital teaching associate, then simulator / simulator then genital teaching associate) and how it affects anxiety in, or readiness for, performing a pelvic exam.

The results of the study should impact the amount of practice students get with pelvic examination, and will positively affect their confidence and performance with patients. It should further lead to safer pelvic examinations for patients. At best, this research will provide important data on the efficacy of a new model in medical education which combines modalities where standardized patients, inanimate models, and medical

equipment are integrated to evaluate trainees' technical, communication, and other professional skills simultaneously (Kneebone, 2006).

### Health Policy

This research adds to the literature on health policy in two areas: medical education, including medical ethics, and quality/patient safety. The future of U.S. medical education depends upon the adoption of methods and technologies that produce improved training for students, better outcomes for patients and lower total costs. Medical schools responded slowly to past challenges, such as increases and decreases in demand for physicians, especially in primary care, and to calls for reform, such as integration among academic disciplines and between preclinical and clinical work. One observer characterized former efforts to modify medical education as "a history of reform without change, of repeated modifications of the medical school curriculum that alter only very slightly or not at all the experience of the critical participants, the students and teachers." (Bloom, 1988) Since Bloom's remark more than 20 years ago, the urgent and ongoing call for reform still resonates. Today, the introduction of new technology is forcing medical schools to make changes. The use of simulation technology to teach pelvic examination provides a new and powerful example of a significant reform to improve the quality of medical education.

Medical schools have a responsibility to deliver ethically informed training programs that develop doctors' skills and are acceptable to the patient volunteers who are a necessary part of medical education. Medical students clearly need to learn and acquire

essential clinical skills, but respecting patients has to be central to the educational curriculum. The patient must be regarded as the student's teacher and not only as a training tool. Past emphasis within curricula has focused on the number of exams performed rather than on competence, obtaining consent and empathetic communication with patients.

The second area where this research adds to the literature on health policy is quality/patient safety. Medical training must at some point use live patients to hone the skills of health professionals. There is also an obligation to provide optimal treatment and to ensure patients' safety and well-being. Simulation-based learning can help develop health professionals' knowledge, skills and attitudes while protecting patients from unnecessary risk.

New technologies and practices proposed in this paper will explore the use of simulation to increase quality in medical education, address ethical concerns and reduce costs. Simulation has the potential to increase the student's confidence and ability to perform proper techniques; ease anxiety and improve learning on the part of the medical student; and provide patients with a better and more thorough exam while reducing the possibility of physical or emotional pain or injury.

### Conclusion

Following the introduction, the paper proceeds with a review of the literature in Chapter Two, which surveys relevant research that considers: 1) simulation and medical education; 2) medical ethics and simulation; and 3) simulation and patient safety.

The chapter also includes background information on medical simulation, standardized patients, pelvic examination and methods employed to teach pelvic examination skills to medical students.

Chapter Three contains the methodology for the research, the operationalization of variables and the hypotheses. A randomized two-armed trial is a special case of repeated measures. The subjects get both treatments (the pelvic exam simulator and the genital teaching associate) in sequence. This feature of the randomized two-armed design is desirable because the study subjects might participate only if they receive a particular treatment. This insures that each subject will receive both treatments.

Chapter Four correlates the findings of each research hypothesis with a discussion of the results as they are conducted. Finally, the conclusions and implications for future research are discussed in Chapter Five.

## Chapter 2: Literature Review

This chapter provides an overview of health policy issues: reform in medical education, the ethics of medical simulation and the relationship between quality/patient safety and simulation. The chapter provides background on patient safety legislation and quality initiatives following the Institute of Medicine report. In addition, the chapter reviews medical simulation, its benefits and challenges, defines and outlines the use of standardized patients, discusses the pelvic examination and how it is taught, provides a history of obstetric/gynecologic simulators, and concludes with a synopsis of the numerous methods employed to teach the pelvic examination.

### Reform in Medical Education

Changes in the healthcare environment intensified the need for reform in medical education. Beginning in the late 1970's, market-driven health care gradually replaced the medical monopoly (Ameringer, 2008). Financial consequences were felt in academic medical centers. The costs of teaching hospitals are approximately 25-30% higher than those of community hospitals because of higher rates of indigent care, a sicker case mix of patients, and the allocation of resources to education and research (Ludmerer, 1999).

Traditionally, insurers were willing to pay a premium for care delivered in teaching hospitals in order to subsidize the education of future physicians. Teaching medical students and residents compromised efficiency, which increased the costs of care in teaching hospitals compared to private hospitals. With the intense cost-cutting of managed

care, however, payers became less willing to subsidize that inefficiency, and they began to cut back on the premium they paid teaching hospitals.

The change to market-driven health care affects medical education in many ways. For example, fewer and fewer clinical faculty are available to serve as teachers and mentors. Instead, today's faculty are under intense pressure to be clinically productive – to see as many paying patients as possible so that they can help keep the medical center financially afloat. Every hour a medical school faculty member devotes to teaching is an hour taken away from patient care. Thus a medical school faculty member can see fewer patients in a day than a colleague in private practice.

Although teachers are important to the learning environment, the opportunity for students to spend adequate time with patients is more critical. In this respect as well, the marketplace negatively impacts clinical learning. Medical students at all levels have less exposure to real-life problem solving and the acquisition of clinical skills in hospital settings. Through the mid-1980s, the average length of stay at teaching hospitals was 10-12 days. Now it is 3-4 days (Ludmerer, 1999). Many patients who once populated hospitals for days at a time now receive outpatient treatment. Short hospital stays force medical schools to conduct clinical education in an atmosphere where speed is the principal mandate for patient care. As a result, students are converted from active learners to passive observers, with negative consequences for their ability to acquire fundamental knowledge and skills.

In part this change in hospital length of stay reflected technologic advances in medical care, such as the increasing use of minimally invasive surgery. This change was also an attempt by third-party payers to reduce hospital costs.

Since the 1980's a persistent stream of reports from foundations, educational bodies, and professional task forces were issued criticizing medical school curricula for rigidity, an excessive use of lectures, and an overemphasis on rote memorization (Christakis, 1995). Other criticisms included a growing divergence between the training of physicians and the needs of their patients, emphasis on research and patient care at the expense of teaching, poor integration between the basic sciences and clinical components of medical school training, hospital-based clinical training that does not let students have the opportunity to observe patients through the entire course of an illness, and a teaching style that does not provide students with lifelong problems solving skills (Cantor et al., 1991). Ludmerer, in the classic history of medical education, *Time to Heal* (1999) detailed how medical education gradually took a back seat in medical schools in academic medical centers, first to a focus on the research enterprise and then, more recently to the re-engineering of the clinical enterprise.

In 2001 the Institute of Medicine (IOM) issued a report on health professions education that offered a new vision:

*All health professionals should be educated to deliver patient-centered care as members of an interdisciplinary team, emphasizing evidence-based medicine, quality improvement approaches, and informatics.*



In 2002, the Association of American Medical Colleges established the Institute for Improvement in Medical Education to provide an organizational focus to medical education reform efforts. The AAMC, in 2004, charged an ad hoc committee of medical school deans with conducting a comprehensive review of medical education and with recommending strategic directions for change. In 2005 the American Medical Association (AMA) and the AAMC agreed that there was “an urgent need for reform in U.S. medical education.” (Voelker, 2005)

In part because of these reports and others calling for change (American Medical Association, 1982; Friedman et al., 1983; Institute of Medicine 1983; Association of American Medical Colleges (AAMC), 1984; Friedson, 1988; Gastel, 1989; Harris, 1991; Shugars, 1991; Council on Graduate Medical Education, 1992; Marston et al., 1992; AAMC, 1992; O’Neill, 1993; IOM Committee on Quality of Health Care in America, 2001; IOM Committee on the Health Professions, 2003; Lawley, 2005; Hoover, 2005) medical curricula are moving away from didactic lectures towards a hands-on experiential environment where students learn by doing.

The Liaison Committee on Medical Education, the body that oversees the accreditation of medical schools, established an educational objective (ED-5-A) to underscore the importance of experiential learning: “The educational program must include instructional opportunities for active learning and independent study to foster the skills necessary for lifelong learning.” Medical schools are evaluated by these criteria.

Curriculum reform is moving toward the creation of a true learner-centered environment that makes active, self-directed learning under the close observation of interested faculty members the core of the experience. To medical educators, the previous lack of a learner-centered curriculum was cause for concern. Currently, medical education focuses on instilling high professional standards and aims primarily at helping medical students develop the power of critical reasoning, the capacity to generalize, the ability to acquire and evaluate information and the intellectual tools to become lifelong learners. Accomplishing these goals requires thoughtful and personalized teaching. Instructors must generalize and synthesize, not just provide the view from their particular specialty. Students need seminars, tutorials, and individualized instruction, not lectures alone, for fully developed reasoning powers.

More and more the inpatient units of teaching hospitals are populated with two types of patients: one group that is desperately ill, requiring intensive care or highly complex procedures; another that is admitted the day of an elective procedure and discharged as soon as possible thereafter, often within 24 hours. It's much harder for learners to acquire problem-solving skills when patients are admitted with their diagnoses known and treatment plans already determined.

In addition, professional regulation, such as the implementation of the 80 hour work week for residents, profoundly influenced medical student education. Residents, who are primarily responsible for day to day care of hospital patients and teaching of medical students, have less time to teach, observe and supervise them. In light of the

decreasing time available for training, exposure to simulated cases is planned to ensure that sufficient material is covered (Gordon, 2004).

### Medical Ethics and Simulation

Just as there were reforms in medical education over the years, similar shifts in focus occurred in medical ethics. As late as the mid-1960s physicians retained a monopoly over medical ethics, but less than 10 years later, consumers dominated the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and were setting the ethical standards (Rothman, 1991). Medical ethics changed from a paternalistic model to a rights-based model; medical decision making was no longer only the business of physicians.

Consumers of health care have higher expectations, not only of the standard of services and level of care provided, but also of the manner in which care is delivered. Patients now actively participate in deciding their care.

Coldicott et al. (2003) highlight changes in values from the argument of “the greatest good for the greatest number,” or *utilitarianism*, which hold that without practice and experience students fail to develop skills of examination to benefit future patients, to more Kantian-or duty-based ethics, which include the importance of patient consent. *Utilitarianism* considers whether more people benefit from an action than are harmed by it. Harm to one individual (the patient) may be sanctioned if it is for the benefit of a larger group (other patients). *Kant's categorical imperative* provides a counter position. Humanity should be seen as an “end in itself, never merely as a means.” Using any one

person as a “means to an end”—for example, using patients as teaching “aids”—is unacceptable.

Medical students face special difficulty in trying to balance their learning needs with ethical duties. Patients may be vulnerable and obtaining consent may be difficult. The conflict between educational needs and ethical requirements is especially acute in the teaching of intimate examinations. In one study (Reid, 2003) students expressed worries that they had been asked to act inappropriately by supervising medical staff and performing intimate exams.

Ubel (2003) suggested that academic medical centers tolerate unethical behavior by routinely allowing medical students to perform pelvic exams on female patients before gynecologic surgery without first obtaining specific informed consent for the examination to take place. He said that although educational pelvic examinations in the operating room pose no physical harm to patients, the examinations involve scrutiny of very private body parts, solely for educational purposes. Discovery by a patient that such an exam occurred without explicit informed consent may lead to other significant harms (not explicitly stated, but presumably embarrassment or mental distress).

Wall (2004) argues that the key element in determining the appropriateness of students performing examinations on anesthetized women before gynecologic surgery is whether there is a benefit to the patient as a result. He believes it is appropriate for a medical student to examine those patients in whose surgery he is going to participate as an active member of the surgical team; however, if pelvic examinations are carried out “solely

for educational purposes” by students who are not actual members of the operating team, such actions are not appropriate unless specific permission has been obtained from the patient by the surgeon in charge of the case. Colton et al. (1988) argue that the intimate examination under anesthesia is of doubtful validity, as it adds little to the mechanical learning gained when using mannequins.

### Simulation and Patient Safety

The use of simulation in medical education became more important as the awareness of medical errors, patient safety and the quality of healthcare increased. Quality of care, as defined by the Institute of Medicine (IOM), is “the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.” In its influential 2001 report, *Crossing the Quality Chasm*, the IOM advanced six aims for a quality healthcare system: patient safety, patient-centeredness, effectiveness, efficiency, timeliness, and equity. Note that patient safety is depicted as one of the six components, in essence making it a subset of quality.

No one would deny that patient safety is an important public policy issue. According to Blendon and Brodie (1997), one of the core beliefs that shape Americans’ views on health policy is that health is an important, but second-level priority. Seldom does the general issue of health care reform top the list of national priorities. Specific health care issues rarely become part of the national political agenda either (Barak Obama made this part of his political platform when running for President and health care reform

is currently a frequent discussion among American people as well as legislators). Medical errors reported in hospitals caught the attention of the American public after the IOM report was issued in 1999 and spurred action from consumer and provider organizations, health care institutions, and government and helped elevate the issue to the top of the health care agenda at that time.

The National Patient Safety Foundation defined patient safety as the avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the processes of health care (National Patient Safety Foundation, 1999). The modern patient safety movement began with the Institute of Medicine report, *To Err is Human: Building a Safer Health System* (Kohn et al. 1999) and provided a wakeup call to healthcare providers. The widely reported IOM report, *To Err is Human*, put patient safety squarely in the forefront of the nation's health care agenda. The report presented the most comprehensive set of public policy recommendations on medical error and patient safety ever proposed in the United States. The report was prompted by three large insurance industry-sponsored studies on the frequency and severity of preventable adverse events, and by media reports on harmful medical errors. The report offered proposals to address medical errors at the policy level based on the estimation that 44,000 to 98,000 Americans die each year from these errors. These numbers represent more deaths than those due to motor vehicle accidents (43,458), breast cancer (42,297), or AIDS (16,516) and do not even include medical harm that is serious, but non-fatal (Kohn et al., 1999).

Medical errors carry a high financial cost as well. The IOM report estimated that medical errors cost the U.S. approximately \$37.6 billion each year, about \$17 billion of those costs are associated with preventable errors. About half of the expenditures for preventable medical errors are for direct health care costs (Kohn et al., 1999).

Awareness of medical errors increased for various reasons, including widely publicized hospital accidents, continuing publicity for malpractice claims, and research that described and estimated the prevalence of inpatient medical injuries (Mills et al., 1977; Brennan et al., 1991, Leape et al., 1991, Leape et al., 1993). As a result, medical errors and hospital safety became highly visible political issues.

*To Err is Human* was the first of three reports issued by the IOM relating to patient safety and healthcare quality. It was followed by *Crossing the Quality Chasm: a New Health System for the 21<sup>st</sup> Century* (National Academy Press, 2001), which called for a transformation of the health care system to one that was patient-centered, safe, effective, and equitable. The third report, *Patient Safety, Achieving a New Standard of Care* (Aspden et al., 2003), described a detailed plan to facilitate the development of data standards for the collection, coding, and classification of patient safety information. Key recommendations of these reports influenced congressional action.

Following the first IOM report, multiple pieces of legislation were introduced during the 106<sup>th</sup> Congress in response to the report's recommendations. Examples include the Medication Errors Prevention Act of 2000 (HR 3672); the Medicare Comprehensive Quality of Care and Safety Act of 2000 (HR 5404); the Medical Error Reduction Act of

2000 (S 2038); the Stop All Frequent Errors in Medicare and Medicaid Act of 2000 (S 2378); the Patient Safety and Errors Reduction Act (S 2738); and the Error Reduction and Improvement in Patient Safety Act (S 2743). However, no legislation emerged from the 106<sup>th</sup>, 107<sup>th</sup>, or 108<sup>th</sup> Congresses.

The Health, Education, Labor and Pensions Committee of the Senate held four hearings in the 106<sup>th</sup> and one hearing in the 107<sup>th</sup> Congress on patient safety where experts in the field supported the recommendations of the Institute of Medicine for congressional action. Findings from the hearings revealed that research on patient safety unequivocally called for a learning environment, rather than a punitive environment, in order to improve safety.

Another key lesson that came out of the IOM report and hearings was that health care could benefit from review of safety and quality management advances in other industries such as the aviation industry. In aviation, for example, mistakes often result from flawed processes rather than a lack of good intentions or even training, so that process change can reduce errors and damage and speed recovery (Reason, 1990). Most patient safety initiatives take place in inpatient settings, with the attempt to reduce medical injuries (Kohn et al., 1999). The pace of initiatives increased since the IOM report and the hospital focus remains.

After the IOM report, the media focused attention on the public's perception of patient vulnerability. In one national poll, 42 percent of respondents claimed they were personally affected by an adverse event, and 32 percent indicated that the error caused



permanent damage (National Patient Safety Foundation, 2002). There was a perception that the health care system was rife with errors (Joint Commission on Accreditation of Healthcare Organizations, 2000).

### IOM Initiatives

A broad array of stakeholders was enlisted to advance patient safety in the wake of the IOM report. The first stakeholder was the federal government. Besides the bills listed previously, the Congress in 2001 appropriated \$50 million annually for patient safety research. This was enough to engage hundreds of new investigators in patient safety research. Research in error prevention and patient safety became a legitimate academic pursuit.

Beginning in 2004 federal funding for patient safety research through the Agency for Healthcare Research and Quality (AHRQ) became almost entirely utilized for studies of information technology. Congress made AHRQ the lead federal agency for patient safety, and AHRQ established a Center for Quality Improvement and Safety, which became the leader in education, training, convening agenda-setting workshops, disseminating information, developing measures, and facilitating the setting of standards.

A number of nongovernmental organizations have also made safety a priority. The Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) led the way, tightening up accountability within healthcare organizations and requiring hospitals to implement new safe practices (Joint Commission on Accreditation of Healthcare Organizations, 2008). The National Quality Forum (NQF), a public-private partnership to

develop and approve measures of quality of care, developed a consensus process that generated standards for mandatory reporting (National Quality Forum, 2002) and created a list of high-impact evidence-based safe practices that the JCAHO and other organizations require hospitals to implement (National Quality Forum, 2003).

The Centers for Medicare & Medicaid Services and the Centers for Disease Control and Prevention joined with more than 20 surgical organizations in a program to reduce surgical complications (Quality Net, 2008), and many other specialty societies, particularly the American College of Physicians, incorporated safety topics into their meetings, education and research.

The National Patient Safety Foundation qualifies as a major force in increasing awareness of patient safety issues (National Patient Safety Foundation, 2008). In addition, the Accreditation Council on Graduate Medical Education and the American Board of Medical Specialties defined competencies and measures in each specialty, both for residency training and continuing evaluation of practicing physicians (American Board of Medical Specialties, 2008).

Regional coalitions sprung up across the country to facilitate stakeholders working together to set goals, collect data, disseminate information, and provide education and training to improve safety. The original list of medication safety practices for hospitals was disseminated in 1999 by the Massachusetts Coalition for the Prevention of Medical Errors, and was later adopted by the American Hospital Association.

The most important stakeholders who mobilized were the thousands of physicians, nurses, therapists, pharmacists, and other healthcare workers in hospitals and clinics who became much more alert to safety hazards. Healthcare workers initiated many important changes to eliminate infections and improve habits of teamwork.

Some of these changes and improvements can be accomplished utilizing simulation, as recommended by the Institute of Medicine's report. The report identified simulation as a means to enhance safety in the medical field. In particular, the Institute of Medicine - Principle 4, Anticipate the Unexpected, states that "...health care organizations and teaching institutions should participate in the development and use of simulation for training novice practitioners," - (such as medical students learning the pelvic examination) – "problem solving, and crisis management, especially when new and potentially hazardous procedures and equipment are introduced. Crew resource management techniques, combined with simulation, substantially improved aviation safety and can be modified for health care use. Early successful experience in emergency department and operating room use indicates they should be more widely applied." (Tuggy, 1998)

The IOM report made several other notable recommendations with regard to medical simulation:

1. Establish interdisciplinary team training programs, such as simulation, that incorporate proven methods of team management.
2. Health care organizations should use and rely on proficiency-based credentialing and privileging to identify, retrain, remove, or redirect physicians, nurses,

pharmacists, or others who cannot competently perform their responsibilities.

3. Use procedures to mitigate injury through simulation training.

4. Create a learning environment. Use simulations whenever possible.

Until the last 5-10 years no requirement existed for recertification in any specialty in American medicine; there was no requirement for demonstrated competency in new procedures, and no formal, required apprenticeship in new techniques. Some individual hospital medical staffs enforced more rigorous criteria, and most states required some form of continuing education. Before these more rigorous requirements were enacted, many physicians received some training before beginning new procedures, driven by individual integrity and the malpractice system.

The data, however, are alarming: a 1991 survey found that 55% of 165 practicing surgeons who participated in a 2-day practical course on laparoscopic cholecystectomy felt the workshop left them inadequately trained to start performing the procedure. Yet 74% of these surgeons admitted that they began performing the procedure immediately after completing the course (Morino et al., 1995).

There are numerous methods of addressing patient safety issues, and eliminating medical errors in general. One of the methods used to address these issues is simulation (Kohn, 1999; Vincent, 2000; Wachter, 2008). Simulation gives medical students and other learners the opportunity to practice skills prior to treating actual patients, thus reducing possible harm to patients through medical error.

The patient safety movement convinced most observers that “learning on patients” is unethical when there are practical, safer alternatives, such as simulation (Aspden, 2003; Ziv, 2003; Wachter, 2008). Through the years, many health care educators found serious ethical and practical flaws in the live patient-based system and have searched for alternatives. Simulation is one such alternative.

Recently, the international patient safety movement and the U.S. federal policy agenda created a receptive atmosphere for expanding the use of simulators in medical training, stressing the ethical imperative to "first do no harm" in the face of validated, large epidemiological studies describing unacceptable preventable injuries to patients as a result of medical mismanagement (Ziv et al., 2003).

With changes in the healthcare environment, a new vision for medical education (IOM, 2001), which included the use of quality improvement approaches, and the LCME emphasis on active learning, patient simulation received growing acceptance as an attractive, viable teaching approach. The opportunity for independent learning on simulators and the availability of simulated “patients” made it less important that fewer faculty were available to teach and there was less exposure to problem solving with actual patients. Simulated patients could be available when needed and for the length of time necessary for complete assessment and problem solving. Simulation addressed the need for quality improvement approaches such as learning about patient safety and practicing on “simulated” patients. In addition, simulation provided an opportunity for hands-on, active learning, an emphasis of the LCME.

## Use of Simulation in Different Fields

Simulation was used as a training tool for many years in different fields other than medicine, notably in the military with training exercises and pilot training. Military trainers existed since at least the Middle Ages, and today many military exercises are performed not with real equipment, but with simulators. Drivers' education is another area with extensive use of simulation.

The use of simulators to train pilots is the best known example of the widespread acceptance of simulation technology. For more than 70 years the Link simulator was used to train combat pilots. Today, commercial airline pilots spend many hours training in sophisticated simulators that mimic every aspect of the aircraft performance. The training is so realistic that pilots no longer conduct "practice" flights in real aircraft. The first time an airline pilot flies a Boeing 777 is on an actual paying flight with real passengers.

Simulators are used in other fields as well. Architects use computer-based simulators to provide virtual walkthroughs of proposed buildings as part of the marketing and approval process. Industrial engineers use similar simulators to predict the ergonomics of assembly processes.

## Medical Simulation

Simulation is a training and feedback method in which learners practice tasks and processes in lifelike circumstances using models or virtual reality; they receive feedback from observers, peers, actor patients, and video cameras. Computer-based medical simulation provides a realistic and economical set of tools to improve and maintain the

skills of health care providers, adding a valuable dimension to medical training similar to professional training in aviation, defense, maritime, and nuclear energy. Medical simulators allow individuals to review and practice procedures as often as required to reach proficiency without harming the patient (Eder-Van Hook, 2004).

The educational benefits of medical simulation in controlled settings are widely understood. Simulation allows the learner to build knowledge and experience through practice and rehearsal in a safe environment where the inconvenience, discomfort, and potential “harm” to real patients are minimized (Cantrell, 2007). Most important, learners can review and practice procedures as often as they need for mastery.

Learners are able to critically analyze their actions or failure to act, to reflect on their technical, psychomotor and affective skills, and to critique the critical decisions of others. Based on the analysis of their mistakes, as well as feedback from the instructor or videotape review of the simulation experiences, learners may repeat the scenario to enhance their learning. Because of patient safety issues, as well as practical considerations in actual clinical settings, this may not be possible in a real life situation, limiting the learners’ experiences (Hovancsek, 2007).

Simulation-based learning is active learning, resulting in the additional advantage of increased retention (Johnson, 1999). The active nature of this type of learning allows participants to build on prior knowledge, relate the simulation scenario to real clinical problems and further develop their critical thinking skills.

After exposure to simulation-based learning, learners report decreased levels of performance anxiety and improved psychomotor and critical thinking skills (Jeffries, 2005). Participants in simulation-based learning also increase their level of comfort with technology so that the patient, rather than the technology, is the focus of care.

Simulation is becoming established “as a safe adjunct to learning on patients. Its real advantage is that it offers learner-centered education, away from the clinical responsibilities of clinical practice. Learners can therefore practice repeatedly and at their own pace” (Kneebone, 2004). The simulation environment offers permission to fail and encourages learners to deliberately learn in a way that would not be possible with actual patients.

Simulation-based medical education includes several tools and approaches, for example:

- A full environment simulator is similar to flight simulators used to train pilots. The pilot is immersed in a complete replica of the cockpit environment. In medicine, sophisticated manikins, known as patient simulators, provide health care professionals with a computer-based patient that breathes, responds to drugs, talks, and drives all the clinical monitors in the operating room, e.g., blood pressure and pulse rate.
- Task trainers provide a simulated subset of functionality, such as how to give a smallpox inoculation or how to insert a chest tube.
- Computer-based training provides software programs that train and assess clinical knowledge and decision-making skills.



Simulated/standardized patients allow students to interact with actors trained to act as patients, providing students with valuable feedback on bedside manner, among other things.

Type	Description
Low-tech simulators	Models or manikins used to practice simple physical maneuvers or procedures
Simulated/standardized patients	Actors trained to role-play patients for training and assessment of history taking, physicals, and communication skills
Screen-based computer simulators	Programs to train and assess clinical knowledge and decision making, e.g., perioperative critical incident management, problem-based learning, physical diagnosis in cardiology, acute cardiac life support
Complex task trainers	High-fidelity visual, audio, touch cues, and actual tools that are integrated with computers. Virtual reality devices and simulators that replicate a clinical setting, e.g., ultrasound, bronchoscopy, cardiology, laparoscopic surgery, arthroscopy, sigmoidoscopy, dentistry
Realistic patient simulators	Computer-driven, full-length manikins. Simulated anatomy and physiology that allow handling of complex and high-risk clinical situations in lifelike settings, including team training and integration of multiple simulation devices

**FIGURE 5: Simulation Tools and Approaches Used in Simulation-based Medical Education (Ziv et al., 2003)**

Simulation poses several challenges to faculty and administrators that adopt simulation as a teaching strategy. These primarily practical concerns include expense, space, computer literacy and technical support (Rauen, 2001). High fidelity simulators are

extremely costly, some, such as an endovascular simulator, as much as \$250,000. A high initial capital cost may be justified given the large number of students that the simulator can train before it either wears out or becomes obsolete. In addition to the cost of simulators, budgets must include supporting equipment, warranty and maintenance fees. The cost of faculty development is a major challenge. Faculty must receive adequate training on the utilization and programming of these simulators, which is often complex even for the most technologically savvy faculty. Cost of training is not included in the purchase price of the simulators. Simulation personnel and other supportive technical personnel must receive ongoing training to keep up with advances in simulation technology. Faculty time is another major issue, because the development of scenarios and integration of simulation-based learning into an existing program is time-intensive.

Space limitations are also a consideration, including space for the simulators and for the supporting equipment. Computer literacy is a necessity when using high-fidelity simulators. Most of these simulators include the use of laptops, personal digital assistants and video cameras for debriefing. Instructors are able to upload x-rays and other web-based information that increases the realism of the simulated scenario. The ability to use these simulators to their maximum potential requires a high level of proficiency in computer skills.

## Outcomes Research and Benefits of Simulation in Medical Education

Outcomes research on the effectiveness of simulation technology in medical education is “scattered, inconsistent and varies widely in methodological rigor and substantive focus.” (Issenberg et al., 2005). However, the weight of the best available evidence (670 journal articles reviewed) suggests that high-fidelity medical simulations facilitate learning under the right conditions (Issenberg et al., 2005). These include the following:

1. **providing feedback** – 47% of the journal articles reported that educational feedback is the most important feature of simulation-based medical education;
2. **repetitive practice**—39% journal articles identified repetitive practice as a key feature involving the use of high-fidelity simulations in medical education;
3. **curriculum integration**—25% journal articles cited integration of simulation-based exercises into the standard medical school or postgraduate educational curriculum as an essential feature of their effective use;
4. **range of difficulty level** – 14% of articles address the importance of the range of task difficulty level as an important variable in simulation-based medical education;
5. **multiple learning strategies** – 10% of the journal articles identified the

adaptability of high-fidelity simulations to multiple learning strategies as an important factor in their educational effectiveness;

6. **capture clinical variation** – 10% of the articles cited simulators that capture a wide variety of clinical conditions as more useful than those with a narrow range;
7. **controlled environment** – 9% of articles emphasized the importance of using high-fidelity simulations in a controlled environment where learners can make, detect and correct errors without adverse consequences;
8. **individualized learning** – 9% of the articles reviewed highlighted the importance of having reproducible, standardized educational experiences where learners are active participants, not passive bystanders;
9. **defined outcomes** – 6% of the articles cited the importance of having clearly stated goals with tangible outcome measures that will more likely lead to mastery of skills;
10. **simulator validity** – 3% of the journal articles provided evidence for the direct correlation of simulation validity with effective learning.

Issenberg et al. (2005) concluded that while research in this field needs improvement in terms of rigor and quality, high-fidelity medical simulations are educationally effective and simulation-based education complements medical education in patient care settings.

Building upon its history in the aviation and defense industries, computer-based simulations and full-body human simulators provide new alternatives to the old medical education model. Simulators provide a learning tool that is well suited to the changing nature of the student population, particularly their comfort with technology. Just as importantly, simulators appeal to students who have different learning styles. They are also able to address the changing environment of health care by producing a specific simulated patient for specific learning objectives.

Some of the documented benefits of simulation are listed in the table below.

Risks to patients and learners are avoided
Undesired interference is reduced
Tasks/scenarios created to demand
Skills practiced repeatedly
Training tailored to individuals
Retention and accuracy are increased
Transfer of training from classroom to real situation is enhanced
Standards against which to evaluate student performance and diagnose educational needs are enhanced

**FIGURE 6: The Benefits of Simulation (Maran, 2003)**

Many articles about medical simulation emphasize the ability of simulators to create realistic situations in which participants “suspend disbelief” or at least agree to believe and behave as if the situation were real. Another key use of simulation is to “allow

individuals to transverse their procedural learning curves without harming patients” (Wachter, 2008). For example, students can practice procedures such as central line or Foley catheter insertion as many times as necessary for confidence, and proficiency.

Growing acceptance of the use of simulation for improvement of patient safety and patient care occurred over the last two decades (Gaba, 2004). Simulation replaces real patient encounters with guided, often “immersive” experiences. For example, simulation is used to replicate the technical and communication components of physical examinations, as well as those of physical diagnosis and treatment of disease. Using simulation to improve safety requires full integration of its applications into the routine structures and practices of health care.

Simulation-based medical education (SBME) has two goals. One is enhanced learning for medical students, more prepared physicians, and improved patient outcomes. Specifically, research shows that simulation based medical education contributes to the reduction of errors during medical treatment by improving competence and performance in a variety of domains, including clinical skills, practical procedures, teamwork, patient management and decision-making (Ziv et al., 2005).

The basic assumption underlying simulation-based medical education is that increased practice in learning from mistakes and in error management in a simulated environment will reduce occurrences of errors in real life. SBME creates conditions in which making mistakes is not harmful or dangerous to patients but is, rather, a powerful learning experience for students and professionals. They are permitted to err and are

provided with the opportunity to practice and to receive constructive feedback which, it is hoped, will prevent repetition of such mistakes in real-life patients.

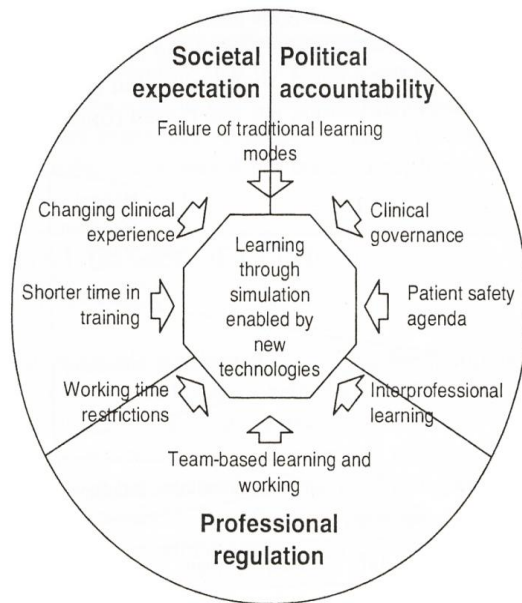
Good simulation creates scenarios that are close to real life and succeeds in instilling within the trainees a mental frame of mind that is similar to what they would go through when handling a real case, analogous to the simulated one (Gordon et al., 2004). This particularly applies to the experience of performing mistakes, and means that, just as in real life, the experience is not an easy one.

The second goal is greater patient safety and comfort. In the case of the pelvic exam, simulation-based training allows medical students the opportunity to focus on the skills and techniques involved in this very intimate procedure, and the absence of an actual patient removes distraction or discomfort associated with an actual person. It also reduces the opportunity for inexperienced students to make errors on real patients, who may sense the nervousness or uncertainty of a student (Ziv et al., 2003).

Beyond training, a commitment to simulation may also improve safety by improving recruitment and retention of skilled personnel, acting as a lever for culture change, and improving quality and risk management activities.

Simulation is now in widespread use in medical education and medical personnel evaluation; however empirical evaluation of it has been limited. Additional evaluation is needed to see how simulation can be more effective. Many factors contributed to the increase in simulation-based training and assessment in procedural skills. These include

the changing profile of hospital patients, political accountability, and more active professional regulation.



**FIGURE 7: Background to Learning Through Clinical Simulation (Bradley, 2006)**

Traditional teaching methods include lectures and use of real patients. Many simulators are ideally suited for independent learning.



**FIGURE 8: Model of Independent Study and Skill Acquisition Using Human Simulation (McIvor, 2004).**



Actual patients may be frequently “off the wards” when instructors and trainees arrive to perform their assessments. Simulators can be readily available at any time and can reproduce a wide variety of clinical conditions and situations on demand. Also, simulators do not become tired or embarrassed or behave unpredictably (as might real, especially ill patients) and therefore may provide a standardized experience for all (Collins, 1998).

Technological advances in diagnosis and treatment, such as newer imaging modalities and endoscopic or laparoscopic procedures, require development of perceptual and psychomotor skills that differ from traditional approaches and that, therefore, require new techniques for training. Concurrent progress in simulation technologies that enable increasingly realistic models offer advantages for such skills acquisition (Issenberg, 2008).

Competence in medicine is “the habitual and judicious use of communication, knowledge, technical skills, clinical reasoning, emotions, values, and reflection in daily practice for the benefit of the individuals and communities being served.” (Epstein, 2002). In the United States, the assessment of medical residents, and increasingly medical students, is largely based on a model developed by the Accreditation Council on Graduate Medical Education (ACGME). This model uses six interrelated domains of competence: medical knowledge, patient care, professionalism, communication and interpersonal skills, practice-based learning and improvement, and systems-based practice (Batalden et al., 2002).

Within any of the domains of competence, learners can be assessed at 4 different levels, according to the pyramid model conceptualized by Miller (Miller, 1990). See Figure 2, Miller's Pyramid, in Chapter 1.

Various assessment methods are well suited to evaluation at these different levels of competence: for example, written instruments, such as exams consisting of multiple choice, questions, are efficient tools for assessing what a student "knows." Conversely, it makes little sense to test the ability to perform a procedure by *writing* about it. So, for evaluation of outcomes that require trainees to demonstrate or "show how" they are competent to perform various skills, the ACGME Toolbox of Assessment Methods (ACGME, 2006) suggests that simulations are the most appropriate instruments.

Especially in the *patient care* domain, the toolbox ranks simulation among the "most desirable" methods for assessing ability to perform medical procedures and "the next best method" for demonstrating how to develop and carry out patient management plans. Within the *medical knowledge* competency examiners can devise simulations to judge trainees' investigatory/analytic thinking or knowledge/application of basic sciences. Simulations are "a potentially applicable method" to evaluate how practitioners analyze their own practice for needed improvements (*practice-based learning and improvement*) and in the area of *professionalism*, simulations are among the methods listed for assessing ethically sound practice (ACGME, 2006).

Problems of medical errors and the need to improve quality and patient safety received increased attention in recent years. Other fields with high-risk performance

environments have long and successfully incorporated simulation technology into their training and assessment programs. Simulation was used to develop and test individual skills, effect collaboration in teams, and to build a culture of safety (Gaba, 2004). Many specialties embraced simulation for training, especially for teaching the skills needed to manage rare or critical incidents. Trainees can make mistakes and learn to recognize and correct them in the simulated environment without fear of punishment or harm to actual patients.

Deliberate practice endorses the idea that educational interventions must be strong, consistent, and sustained to promote lasting skill and knowledge attainment (Cordray, 2006). Simulation provides the opportunity for deliberate practice. Learners can be engaged with well-defined learning objectives or tasks at the appropriate level of difficulty. Focused, repetitive practice can lead to rigorous, precise educational measurements that yield informative feedback from educational sources and where trainees also monitor their own learning strategies, errors, and levels of understanding. Then learners can engage in more deliberate practice and continue with evaluation to reach a mastery standard and advance to another task or unit (McGaghie, 2008). In a research study probing the association between hours of simulation-based practice and standardized learning outcomes, data analysis demonstrated a highly significant achievement increase across five categories of simulation-based practice. More practice produced increasingly higher outcome gains, with a dose-response relationship between hours of simulator practice and standardized learning outcomes (McGaghie, 2006).

Simulation is designed to improve the quality of medical education. Increased safety is the aim, and improving skills and techniques utilizing simulation is the method for achievement. The knowledge, skills, and attitudes needed for safe practice are not normally acquired in medical school and to some extent are ignored. Safety is not modeled by mentors and teachers. Physicians avoid the question of how safety can become central to their work. A general call to embrace safety may influence a few people, but will not change systems.

### Simulation and the Pelvic Exam

This research seeks to evaluate the impact of simulation technology to teach pelvic examination. The use of simulation may increase learning and proficiency while maintaining or reducing costs, and it promotes patient safety and comfort.

Today there is no recognized “best method” for teaching the pelvic examination. Inasmuch as this exam involves female genitalia, it is particularly difficult both to teach and to learn. The sensitive nature of this exam presents a number of challenges that are both personal and methodological. Present instruction using a variety of methods does not assure that students have adequate learning experience or can be observed practicing proper techniques. There is no way to insure quality.

Since the 1970’s the most common method of teaching the pelvic examination utilizes a standardized patient (SP), a person who is trained to completely simulate a patient or any aspect of a patient’s illness depending on the educational need. The SP used to teach the pelvic examination was known by many different names, but most recently the

genital teaching associate (GTA) (Beckman, 1986, Godkins, 1974, Hale, 1977, Holzman, 1977, Kleinman, 1996, Kretzshmar, 1978, Lesserman, 1982, Livingstone, 1978, Muggah, 1988, Nelson, 1978, Plauche, 1985, Stillman, 1990, Vontver, 1980, Wanggren, 2005).

### Standardized Patients

Standardized patients (SPs) are people who train to completely simulate a patient or any aspect of a patient's illness depending on the educational need. They can portray patients during an interview and physical examination with a medical student. The role of the standardized patient has expanded greatly and SPs are utilized in many different medical settings for training and evaluation.

In use since 1963, SPs were introduced at the University of Southern California to work with neurology clerkship students. Three significant events led to Dr. Howard Barrows' creation of the first standardized patient (SP). As a chief resident in the New York Neurological Institute, Barrows worked on the service of an attending physician who observed all medical students work up a patient from beginning to end. When asked why, the physician replied that no one else was watching students. Barrows noted that in the absence of observation and feedback, errors could persist. The second major event occurred as Barrows selected and managed patients for the neurology board examination. When patients were debriefed after the exam, one described a physician who was hostile and performed an uncomfortable examination. When told that the physician would be spoken to, the patient said that he "fixed" the examinee by "changing the Babinsky from one side to the other" and changed his sensory findings. The third triggering event for

Barrows came when he developed a set of films on the neurological exam using an artist's model. He noted that the films did not include the elements of observation and feedback, so important for learning. Barrows began to think about teaching the model to display a neurological problem, like the patient who could change his findings at will. In his first case with third year neurology clerks at the University of Southern California in 1963, he taught a model to portray the signs, symptoms and history of a paraplegic multiple sclerosis patient. Dr. Barrows also developed a checklist that the SP used to evaluate the performance of a trainee (Wallace, 1997).

Pediatrician Paula Stillman established the standardized patient as both a credible teaching methodology and a reliable evaluation tool. Dr. Stillman trained another set of standardized patients in 1970 at the University of Arizona where she was the pediatric clerkship director. In her pilot program local actors portrayed the "mothers" of imaginary children. The actors would describe the illness the unseen child was suffering from, requiring the medical students taking the history to develop differential diagnoses based on the mother's testimony (Wallace, 1997). In 1984, Stillman and colleagues reported the first multi-institutional standardized patient examination, when a number of residency programs in the northeast administered the same examination to their residents.

The term standardized patient (SP) went through many metamorphoses, as the process itself was refined since its inception in 1963. Many other names attempted to describe this phenomenon: programmed patient, patient instructor, patient educator, professional patient, surrogate patient, teaching associate, and—the more generic term—

simulated patient. What all of these terms are referring to is a person rigorously trained to take on the characteristics of a real patient in order to provide an opportunity for a student to learn or be evaluated on skills firsthand. While working with the standardized patient, the student can experience and practice clinical medicine without jeopardizing the health or welfare of real, sick patients.

The expression "standardized patient" was coined by the Canadian psychometrician Geoffrey Norman, who was looking for a designation that would capture one of the technique's strongest features, the fact that the patient challenge to each student remains consistent. The term was generally accepted in the 1980s, when the focus of medical education research using simulated patients turned toward clinical performance evaluation. The standardized patient offers the student an opportunity to come face to face with the totality of the patient, with his "stories," physical symptoms, emotional responses to his illness, attitudes toward the medical profession, stresses in coping with life, work and his family—in other words, everything a real patient brings to a clinician, overt and hidden. This compels the student to go about the process of unfolding all that he needs to know from the interaction with the patient in order to assist that person to heal.

As part of medical education, medical schools use standardized patients to depict realistic patient interactions and presentations of disease. These standardized patients discuss their symptoms with the student. The medical student in turn conducts a patient interview and then may perform a physical examination. Through these interviews, medical

students learn how to communicate with patients in a situation that does not require the use of actual patients (Brender et al., 2005).

Standardized patient interviews are one of several methods for teaching clinical skills and measuring the abilities of medical students. These simulated interactions help students identify the symptoms and signs of a particular disease. The student is able to improve his or her physical examination skills in order to aid in making an accurate diagnosis. In addition, standardized patients come from diverse backgrounds and expose students to cultural issues. Thus, the medical student can learn how to identify and understand the physical, emotional, social and cultural impact of illness.

Standardized patients are often trained to measure the interviewing and examining skills of the student with whom they interact. In addition, experienced instructors may observe the standardized patient interview and physical examination to evaluate clinical skills and recommend improvements. To become a licensed physician in the United States, medical students are now required to pass a clinical skills assessment with standardized patients as part of their medical licensing examinations.

The use of standardized patients avoids mistreatment or possible patient safety issues related to actual patients. The standardized patient is paid to be examined repeatedly by students. The SP is prepared for students to perform inadequately and is prepared to be used as a teaching and assessment tool. There is not the concern that student's will make inappropriate remarks in the teaching situation or use poor examination techniques.



The standardized patient provides a transition to the real patient for medical students (Barrows, 1993). Medical students are able to work with standardized patients without embarrassment about their neophyte status as they learn to take histories and conduct physical examinations. Working with SPs, students can perfect their history and physical examination techniques until they become confident. Then students are able to take a complete history from actual patients and examine them without distractions from concerns about their ability or technique. In addition, patients then feel as though they are receiving a professional service from the students and not experimented upon by novice physicians.

The use of simulated patients has several advantages (Williams et al., 2001):

- *Convenience*: SPs are able to provide cases that are needed at the time they are needed. They can be trained to respond more consistently in the examination than the real patient. SPs may tolerate more students in an examination than real patients.
- *Standardization*: The use of standardized clinical scenarios allows direct comparison of the students' clinical skills, locally as well as nationally and internationally.
- *Compression/expansion of time*: Use of SP simulations allows students to have a longitudinal experience with patients and to follow a case in a compressed time frame.

- *Safety*: Simulations allow students to be put in clinical situations that they could not manage alone in a real clinical setting.
- *Efficiency*: A physician can train a number of SPs who can then teach/evaluate students. This leaves the physician free to concentrate on specific areas where his/her expertise is most useful.

At the same time, SPs are case specific and are able to assess clinical competency in a limited area only. Multiple encounters may be needed for broad ranged training or testing. Also, while SPs are proficient in simulating the symptoms, emotional states and even certain examination findings (neurological examination, for example), they may not be able to simulate certain other signs such as heart murmurs or lung sounds. Recruitment of SPs may also be difficult, time consuming and more expensive than using 'real' patients.

Genital teaching associates, a type of standardized patient, teach medical students how to conduct a proper pelvic exam and provide feedback on technical and communication skills during the exam. The use of standardized patients reduces anxiety while improving student performance in conducting the pelvic examination (Holzman et al., 1977).

In a survey of 142 medical schools in U.S. and Canada in 1989, 94 of 136 (70%) reported that standardized patients were used in various ways, including teaching the breast, pelvic, and male genitourinary examinations, as well as assessing history taking and the physical examination, patient education and counseling, and interviewing skills (Stillman et al., 1990).

A 1993 AAMC survey sent to all 142 North American medical schools requested information on the use of standardized patients. Of the 138 schools responding, 111 reported standardized patients for both teaching and evaluation and 39 of those schools were using standardized patients in a comprehensive examination to assess clinical skills before graduation (Barrows, 1993).

### Pelvic Examination and How it is Taught

The American College of Obstetricians and Gynecologists (ACOG) recommend that all women who are or who have been sexually active or who have reached age 18 should undergo an annual Pap test and pelvic examination (ACOG, 1995). The pelvic exam, with an accompanying Pap smear, is a critical examination for women, during which abnormal pathology can often be detected early. A survey discovered that 17% of respondents are not visiting their doctors annually and 28% do not have Pap tests each year. Of the women who are not visiting their physicians annually, 41% do not think that annual physicals and Pap tests are necessary, as they do not have any current health problems; 30% dislike the exam so much that they put it off until they have a problem; 26% say they don't have insurance and can't afford to go; 19% "forget to do it;" 17% were not aware that an annual exam is recommended; 13% are "afraid of what the doctor might find"; and nine percent don't go because they don't like their doctor (Sirovich, 2004).

New guidelines issued by the American College of Obstetricians and Gynecologists in November 2009 indicated women should start getting cervical cancer screenings at age 21 instead of 18, and that women could wait longer between the screenings - - regardless

of when a woman becomes sexually active. Women in their 20s with normal Pap smear results should now get screenings every two years instead of every year, and women in their 30s can wait three years between screenings. It is not clear how recommendations will be implemented or what the effect will be on women's health outcomes.

Research suggests **patient** and **provider** anxiety are impediments for women obtaining gynecological care (Frye, Weisberg, 1994). Adult women indicate negative feelings and issues that persist in their attitude about, and experiences with, pelvic examinations (Osofsky, 1967, Magee, 1975; Petravage, 1979, Areskog-Wijma, 1987). Eighty-five percent of community college students in one poll reported negative feelings about their last pelvic exam, including descriptions of vulnerability, humiliation, dehumanization and anxiety (Weiss and Meadow, 1979). The concept of fear of the pelvic examination by the patient has frequently been identified in studies of the pelvic examination: Duarsson and Rochner, 1981, reported 66% expressing fear; Weiss and Meadow, 1979, reported 71% expressing fear.

Patients are not alone in their anxiety and fear regarding the pelvic examination. Fifty percent of medical students surveyed reported they thought they would experience greater anxiety examining sexual organs, and would neglect the pelvic examination because of their discomfort (Mudd and Siegel, 1969). More recently, Rees et al. (2009) suggest a staged approach to teaching intimate exams with manikins because medical students are so anxious about examining intimate body regions. They also call for more research to explore in depth students' anxieties about examinations of intimate body

regions and how those views are shaped by interactions with peers, patients and physicians.

The pelvic examination has traditionally been taught by textbook assignments, lectures reviewing anatomy, audiovisual materials, and modeling of specific techniques by faculty. Emphasis in the traditional instructional system was on technical skills, rather than the social and psychological aspects of the exam.

Teaching medical students and residents how to conduct pelvic examinations causes anxiety on the part of the student (Mudd and Siegel, 1969; Rees et al., 2009). Buchwald (1979) reported six reactions to the first pelvic exam performed by medical students: fear of hurting the patient, fear of being judged inept, fear of inability to recognize pathology, fear of sexual arousal, fear of finding the examination unpleasant, and disturbance of the doctor-patient relationship.

Teaching medical students how to conduct a proper pelvic examination is problematic because direct observation of exam technique is not possible. Once a student places his or her examining fingers into the patient's vaginal vault, the instructor cannot see what the student is doing, nor can the instructor intervene to place the student's hands in the correct position or anatomical location.

Performance of an initial pelvic examination can be an emotionally traumatic experience for medical students. Students are anxious to perform the examination in a professional manner, but are unsure of what to look for, what to palpate, how to perform the technical aspects, and what to say to the patient in the process. Students reportedly

become so anxious during the performance of an initial pelvic examination that learning is inhibited and in some cases even blocked (Vontver, 1980).

Current teaching of the pelvic examination in clinics, in the operating room and in patient wards provides inadequate learning environments for students performing the exam for the first time. Verbal feedback about performance is often difficult for a number of reasons, including awkward or complex clinical settings and inadequate time. As a result, many processes to teach and assess pelvic exam skills were developed, analyzed and incorporated into medical school training. Despite these processes, it is possible for a student to graduate from medical school having never learned proper pelvic examination technique (Pugh and Youngblood, 2002).

It is easy to imagine how a medical student conducting a pelvic examination for the first time on a real patient may hurt the patient or conduct the examination incorrectly. Learning to conduct a pelvic exam is anxiety-producing for medical students and the anxiety may affect performance as well as learning. In this study, the pelvic exam technique was taught using a pelvic exam simulator and a standardized patient. This follows the Institute of Medicine's recommendation (Kohn et al., 1999) to use simulation as one method to address patient safety issues.

#### History of Obstetrics/Gynecological Simulators

The use of small wax or wooden figures to illustrate reproductive processes of childbirth dates back to the ninth century (Cody, 2005). Buck (1991) reviewed the development of simulators in medical education and reported that "obstetric mannequin

torsos” were among the earliest examples of simulators used in the history of medicine. Known then as “phantoms,” such obstetric simulators were developed in the 1600s as a way to teach midwives how to manage the difficulties of childbirth. Gregoire and his son, surgeons in Paris, developed an obstetric simulator made of wicker and used this and a dead child for simulating normal and abnormal processes of childbirth to teach midwives during the 1700s. Sir William Smellie, known as the father of British midwifery, refined the Gregoire approach by using a pelvis made from human bones covered by leather (Wilson, 1995). Madame du Coudray, midwife in the court of Louis XV, continued the use of childbirth simulators for training midwives in France (Gelbart, 1998). She was known in the 1700s for creating “the Machine,” an anatomically correct, life-size manikin birthing pelvis, made of wicker, flesh-colored fabric, and leather and padded with sponges.

The use of obstetric phantoms for teaching obstetrics continued through the 1800s and 1900s. Schutze, Director of the University Women’s Clinic in Jena, Germany, during the 1890s modified obstetric phantoms by creating interchangeable pelvic floors and sacral promontories to better simulate pelvic anatomy for teaching clinical pelvimetry. Dougal, of Manchester, England, in the early 1900s created simple, inexpensive glazed earthenware obstetric “basins” to simulate a female pelvis (Dougal, 1933). Wakerlin and Whitacre (1952) created a transparent, plastic female abdominal-pelvis torso modeled on the anatomy of a typical European female. Since the 1950s a number of objects or more elaborate part-task trainers were developed for training and practicing of procedures or for examining the female pelvis.

The pelvic examination simulator, developed in the late 1990s, is a partial manikin, umbilicus to mid-thigh that is constructed in the likeness of an adult human female. The manikin is instrumented internally with a computer-generated interface for the purpose of immediate visual feedback. The device allows students to see which structures are touched and how much pressure is applied while the pelvic exam is performed.

#### Methods Used to Teach Pelvic Examination

Numerous methods were employed to teach the pelvic examination. In the 1970's and 1980's Gynny was a popular plastic model used for teaching the pelvic exam (Rakestraw et al., 1985) and studies were designed to determine whether or not students learned more when Gynny was part of the instruction. The conclusion was that students who used the Gynny model performed better and rated the learning experience higher than those without it. Students who did not have the Gynny experience "felt they would have performed better, been less anxious, and felt more confident if Gynny had been a part of their training." A randomized study (Nelson, 1978) was conducted which compared teaching methods utilizing professional patients or plastic models. Training on a professional patient significantly increased the student's chance of palpating one or both ovaries, reduced the student's anxiety about performing the pelvic exam, and may have improved the student's gentleness with the patient. The recommendation was to replace teaching on the plastic model with use of the professional patient.

Plauche et al. (1985) recognized that the use of plastic models such as Gynny were inadequate in several ways. The models lacked pliability and resilience and did not



provide a realistic examination experience. Another major deficiency of the plastic model was the lack of feedback to the students about whether they had accurately palpated the appropriate organs or caused discomfort during the examination.

In addition, students were taught the pelvic exam by learning on each other or have even been asked to provide their own live model (Schneidman, 1977). Pelvic exams were taught on patients in clinics (Berry et al., 2003), during adolescent medicine rotations (Neinstein et al., 1986, Rabinovitz et al., 1987), under anesthesia with and without consent (Abraham, 1995, Coldicott et al., 2003, Ubel et al., 2003, Wall et al., 2003, Wilson, 2005, Goedken, 2005), as well as on inexperienced volunteers (Perlmutter et al., 1974, Carr, 2004; Hendrickx et al. 2006) and cadavers (Munger et al., 1981).

Leserman and Luke (1982) argue for using women from the community to teach medical students how to conduct routine pelvic exams rather than medical school faculty. Women trained in technical and communication skills emphasizing the patient-physician relationship are able to address specific problems identified with physician's treatment of patients. Problems includes lack of sensitivity to and respect for women; ignoring patient education thus limiting patient participation in health care decisions; not presenting choices to patients such as the optional use of drapes and mirrors; and ignoring patient comfort by not doing such things as warming the speculum (Billings and Stoeckle, 1977, Corea, 1977, Boston Women's Health Collective, 1976). Also counted among the problems were the use of medical terminology that patients do not understand, and judgmental attitudes about patient's lifestyles and sexual preferences.

The use of mental practice is another method advocated for learning the pelvic exam (Rakestraw et al., 1983). Mental practice, in most cases, facilitates skill acquisition (Richardson, 1967 and Richardson, 1967). It is also said to assist in the learning of any skill in which sequencing is a major part (Summers, 1977) and when mental factors are important in the performance of the skill (Cratty, 1973). According to Oxendine (1969), the sequence of physical practice and mental practice results in the greatest improvement in skill performance. There are several types of mental practice. The first type includes a review of the skill performance immediately before beginning the performance or physical practice. The second takes place after the first physical practice and before a second practice or performance. A third type of mental practice is used to develop variant strategies.

Professional, simulated, or programmed patients, including graduate students, nurses, and prostitutes were employed to help students learn pelvic exam techniques (Godkins et al., 1974, Rochelson et al., 1985, Siwe et al., 2007). These women were knowledgeable in interpersonal skills and in anatomy and comfortable with their own sexuality. At first, the professional simulated patient was used as a patient substitute with all the instruction coming from the physician (Johnson et al., 1975). Kretzschmar (1971, 1978) introduced the concept of the programmed patient serving as both the patient and the instructor. He thought that with no physician present, the interactions were more likely to be open and realistic. The patient began stressing the communication/interpersonal skills integrated with the practical/technical skills to provide a quality pelvic examination.

Holzman (1977) investigated the impact of two methods of pelvic exam instruction, with the professional patient in the experimental group versus the clinic patient for the control group. At the conclusion of the study he reported that students receiving training from professional patients scored significantly better in psychomotor and interpersonal skills than did those who received outpatient instruction by a gynecologist. Siwe et al. (2007) compared the same two models of learning the pelvic examination for medical students by measuring perceived distress and learning outcome in terms of skills. Students trained with professional patients were reported to be more skillful in palpating the uterus and ovaries and also performed more pelvic examinations during the clinical clerkship than did the students trained with clinic patients. Again, use of professional patients increased the confidence of students who performed the pelvic examinations, made them more competent, and improved their skills in performing the examination.

Since the mid-1970s, the standard method for teaching pelvic examination uses simulated patients, or gynecologic teaching associates (GTAs). The GTA approach resulted in significant reductions in both student and patient awkwardness and embarrassment, as well as an improvement of the sensitivity of the student/patient encounter (Livingstone and Ostrow, 1978). Muggah et al. (1988) regard the GTA model as a superior method of teaching the skills necessary to perform a sensitive and thorough history and physical examination. GTA techniques reduce medical students' performance anxieties, and with the provision of immediate feedback and positive reinforcement, learning is enhanced.

Wanggren et al. (2005) also report that the use of teaching associates reduced stress and anxiety; medical students were relieved, calmer, and more secure after the training. Students were able to learn and integrate their clinical skills in a safe environment that allowed them to gain confidence and competence. In a similar study with nurse practitioner students (Theroux, 2006), the standardized patients provided immediate feedback to students, decreased their feelings of anxiety, and increased their confidence in performing examinations. Using SPs was more effective than teaching using voluntary peer examinations.

In another study, Shain et al. (1982) evaluate the gynecology teaching associate versus the pelvic model approach to teaching the pelvic exam (in this case with possible abnormal as well as normal findings) to see if they correlated with cognitive objective test scores. Students were divided into matched pairs, according to gender, age, minority versus nonminority status, level of achievement (combination of Medical College Admission Test score and class rank) and prior pelvic examination experience. Individuals from each matched pair were randomly assigned to alternate training techniques, Gynny or GTA. The only variable that correlated with student performance was the instructional modality. GTA-trained students reported higher mean scores on all measures of communication and manual skills. Shain et al. conclude that the GTA experience contributed to greater student competence and confidence, and that this resulted in superior performance.

GTAs continued to evolve as educational specialists (Plauche and Baugniet-Nebrija, 1985). GTAs are taught the appropriate anatomy, as well as the names of pelvic exam instruments and their proper use. GTAs observe the examination with mirrors to make sure students are correct in identifying the external genitalia as the students name and explain the function of these structures. The GTAs learns to perceive proper palpation of the abdomen and internal pelvic organs. They provide immediate feedback about what is felt and whether the exam is properly performed. The GTA tells the student whether the proper pressure is applied and whether the examination is causing her any discomfort.

In addition to technical skills, GTAs teach communication skills as well.

Beckmann (1986) reported that 95% of the students he studied rated GTA sessions as good or outstanding with regard to communication skills. A comparison of GTA trained and physician trained students at the completion of the obstetrics/gynecology clerkship indicated that GTA trained students demonstrated better interpersonal skills than did the physician trained students ( $p=.01$ ). The authors recommended that teaching by GTAs be incorporated into the teaching of pelvic examinations and other aspects of a women's health curriculum (Kleinman et al., 1996).

Abraham (1995) indicated "there is an urgent need to improve our teaching experience concerning vaginal and speculum examination and the first step is to realize how inadequate our teaching is at present." In this study, medical student perception of their own psychomotor skills was studied in conjunction with attitudes to different methods of teaching the gynecological examination. Students rated their physical skills

poorly, only 7% feeling confident they could detect an abnormality and only 14% considering their ability to perform a Pap smear was good or very good.

Sexual experiences affect the attitudes of medical students learning the gynecological examination. Both male and female students who were sexually experienced felt they were more able to conduct a gynecological examination with sensitivity, put the woman at ease and to explain to the woman what was done and why. Male students who had not experienced sexual intercourse were more likely to lack confidence in their ability to perform a speculum examination, to take a Pap smear and to detect an abnormality during a gynecological examination (Abraham, 1996).

A mechanical simulator was first reported to be used to assess pelvic examination skills in 2001 (Pugh et al.) at Stanford. The e-pelvis, an electronic manikin, allowed examiners and instructors to visualize on a computer screen the location and intensity of touch applied during simulated pelvic exams. A study of 87 medical students at Stanford conducting pelvic exams divided the subjects into three groups: those using the simulator (e-pelvis), those using the manikin, and control groups. Educators rated the simulator group higher than both the manikin and control group in ending skill levels. The simulator group was also rated highest on rapport when compared to the manikin and control groups. The study concluded that the addition of real time visual feedback for medical students learning to perform female pelvic exams may provide a superior educational experience when compared to traditional learning modalities (Pugh et al., 2001). Data collected from the e-pelvis pressure sensors in the previous study were objectively analyzed to evaluate

user performance and simulator validity. The findings validate the simulator as a reliable measurement tool (Pugh and Rosen, 2002).

Pugh indicated (2002) that objective assessment of clinical and technical skills was possible using the e-pelvis simulator. Four novel performance indicators were defined: the time to perform a complete examination, the number of critical areas touched during the exam, the maximum pressure used, and the frequency at which these areas were touched. The performance indicators were compared with written assessment scores. Results showed that the new assessment measures provide an objective, reliable and valid method of assessing students' physical examination techniques on the pelvic exam simulator.

Interns are also subjected to pelvic examination skills teaching and assessment. In 2003, two articles were published that examined pelvic examination skills in interns (Dugoff et al., 2003 and Herbers et al., 2003). In Colorado, interns who were entering obstetrics and gynecology and internal medicine were evaluated on pelvic and breast examination skills with a 26 point objective structured clinical examination (OSCE). It was noted that there was no correlation between the number of previous breast and pelvic examinations that were performed and the performance on the skills assessment. Also, the performance on the examination did not correlate at all with an intern's perceived level of competence. In a randomized controlled trial of internal medicine interns from three residency programs, interns randomized to training by GTAs had significantly higher scores at follow-up than did interns in the control group. The conclusion was that

specialized trainers can reliably evaluate and improve the pelvic exam skills of interns, and that improvements are demonstrable three months after training.

Even at the resident level, the pelvic examination is a procedure frequently complicated by difficult communication, sexual tension, and iatrogenic pain (Lang, 1990). Among the majority of residents in this study, there was a failure to identify and deal with patients' discomfort.

The pelvic examination continues to be one of the most difficult physical examination procedures to teach, due to the technical and interpersonal skills it requires. Many methods were used to teach the pelvic examination in the past. A new model, combining systems of learning technology and methodological innovation will be tested.



## CHAPTER 3: Methods

In this chapter, rationale for use of the randomized two-armed design for this study is explained, including advantages and disadvantages of the method. There are descriptions of the study population and *The Fear of Pelvic Examination Scale* and its validity. Human subject's protection, data collection procedures and techniques of data analysis are described. Each research question is outlined, with statistical methods described that are used to answer the questions. Finally, limitations of the study are detailed.

### Hypotheses

The study attempts to answer the question, "How can knowledge of fear, performance and blood pressure during simulation-based pelvic examination training reduce anxiety and increase student performance in order to help reduce medical errors and improve medical education?" In this study, there are six hypotheses based on the possible association between fear, blood pressure, order of training and performance. Fear, blood pressure and order of training will serve as the predictor variables and performance as the outcome. The basic proposition is that fear, blood pressure and order of training will be related to performance.

Hypothesis one (H<sub>1</sub>): Students will exhibit less fear before the second training period, whether it is genital teaching associate or simulator training.

Hypothesis two (H<sub>2</sub>): Performance scores after the pelvic exam training, whether simulator or genital teaching associate training are expected to increase from the first training period to the second period.

Hypothesis three (H<sub>3</sub>): There will be a direct relationship between blood pressure and performance.

Hypothesis four (H<sub>4</sub>): There will be a direct relationship between blood pressure and fear.

Hypothesis five (H<sub>5</sub>): There will be a direct relationship between fear and performance.

Hypothesis six (H<sub>6</sub>): There will be a statistically significant difference in the fear scores, learner performance scores and blood pressure readings by gender.

There are two possible indicators of fear – *The Fear of Pelvic Examination Scale* scores and the blood pressure reading. Both are discussed in detail below.

### Research Design

A randomized two-armed design was selected for the study; it represents a special kind of “repeated measures” experiment. In certain cases volunteers might be willing to participate only if they receive a particular treatment. In the case of medical students, who are usually competitive, they would consider themselves at a disadvantage if only part of them received a particular treatment; therefore, all medical students in this study received both treatments.

The effectiveness of teaching the pelvic examination with genital teaching associates has been documented, but teaching using the pelvic examination simulator has not. It would be unethical to assign one group to learn with a proven method and the other to be taught using an untried method. The two-armed design insures that each subject will receive both treatments, as was the case in this study.

The subjects get both treatments in sequence. There is no separate comparison group. In effect, each subject serves as his or her own control. The simplest two-armed design was employed in this study, with two treatments and two periods, with half the subjects receiving treatment A (simulator) first, followed by treatment B (genital teaching associate), and the other half receiving treatment B first, followed by treatment A.

Ideally in a two-armed design, a subject is randomly assigned to a specific sequence for treatment. In this study, the M2 class was randomized into two groups by computer. All medical students learn the pelvic examination on the pelvic exam simulator (SIM) and with the genital teaching associate (GTA) as a curriculum requirement for M2 Foundations of Clinical Medicine course. One group received pelvic examination instruction on the simulator before receiving pelvic exam instruction from the genital teaching associate. The second group received pelvic exam instruction from the genital teaching associate before receiving pelvic exam instruction on the simulator.

#### Protection of Human Subjects

On January 3, 2008 the research study, “Pelvic Examination Skills Taught with a Pelvic Exam Simulator and with Genital Teaching Associates” was approved by expedited

review according to 45 CFR 46.110 Categories 4 and 7, Virginia Commonwealth University, Institutional Review Board (IRB) Panel B, Office of Research Subjects Protection. The approval included the Protocol (Research Synopsis) and Consent/Assent (Research Subject Information and Consent Form). The IRB Panel waived all elements of consent for the genital teaching associates. The Virginia Commonwealth University School of Medicine contract with Eastern Virginia Medical School's Theresa A. Thomas Professional Skills Teaching and Assessment Center provides genital teaching associates for teaching the pelvic examination to medical students and includes the GTAs participation in educational research. The GTAs were not subjects in the research study. See Appendix A for University IRB approval form. The original IRB form was later amended because of possible high blood pressure readings by medical students before the study started.

The intention was to blind study participants to their arrival blood pressure readings. Every participant, without exception, wanted to know his/her readings. Because the IRB submission was already being amended to inform students of possible high blood pressure readings, it was decided that allowing students to know their blood pressure readings after the initial session would not interfere with the study. It would also provide an opportunity to educate student's about national blood pressure guidelines. The form that was developed, Reporting of Baseline Blood Pressure Form, was filled out and given to students after the initial blood pressure reading. See Appendix A.

## Study Population and Consent

All second year medical students (N=186) in the School of Medicine at VCU were potential research subjects. The purpose of the study (See Research Subject Information and Consent Form) was explained to medical students in groups of eight in the M2 Foundations of Clinical Medicine course the month before the beginning of the study and prior to an unrelated standardized patient encounter. Students were encouraged to ask questions related to the study and were given the opportunity to provide written consent for participation or to opt out of the study altogether. Students were given the option of providing written consent at the time, providing written consent at a later date prior to the beginning of the study, or of not providing consent to participate in the study at all. Students could drop out of the study at any point after providing consent and were given a consent form with contact information for questions. See Appendix A for Research Subject Information and Consent form.

Most students who enrolled in the study did so at the end of the explanation of the study. There was no reason to believe that the medical students who enrolled in the study were different than those who opted not to participate.

A list of VCUCard numbers was obtained from the Curriculum Office and labels were printed with participant's names and the last 6 digits of their VCUCard, which was the study identifier. The name and identifier labels were put on an envelope, with multiple identifier labels placed inside the envelope. When study participants completed the *Fear of Pelvic Examination Scale*, or had their blood pressure monitored, each paper was

labeled with the study identifier. Evaluations were also labeled with the study identifier. After the study, envelopes with names and identifiers were separated from the data sheets to insure anonymity of study participants.

The following represents the overall experimental design of the study:

Random Assignment	Pre Training 1	Training Period 1	Immediate Post Training	Pre Training 2	Training Period 2	Immediate Post Training
<b>SG Group</b>	Demographics F-PEXS BP	SIM Training Monitor BP	LPERF*	F-PEXS	GTA Training Monitor BP	LPERF**
<b>GS Group</b>	Demographics F-PEXS BP	GTA Training Monitor BP	LPERF**	F-PEXS	SIM Training Monitor BP	LPERF*

**FIGURE 9: Research Design**

\*Pelvic Examination Workshop Using the Pelvic Exam Simulator

\*\*Pelvic Examination Workshop with Genital Teaching Associate

Students who consented to participate in the study completed a short experience and demographic questionnaire, had an arrival blood pressure taken before their first training session, filled out the *Fear of Pelvic Examination Scale* before both the SIM and GTA training, and had their blood pressure monitored while conducting the pelvic exam on both the SIM and GTA. Each student had his or her blood pressure taken three times during the study.

All medical students, whether in the study or not, learn the pelvic examination on the pelvic exam simulator and with the genital teaching associate as a curriculum requirement for M2 Foundations of Clinical Medicine course. The entire M2 class was

randomized into two groups by computer. Half the class received training on the pelvic exam simulator first and the other half received training with the genital teaching associate first. Students not participating in the study completed training with the pelvic exam simulator and genital teaching associate, but did not have their blood pressure monitored before or during the training. Also, they did not complete the demographics questionnaire or the *Fear of Pelvic Examination Scale*.

All second year medical students, whether participating in the study or not, were required to view the video, *Pelvic Examination*, produced by the *New England Journal of Medicine* (Edelman et al., 2007), before their initial session. The video was linked to the FCM curriculum website for easy access by all students.

#### Data Collection

Pelvic exam training began in January, 2008 and ended in April, 2008. Students providing consent to participate in the study completed a brief questionnaire prior to their first encounter which requested information about age, gender, experience conducting pelvic exams, experience with simulators and current medication taken for high blood pressure. Responses will be compared by age and gender. See Appendix C.

Study participants had an arrival blood pressure taken with a Dinamap machine by a senior nursing student. The Dinamap provided a paper readout and documented the blood pressure before training with either the SIM or GTA, whichever encounter occurred first. The intent was to compare the arrival blood pressure with the same readings during the pelvic examination on both the GTA and SIM.

Systolic blood pressure has been used to measure anxiety (Hildrum et al., 2008; Player et al., 2008; Tanabe et al., 2008; Howell et al., 2007; Smolen et al., 2002; Knight et al., 2001; Shinn et al., 2001; Paterniti et al., 1999; Raikkonen et al., 1999; Jones-Webb et al., 1996; MacDonald et al., 1993; McGrady et al., 1990; Johnson, 1989) in a number of different settings, including conducting pelvic exams (Williams et al., 1992) and taking sexual histories (Deladisma et al., 2007). Blood pressure was automatically measured on the participants every five minutes during the SIM and GTA sessions with the Dinamap blood pressure monitor. This non-invasive monitor has been used by hospitals on ICU patients to capture up to 100 readings within a 24 hour period.

Each blood pressure reading was converted to mean arterial pressure (MAP), using the formula  $MAP = [(2 \times \text{diastolic}) + \text{systolic}] / 3$ . For blood pressure readings taken during the GTA and SIM sessions, the highest MAP was noted for each session.

#### *The Fear of Pelvic Examination Scale*

The F-PEXS questionnaire was designed to measure different aspects of experiencing fear in the pelvic exam situation, and was developed by Karin Siwe at Linköping University in Sweden (Siwe, 2007). Written permission (via email) was obtained from Siwe to use the F-PEXS in the study. According to Siwe, the questionnaire was shown to have a very good reliability (e.g. Cronbach's alpha is .96) and good construct validity. In the validation study at Linköping University, students rated their fear at the prospect of performing seven consecutive steps of the pelvic exam, i.e. separating the labia minora; inserting fingers into the vagina; placing the outer hand on lower



abdomen; pushing the outer hand deep into abdomen; and bimanually palpating the uterus and ovaries. For each of the seven steps the students rated stress, discomfort, impulse to avoid the situation, disturbing thoughts/associations and global fear by giving a score between 0 and 6 (0 = not at all, 6 extremely strong/intense). In the F-PEXS, scores for all seven steps of the five aspects of fear are summed up to give a total score for each stage of measurement (range = 0-210). The higher the score, the greater the fear the individual experiences of the gynecologic examination in question. Students completed the *Fear of Pelvic Examination Scale* before learning with the pelvic exam simulator and before examining the standardized patient or genital teaching associate. A total F-PEXS score was calculated for each GTA and simulator session. See Appendix B for permission to use the F-PEXS and the F-PEXS scale.

The convergent validity of the F-PEXS was tested by means of its correlation with the Spielberger State (SSAI) and State-Trait Anxiety Inventory (STAI), and Beck's Anxiety Inventory (BAI). Siwe (2007) hypothesized that the F-PEXS would have the highest correlation with the SSAI, measuring general anxiety at the very moment, followed by its correlation with the BAI, measuring present anxiety symptoms, followed by its correlation with STAI, measuring anxiety tendency in general, i.e.  $(F-PEXS \times SSAI) > (F-PEXS \times BAI) > (F-PEXS \times STAI)$ .

The correlation between the F-PEXS and the SSAI was .69, and higher than with the other two scales. The correlations of F-PEXS with the BAI and STAI were about the same, .39 and .44 respectively. No *p*-values were reported, however, correlations in the

range of 0.39 -0.69 are meaningful. These three correlations (Siwe, 2007) indicate the F-PEXS clearly measures in the field of anxiety, but in such a way that its domain is different from e.g. situational anxiety as a general anxiety reaction (SSAI), general tendency to react with anxiety (STAI) or having clinical anxiety symptoms (BAI). The author (Siwe, 2007) did not show discriminant validity so without both convergent and discriminant validity, construct validity cannot be assumed.

Reliability of a test, as estimated by Cronbach's alpha, refers to the tests consistency and accuracy. This capacity depends on the amount of error variance in the test. The less error the tests measurement comprises, the greater the reliability of a test. The Cronbach's alpha coefficients for Time 1 was 0.96 and for Time 2, 0.96. These coefficients are extremely high, which means that the test has a very good reliability in terms of internal coherence of the separate items.

#### Pelvic Examination Training at VCU

Genital teaching associates (GTAs) taught students the pelvic examination in 90 minute sessions with three medical students per group. Four sessions were conducted simultaneously in clinical teaching rooms. Each student participating in the study was hooked up to the Dinamap machine on his or her non-dominant arm while conducting the pelvic examination.

At the conclusion of the GTA pelvic examination training, the GTA evaluated the learning performance of each individual student, using a 5 point Likert type scale, where 1 was Expectations Unmet and 5 was Met Expectations. The six components of the

evaluation were: familiarity with pelvic exam procedure (ready to practice), active participant, at ease while practicing skills, actively supports group learning, attends to GTA modesty and dignity (this is the one component that was different from the simulator evaluation), and seeks feedback. There was a possible total evaluation score of 30.

Individual items were totaled to determine a total score for comparison with the simulator group. See evaluation form labeled Pelvic Examination Workshop With the Genital Teaching Associate in Appendix E.

Women's health nurse practitioners from the School of Nursing conducted pelvic exam training for medical students on the pelvic examination simulator in the Clinical Skills Center in the School of Nursing. Two 90 minute sessions with one nurse practitioner and three students each were conducted simultaneously. First, there was a demonstration of all the steps of the pelvic examination by the instructor, and then each student performed the pelvic exam on the simulator. Students were allowed to perform the pelvic examination at their own pace, and the amount of time varied, depending on the skill and confidence of each student. The Director of the Clinical Skills Center at the School of Nursing trained the nurse practitioners who taught the medical students so that the teaching would be uniform and as consistent as possible. This included use of a standardized checklist for skills (see Appendix G). First, each nurse practitioner demonstrated the proper pelvic examination technique on the simulator, following the steps on the checklist. Then each student in the group had an opportunity to conduct the same examination on the simulator. If the student was a study participant, he or she was

hooked up to the Dinamap machine, on the non-dominant arm, which automatically took blood pressure readings every five minutes. The average length of time for each student to conduct a complete pelvic examination was 15 minutes.

At the conclusion of the pelvic examination simulator training, the performance of each individual student was evaluated in the same manner as after the genital teaching associate training, except in this case by a nurse practitioner. One component of this evaluation was different than that from the GTA evaluation, “palpates ovaries independently.” The total possible evaluation score was 30. Individual items were totaled to determine a total score for comparison with the GTA group. See evaluation form labeled Pelvic Examination Workshop Using the Pelvic Exam Simulator in Appendix F.

Prior Experience and Demographics
Dinamap Blood Pressure Readings
Fear of Pelvic Examination Scale (F-PEXS)
Pelvic Examination Workshop Using the Pelvic Exam Simulator (LPERF)
Pelvic Examination Workshop With Genital Teaching Associate (LPERF)

**FIGURE 10: Data Collection Instruments**

## Data Analysis

Data analysis will consist of both descriptive and inferential statistics using the Statistical Package for the Social Sciences (SPSS) and SAS. Descriptive statistics such as means/standard deviations and frequency counts/percentages will be used to describe the students in terms of age, gender, previous experience conducting pelvic examinations, previous use of the pelvic exam simulator, and use of other medical simulators. The alpha level used for significance will be .05.

Question 1: Does the self-reported Fear of Pelvic Examination Scale (F-PEXS) score change from the first to the second training session? For  $H_1$ , the mean F-PEXS score was estimated for students in both sequences (GS, SG), before each training session (i.e. GTA1, SIM2, and SIM1, GTA2). The change in F-PEXS scores for each sequence was computed as the decrease in the F-PEX score from the first to the second training session (i.e. GS change =  $GTA1 - SIM2$ , SG change =  $SIM1 - GTA2$ ). Paired  $t$ -tests were used to determine if there were statistically significant changes in F-PEXS scores for either of the training sequence groups. Furthermore, a two sample independent  $t$ -test was used to compare the changes between the sequence groups (i.e. did learning with GTA, then SIM result in different change in F-PEXS scores than learning with SIM, then GTA?) since the sample size was large enough to assume the means were normally distributed via the Central Limit Theorem. Similar analyses were completed for scores on each of the seven consecutive steps of the pelvic exam to determine more specific areas of anxiety using the subscale score as the response variable.

Question 2: Does the learner performance of the student on the evaluation increase from the first to the second training session? For  $H_2$ , the mean LPERF score was estimated for students in both sequences (GS, SG), after each training session (i.e. GTA1, SIM2, and SIM1, GTA2). Paired  $t$ -tests were used to determine if there were statistically significant increases in LPERF scores for either of the training sequence groups. Similar analyses were completed for LPERF scores on each of the six components of the evaluation of performance exam to determine more specific areas of anxiety.

Question 3: Is there a relationship between the blood pressure and the learner performance scores of the medical students? For example, does higher blood pressure lower performance scores? For  $H_3$ , the relationship between LPERF (performance) scores after each training session and MAP was tested using the linear mixed model for students in both sequences for both sessions (i.e. GTA1, SIM2, and SIM1, GTA2). A linear mixed-effects model was used in order to account for correlations in the data due to the repeated measures. Another advantage of the mixed model is that it can appropriately handle missing data, assuming the data are missing are random. The outcome variable in the mixed model was LPERF, and fixed effects were included for MAP, Period (session 1 or session 2), treatment (GTA or SIM), all possible 2-way interactions, and the 3-way interaction. In addition, the model included a random effect for sequence group nested within subject. To describe the four relationships between LPERF and MAP, slopes were estimated. These slopes describe the amount of change in the response variable, LPERF, expected to occur given an amount of change (usually 1 unit) in the predictor variable,

MAP. Positive slopes indicate that high MAP scores are associated with high LPERF scores (and low LPERF scores are associated with low MAP scores), while negative slopes indicate high MAP scores are associated with low LPERF scores (and low MAP scores are associated high LPERF scores). Tests comparing each slope to zero were used to determine if the relationships were statistically significant.

Question 4: Is there a relationship between the MAP (difference from arrival) and the self-reported Fear of Pelvic Examination Scale score (FEAR)? For H<sub>4</sub>, the relationship between FEAR scores before each training session and MAP was estimated for students in both sequences for both sessions (i.e. GTA1, SIM2, and SIM1, GTA2). The same model and methods as described for Question 3 will be used, except the outcome variable will be FEAR.

Question 5: Is there a relationship between the self-reported F-PEXS (FEAR) score and the performance (LPERF) score? For H<sub>4</sub>, the relationship between F-PEXS scores before each training session and LPERF scores after each training session was estimated for students in both sequences for both sessions (i.e. GTA1, SIM2, and SIM1, GTA2). The same model and methods as described for Question 3 will be used, except the outcome variable will be LPERF and the primary predictor variable (fixed effect) will be F-PEXS (FEAR).

Question 6: Is there a difference between the fear, performance and blood pressure readings by gender? Three linear mixed models will be used to test for differences between the genders in each of the response variables, FEAR, MAP and LPERF, while

adjusting for period, treatment, and sequence effects. The models will include main effects for gender, treatment, period, and sequence group. The difference in FEAR, MAP and LPERF scores between genders will be estimated and statistically compared to zero.

### Study Limitations

The GTAs conduct teaching sessions at VCU as well as at other institutions and have extensive experience in evaluating students who are learning to conduct pelvic examinations. The GTAs use a standardized checklist as a guide for teaching and evaluation. The women's health nurse practitioner who trained all the NPs in the teaching and evaluation process on the simulator is an experienced teacher and clinician. She was responsible for training all the other NPs in an attempt to decrease this variability and to increase inter-rater reliability. She utilized a standardized checklist for the pelvic examination and either taught or oversaw all teaching sessions. There were more nurse practitioner evaluators compared to GTA evaluators, which could lead to more variability in the evaluations by the nurse practitioners compared to the GTAs.

Blood pressures were taken before the first intervention (arrival), either SIM or GTA. The blood pressures were converted to MAPs and compared to the average MAPs for the U.S. population by age group (National Heart Lung and Blood Institute, 2003). The study participants in the age group 20-24 (84; 50%) had an arrival MAP mean of 95.6, with a 95% confidence interval for the mean of 93.7 (lower bound) and 97.4 (upper bound). According to *The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure* (2003) the average blood



pressure for the U.S. population for ages 20-24 is 120/79, with a MAP mean of 92.7. The study participants aged 20-24 had a significantly higher MAP mean than the U.S. population of the same age. This is the only age group of study participants who had significantly higher MAP means than the U.S. population in the same age category. The higher MAP of participants ages 20-24 may influence the results of the study by influencing the overall fear of conducting the pelvic exam or the performance scores

The following chapter, Chapter 4, Results, will detail the analyses that were used to answer the study questions. In addition, the models will be examined and results explained.

## CHAPTER 4: Results

The findings of the study are outlined in this chapter. First is a description of the data screening. Then, variable recoding procedures are described. There is an overview of the characteristics of the study participants. Finally, the findings specific to each research question are presented. The chapter concludes with a summary of the findings.

### Data Review

Prior to data analysis, variables in the dataset were examined for accuracy of data entry and missing values. The dataset contained 168 cases, and all independent and dependent variables were examined.

The 35 individual data cells for the *Fear of Pelvic Examination Scale* were summed (as Siwe, 2007 designed the scale to be summed) to determine a FEAR score for the simulator (SIM) and genital teaching associate (GTA) training. Each FEAR score could range from 0-210. The performance scores (LPERF) were totaled to come up with an LPERF score for both the SIM and GTA training. Each performance score had a possible value of 30. Each individual blood pressure reading was converted to mean arterial pressure (MAP) using the formula  $MAP = [(2 \times \text{diastolic}) + \text{systolic}] / 3$ . The highest MAP was noted for each training session. The highest MAP for both the SIM and GTA training were subtracted from the arrival MAP (previously called baseline) to come up with one MAP score for each training session which was called “difference from arrival.”

## Previous Experience

Of the potential 186 second year medical students, 170 students consented to participate in the study at the small group session where the purpose of the study was explained and questions answered. Four students took the consent forms with them and later agreed to participate and returned the forms before the study started. A total of 175 students (94.1%) of the eligible students became study participants. After the study began, a total of 6 students (3.4%) dropped out of the study, one after the simulator training, and the other five before the GTA training, which was their first intervention. One additional student was eliminated from the study when he indicated that he had previously conducted more than 20 pelvic examinations. With that experience, it would be expected that his comfort level with conducting pelvic examinations was not at the same baseline level as the other medical students.

Of the 168 final participants, 140 (83.3%) indicated they had no previous experience performing pelvic examinations. Of the 28 (16.6%) who indicated experience with performing pelvic exams, 24 out of 28 (85.7%) stated that he/she observed someone conducting a pelvic exam, such as a preceptor or at a clinic. These participants were included in the study because they did not actually perform the pelvic examination themselves. Four participants did not answer the question.

Out of the 166 who answered the question which asked about experience with the METI simulator, no one indicated they had any experience with the METI (and only)

pelvic exam simulator used in the study. The METI simulator was on the market less than a year at the time.

Sixty nine out of the 166 (41.6%) who answered the question about experience with other medical simulators indicated they had previous experience using one or more simulator. Experience included use of the Virtual IV simulator (99%), CPR simulators (8.7%), a surgical simulator (1.4%), and a childbirth simulator (2.9%). None of these simulators was similar to the pelvic examination simulator.

Of the 166 participants who were asked if they were taking any medication that might affect blood pressure, 10 (6%) indicated they were taking medication that might have an effect. These findings were analyzed by the physician expert on the research study, who determined that all the drugs listed, with the exception of singular and prevocid, would have an effect on blood pressure, but would not affect the change in blood pressure used as the comparison variable. Also noted was that none of the drugs should alter response to stress, including singular or prevocid.

### **Age of Participants**

The ages of study participants ranged from age 22 to age 45 (mean 25.37 and median 24.5), with 79.2% of participants between the ages of 23 and 26, and 90.5% between the ages of 23 and 28.

## Gender of Participants

Eighty one (48.2%) participants were female and eighty seven (51.8%) participants were male.

## Study Questions

Q1. Does the self-reported Fear of Pelvic Examination Scale (FEAR) score decrease from the first to the second training session?

## Primary Analyses

The mean FEAR score before each training session by sequence group is summarized in Table 1. For students who received the GTA training session first, followed by the SIM training session, mean FEAR scores decreased significantly. The average decrease was 21.7 (95% CI = 15.3, 28.1). For students who received the SIM first followed by the GTA, mean FEAR scores decreased nominally, but not significantly. The average decrease was 4.1 (95% CI = -2.2, 10.3). The decrease in FEAR scores between the first and second sessions was significantly greater for the GS sequence as compared to the SG sequence (difference in decreases = 17.7, 95% CI = 8.7 to 16.7;  $p$ -value = 0.0002).

**TABLE 1: The Mean FEAR by Treatment and Session and Mean Decreases in FEAR (N=163)**

Sequence	Session 1	Session 2	Period 1 to Period 2 Decrease		
	Mean (SE)	Mean (SE)	Mean (SE)	95% CI	$t$ (df), $p$ -value
GS	45.87 (3.55)	24.51 (3.59)	21.70 (3.26)	(15.26, 28.14)	6.21 (80), < 0.0001
SG	49.51 (3.49)	45.91 (3.49)	4.05 (3.18)	(-2.24, 10.33)	1.37 (84), 0.1734
GS – SG			17.67 (4.56)	(8.66, 26.66)	3.87 (164), 0.0002

The average FEAR score before the GTA training sessions was not significantly different for students who had GTA training in the first session (i.e. no previous training session) as compared to those who had GTA training the second session (i.e. already received SIM training) (45.87 vs. 45.91;  $t = 0.008$ ,  $df = 165$ ,  $p$ -value = 0.9936). The average FEAR score before the SIM training sessions were, however, significantly lower for those who had SIM training in the second session (i.e. already received GTA training) as compared to those who had SIM training in the first session (i.e. no previous training session) (24.5 vs. 49.5;  $t = 4.99$ ,  $df = 165$ ,  $p$ -value < 0.0001).

### Secondary Analyses

As described in the previous chapter, the seven consecutive steps of the pelvic exam FEAR scores are measured on: (1) Turn the lights on; Inspecting external genitalia; (2) Separating the labia minora; (3) Inserting fingers into the vagina; (4) Placing the outer hand on lower abdomen; (5) Pushing the outer hand deep in the abdomen; (6) Bimanually palpating the uterus; and (7) Bimanually palpating the ovaries. The mean FEAR score before each training session by sequence group is summarized in Table 2 for each of the consecutive steps. For students who received the GTA training session first followed by the SIM training session, mean FEAR scores for all seven steps decreased significantly from the GTA session to the SIM session ( $p$ -values range from < 0.0001 to 0.0022). The decrease for each step ranged from 1.4 to 3.95. For students who received the SIM first followed by the GTA, mean FEAR scores in general did not change significantly from the SIM session to the GTA session ( $p$ -values > 0.05), with the exception of Step 2, where

scores did increase significantly (increase = 1.1;  $p$ -value = 0.0445). Furthermore, the decrease in FEAR scores between the first and second sessions was in general significantly greater for the GS sequence as compared to the SG sequence for all steps (difference in decreases range from 2.0 to 3.6,  $p$ -values range from < 0.0001 to 0.0128), with the exception of Step 4 where the increases were not significantly different ( $p$  = 0.2813).

**TABLE 2: The Mean FEAR by Treatment and Session and Mean Decreases in FEAR for each Consecutive Step (N=165)**

	Period 1	Period 2	Period 1 – Period 2 Comparison		
	Mean (SE)	Mean (SE)	Mean (SE)	95% CI	t (df), $p$ -value
Step 1					
GS	6.41 (0.55)	3.67 (0.54)	2.77 (0.58)	(1.63, 3.90)	4.16 (80), < 0.0001
SG	5.77 (0.52)	5.02 (0.53)	0.74 (0.56)	(-0.36, 1.85)	1.60 (85), 0.1136
GS – SG			2.02 (0.80)	(0.43, 3.61)	2.52 (165), 0.0128
Step 2					
GS	7.61 (0.60)	4.22 (0.62)	3.39 (0.63)	(2.14, 4.64)	4.92 (81), < 0.0001
SG	8.22 (0.60)	7.08 (0.59)	1.14 (0.62)	(-0.08, 2.26)	2.04 (85), 0.0445
GS – SG			2.25 (0.88)	(0.51, 4.00)	2.55 (166), 0.0118
Step 3					
GS	9.23 (0.73)	5.28 (0.69)	3.95 (0.75)	(2.47, 5.43)	4.70 (81), < 0.0001
SG	10.17 (0.67)	9.22 (0.72)	1.07 (0.74)	(-0.38, 2.52)	1.68 (84), 0.0966
GS – SG			2.88 (1.05)	(0.81, 4.95)	2.74 (165), 0.0068
Step 4					
GS	2.85 (0.49)	1.41 (0.50)	1.44 (0.49)	(0.47, 2.41)	3.17 (81), 0.0022
SG	3.57 (0.49)	2.87 (0.48)	0.70 (0.48)	(-0.25, 1.64)	1.37 (85), 0.1755
GS – SG			0.74 (0.69)	(-0.61, 2.10)	1.08 (166), 0.2813
Step 5					
GS	3.95 (0.59)	1.80 (0.50)	2.15 (0.58)	(0.99, 3.30)	4.20 (81), < 0.0001
SG	3.76 (0.49)	4.09 (0.58)	-0.34 (0.57)	(-1.46, 0.79)	-0.53 (85), 0.5949
GS – SG			2.48 (0.82)	(0.87, 4.10)	3.04 (166), 0.0028
Step 6					
GS	7.88 (0.66)	3.98 (0.63)	3.90 (0.63)	(2.65, 5.15)	6.53 (81), < 0.0001
SG	8.87 (0.62)	8.37 (0.64)	0.50 (0.62)	(-0.72, 1.72)	0.77 (85), 0.4443
GS – SG			3.40 (0.89)	(1.65, 5.15)	3.84 (166), 0.0002
Step 7					
GS	7.93 (0.66)	4.06 (0.63)	3.87 (0.61)	(2.67, 5.06)	6.73 (81), < 0.0001

SG	9.10 (0.62)	8.81 (0.64)	0.29 (0.59)	(-0.88, 1.46)	0.47 (85), 0.6400
GS – SG			3.58 (0.85)	(1.90, 5.25)	4.22 (166), < 0.0001

The average FEAR score before the GTA training sessions was not significantly different for any of the individual steps for students who had GTA training in the first session (i.e. no previous training session) as compared to those who had GTA training the second session (i.e. already received SIM training) with differences (GTA session 1 – GTA session 2) ranging from -0.89 to 1.39 (*p*-values range from 0.0703 to 0.9936). The average FEAR score before the SIM training sessions were, however, significantly lower for all steps for those who had SIM training in the second session (i.e. already received GTA training) as compared to those who had SIM training in the first session (i.e. no previous training session) with differences (SIM session 1 – SIM session 2) ranging from 1.95 to 5.04 (*p*-values range from < 0.0001 to 0.0057).

Q2. Does the learner performance score of the student on the evaluation (LPERF) increase from the first to the second training session?

#### Primary Analyses

The learning activity performance score (LPERF) is derived from observations of participants by instructors (nurse practitioner faculty or GTAs) in each setting. Thus the scores have validity only for that learning activity (simulator or GTA) and cannot be compared across settings.



**TABLE 3: The Mean LPERF by Treatment and Session (N=165)**

	Period 1	Period 2
	Mean (SE)	Mean (SE)
Learner Performance		
GS	28.70 (0.32)	27.28 (0.37)
SG	24.95 (0.37)	28.90 (0.31)

When working with the GTA, learning activity performance scores are not affected by the sequence of instruction (28.7 vs. 28.9;  $t = 0.45$ ,  $df = 166$ ,  $p$ -value = 0.6512). When working with the simulator, however, learner performance scores are affected by the sequence of instruction. Scores increase significantly for students who already worked with the GTA (24.95 vs. 27.28;  $t = 4.45$ ,  $df = 166$ ,  $p$ -value < 0.0001).

#### Secondary Analyses

The mean LPERF score after each training session by sequence group is summarized in Table 4 for each component. As described in the previous chapter, the six components of the evaluation are measured on (1) familiarity with pelvic exam procedure (ready to participate); (2) active participant; (3) at ease while practicing skills; (4) actively support group learning; (5) attends to GTA modesty and dignity; and (6) seeks feedback. For students who received the GTA training session first, followed by the SIM training session, mean LPERF scores decreased significantly for components 1 and 3 (decreases range from 0.21 to 0.28,  $p$ -values from 0.0186 to 0.0088) from after the GTA session to after the SIM session, while there were not statistically significant changes in LPERF scores for components 2, 3, or 6. For students who received the SIM first followed by the

GTA, mean LPERF scores increased significantly for all components from after the SIM session to after the GTA session (increases range from 0.36 to 0.92,  $p$ -value from  $< 0.0001$  to  $0.0006$ ). Furthermore, the increase in LPERF scores between the first and second sessions was significantly greater for the SG sequence as compared to the GS sequence for all components (difference in increases range from 0.48 to 1.2,  $p$ -values all  $< 0.0001$ ).

**TABLE 4: The Mean LPERF by Treatment and Session for each Component (N=165)**

	Period 1 Mean (SE)	Period 2 Mean (SE)
Component 1		
GS	4.68 (0.07)	4.40 (0.11)
SG	3.78 (0.11)	4.70 (0.07)
Component 2		
GS	4.78 (0.06)	4.71 (0.08)
SG	4.37 (0.08)	4.81 (0.06)
Component 3		
GS	4.82 (0.06)	4.61 (0.07)
SG	4.27 (0.07)	4.80 (0.06)
Component 4		
GS	4.83 (0.05)	4.77 (0.07)
SG	4.44 (0.07)	4.85 (0.05)
Component 5		
GS	4.83 (0.05)	4.22 (0.10)
SG	3.64 (0.10)	4.93 (0.05)
Component 6		
GS	4.76 (0.07)	4.59 (0.09)
SG	4.45 (0.08)	4.80 (0.07)

The average LPERF scores after the GTA training sessions were not significantly different for students who had GTA training in the first session (i.e. no previous training session) as compared to those who had GTA training the second session (i.e. already received SIM training). The average LPERF scores after the SIM training sessions were however significantly greater for all components for those who had SIM training in the second session (i.e. already received GTA training) as compared to those who had SIM training in the first session (i.e. no previous training session).

Q3. Is there a relationship between the blood pressure and the performance scores of the medical students?

The slopes (i.e. the change in LPERF for a 1 unit change in MAP) estimated using the linear mixed model for each combination of treatment and session are summarized in Table 5. There was no evidence of a statistically significant relationship between MAP and LPERF for any of the treatments at any of the periods (all  $p$ -values  $\geq 0.2072$ ).

**TABLE 5: Estimates of the Relationship between MAP (X) and LPERF (Y) (N=143)**

Treatment/Period	Slope	SE	DF	t Value	P value
SIM (Session 1)	0.006625	0.02918	144	0.23	0.8207
GTA (Session 1)	-0.02402	0.03123	144	0.77	0.4430
SIM (Session 2)	0.03980	0.03142	144	1.27	0.2072
GTA (Session 2)	0.01061	0.02373	144	0.45	0.6554

Q4. Is there a relationship between the blood pressure and the self-reported *Fear of Pelvic Examination Scale* (FEAR) score?

The slopes (i.e. the change in FEAR for a 1 unit change in MAP) estimated using the mixed model for each combination of treatment and session are summarized in Table 6. There was not evidence of a statistically significant relationship between FEAR and MAP for any of the treatments at any of the periods (all  $p$ -values  $\geq 0.1532$ ).

**TABLE 6: Estimates of the Relationship between MAP (X) and FEAR (Y) (N=141)**

Treatment/Period	Slope	SE	DF	t Value	Pr > [t]
MAP slope SIM (Session 1)	-0.4684	0.3262	142	-1.44	0.1532
MAP slope GTA (Session 1)	0.06617	0.3487	142	0.19	0.8498
MAP slope SIM (Session 2)	-0.06628	0.3510	142	-0.19	0.8505
MAP slope GTA (Session 2)	0.1530	0.2663	142	0.57	0.5665

Q5. Is there a relationship between the self-reported Fear of Pelvic Examination Scale score (FEAR) and the performance score (LPERF)?

The slopes (i.e. the change in LPERF for a 1 unit change in FEAR) estimated using the mixed model for each combination of treatment and session are summarized in Table 7. There was not evidence of a statistically significant relationship between FEAR and LPERF for any of the treatments at any of the periods (all  $p$ -values  $\geq 0.0914$ ).

**TABLE 7: Estimates of the Relationship between FEAR (X) and LPERF (Y) (N=159)**

Treatment/Period	Slope	SE	DF	t Value	Pr >  t
FEAR_Total slope SIM (Session 1)	0.01526	0.008985	160	1.70	0.0914
FEAR_Total slope GTA (Session 1)	-0.01279	0.008300	160	-1.54	0.1253
FEAR_Total slope SIM (Session 2)	-0.00712	0.009433	160	-0.75	0.4516
FEAR_Total slope GTA (Session 2)	-0.00873	0.01032	160	-0.85	0.3987

Q6. Is there a statistically significant difference between the fear scores, learner performance scores and mean arterial pressure by gender?

The differences in fear, learner performance and blood pressure readings between the genders are summarized for each combination of treatment and session in Table 8. These estimates were obtained from the linear mixed effects model and adjust for any effects due to treatment, sequence, or session. Males had significantly greater FEAR scores than females (45.7 vs. 36.6;  $t = -2.06$ ,  $df = 164$ ,  $p\text{-value} = 0.0408$ ). There was not a statistically significant difference between males and females in the mean LPERF scores ( $t = -1.25$ ,  $df = 166$ ,  $p\text{-value} = 0.2122$ ) or the mean MAP ( $t = .08$ ,  $df = 148$ ,  $p\text{-value} = 0.9334$ ).

**TABLE 8: Mean Adjusted LPERF (N=165), FEAR (N=163), MAP by Gender (N= 147)**

	LPERF			FEAR			MAP		
	Mean	SE	95% CI	Mean	SE	95% CI	Mean	SE	95% CI
Females	22.85	0.22	(22.42, 23.29)	36.6	3.2	(30.5, 42.9)	2.80	0.95	(0.91, 4.69)
Males	23.24	0.21	(22.82, 23.65)	45.7	3.1	(39.7, 51.7)	2.69	0.92	(0.87, 4.51)
F – M	-0.38	0.31	(-0.99, 0.22)	-9.1	4.4	(-17.8, 0.4)	0.11	1.33	(-2.52, 2.74)

#### Unexpected Results

At the onset of the study, it was noted that participant's arrival (formerly baseline) blood pressures were possibly in the range recommended by the U.S. Preventive Services Task Force (2007) for hypertension screening. This was unexpected due to the age and general good health of the medical student population. The elevated blood pressure rates were possibly due to the anxiety levels of students before conducting the pelvic examination.

The decision was made to amend the submission to the VCU IRB to provide information to student's whose arrival blood pressure exceeded 140 mm Hg systolic and 90 mm Hg diastolic. The student's were given the High Baseline Blood Pressure Form (see Appendix B) with their blood pressure recorded on it, a reference to the guidelines, a phone number for physician referral, and a recommendation to postpone the scheduled session and to reschedule it.

## Summary

One hundred sixty eight second year medical students participated in the study and more than 90% were between the ages of 23 and 28. Approximately 50% of study participants were male and 50% were female.

For students who received the GTA training session first, followed by the SIM training session, mean fear scores decreased significantly. The average fear score before the GTA training sessions was not significantly different for students who had GTA training in the first session (i.e. no previous training session) as compared to those who had GTA training the second session (i.e. already received SIM training). The average fear score before the SIM training sessions were, however, significantly lower for those who had SIM training in the second session (i.e. already received GTA training) as compared to those who had SIM training in the first session (i.e. no previous training session).

The average learner performance score after the GTA training sessions was not significantly different for students who had GTA training in the first session (i.e. no previous training session) as compared to those who had GTA training the second session (i.e. already received SIM training). The average learner performance score after the SIM training sessions were, however, significantly greater for those who had SIM training in the second session (i.e. already received GTA training) as compared to those who had SIM training in the first session (i.e. no previous training session).

There was no evidence of a statistically significant relationship between blood pressure and learner performance, fear and blood pressure, or fear and learner performance for any of the treatments at any of the periods.

According to the gender analysis, males had significantly more fear than females. There was not a statistically significant difference between males and females in the mean learner performance scores or the mean arterial blood pressure scores.



## CHAPTER 5: Discussion

Chapter Five presents a synopsis of the study and an interpretation of the results as described in Chapter Four. The findings of the study are reviewed in the context of the research hypotheses, and applications to the literature are discussed. Finally, limitations of the study, both to internal and external validity, are examined and recommendations for future research are outlined.

### Summary and Overview of the Problem

Medical education is changing. Physicians have less time for teaching clinical skills and for direct observation of medical students, due to sicker patients in the hospital setting and shorter hospital stays, competing demands of research and patient care and implementation of the eighty hour work week for residents. Another major factor influencing medical education has been the consumer movement, which created greater scrutiny of physicians and an increased awareness of medical errors, patient safety, and the quality of healthcare. The emphasis on safety and quality brought increased attention to the roles and supervision of trainees in the care of patients.

Teaching the pelvic examination has always been ethically complex. Over the years many questions have arisen about medical students learning to conduct the pelvic examination on actual patients in the clinical setting. Examinations of women under anesthesia have been particularly controversial. Changes in the methods of teaching the pelvic examination were inevitable.

Medical students have a fear of injuring patients when conducting the pelvic examination. The introduction of simulation represents a practical, safer alternative to learning on patients. The IOM report recommends the use of simulation training to mitigate injury and simulation training to teach pelvic exam skills aptly applies this recommendation. The use of the pelvic examination simulator and genital teaching associates to teach pelvic exam skills optimizes limited resources, and addresses safety and ethical concerns.

#### Purpose of the Study

The purpose of the study was to evaluate outcomes of a curriculum change which provided novice medical students with more practice in pelvic examination skills. In fact, this curriculum change doubled the time spent practicing a pelvic exam with skilled supervision. The educational intervention utilized a new pelvic examination simulator, and thus introduces a new model for teaching pelvic examination skills to second year medical students. Before 2008 VCU School of Medicine second year students had only one opportunity to learn and practice the pelvic examination, working with GTAs during the Foundations of Clinical Medicine (FCM) course. The FCM course committee sought additional practice opportunities for students before performing the pelvic exam on actual patients in their third year of medical school. This curricular need coincided with the availability of a new and previously untested pelvic examination simulator. A primary goal of the study was to understand how combining a mechanical simulator workshop with the genital teaching associate workshop would address the need for additional practice.

Utilizing both teaching methods, the potential existed for development of a new model for teaching pelvic examination skills to medical students.

#### Review of Outcomes Framework and Research Question

The current study addresses learning at Level 3A, *Declarative Knowledge*, of the Seven Level Outcomes Framework, or *Knows*, according to Miller's Framework, Level 3B, *Procedural Knowledge*, or *Knows How*, and Level 4, *Competence*, or *Shows How*. These formative assessments require ongoing feedback to students and faculty regarding their effectiveness as they proceed through instruction that leads to *Performance* (in the clinical setting), the degree to which participants do what is intended of them in practice. The pelvic examination educational intervention in this study expects students to demonstrate or "show how" to conduct the exam on both the simulator and GTA. The source of data is observation in the educational setting. Level 4 is the highest level outcome possible for medical students, and exceeds the usual outcome measures for medical education of participation, satisfaction, and declarative knowledge. The use of simulation moves medical students from passive observers to active learners. The ultimate outcome measures would be clinical performance, patient health and community health. These delayed outcomes are not feasible measures for an intervention with novice learners.

This study was designed to answer the following research question: Does the sequence of simulator and genital teaching associate affect fear, blood pressure and/or performance in the learning activity in simulation-based pelvic examination training for

second year medical students? Learning more about fear and anxiety of medical students before conducting pelvic examinations could lead to a better training model.

### Methodology

A randomized two-armed design was utilized to provide all medical students with pelvic exam training on both the pelvic exam simulator and with a genital teaching associate in alternate sequences. After IRB approval, 168 second year medical students at Virginia Commonwealth University School of Medicine were enrolled in the study. Data were gathered via a short questionnaire (previous experience and demographics), blood pressure readings, the *Fear of Pelvic Examination Scale* scores and learning activity performance scores. Data analysis consisted of descriptive statistics, paired sample *t*-tests, independent sample *t*-tests and use of the linear mixed model. These statistical tests were used to determine the relationship between fear, blood pressure readings and learning activity performance during each training period.

### Study Findings

In this section, the findings of the study are reviewed in the context of the hypotheses and research objectives. Additionally, both theoretical and practical implications are presented in light of the literature review.

### *Hypotheses*

**Hypothesis one (H<sub>1</sub>) Students will exhibit less fear before the second training period, whether it is genital teaching associate or simulator training.**

Both sequence groups experienced a decrease in FEAR scores before the second training period as compared to before the first training session; however, the GS sequence had a larger decrease in FEAR scores from Period 1 to Period 2 than the SG sequence (decrease of 21.7 vs. decrease of 4.1,  $p$ -value = 0.0002). FEAR before the simulator training was significantly lower for the GS sequence as compared to the SG sequence (24.5 vs. 49.5,  $t=3.87$ ,  $df= 164$ ,  $p$ -value < 0.0001).

**Hypothesis two (H<sub>2</sub>) Learner performance scores after the pelvic exam training are expected to increase from the first training period to the second period.**

The learning activity performance score (LPERF) is derived from observations of participants by instructors (nurse practitioner faculty or GTAs) in each setting. Thus the scores have validity only for that learning activity (simulator or GTA) and cannot be compared across settings. When working with the GTA, LPERF scores are not affected by the sequence of instruction (28.7 vs. 28.9,  $t = 0.45$ ,  $df = 166$ ,  $p$ -value = 0.6512). However, when working with the simulator, LPERF scores are affected by the sequence of instruction. The scores increased significantly for students who had already worked with the GTA. (25.0 vs. 27.3,  $t = 4.45$ ,  $df = 166$ ,  $p$ -value<0.0001.)

**Hypothesis three (H<sub>3</sub>) There will be a direct relationship between blood pressure and performance.**

The hypothesis indicated that the higher the blood pressure reading, the lower the learning performance scores by students after each training. There was not a statistically

significant relationship between MAP and LPERF for any of the treatments at any of the periods (all  $p$ -values  $\geq 0.2072$ ).

**Hypothesis four (H<sub>4</sub>) There will be a direct relationship between blood pressure and fear.**

The hypothesis was that the higher the blood pressure reading, the higher the fear score of the student conducting the pelvic examination. There was not a statistically significant relationship between MAP and FEAR for any of the treatments at any of the periods (all  $p$ -values  $\geq 0.1532$ ).

**Hypothesis five (H<sub>5</sub>) There will be a direct relationship between fear and performance.**

The hypothesis supposed that the higher the fear of performing a pelvic examination, the lower the learning activity performance would be. There was no evidence of a statistically significant relationship between FEAR and LPERF for any of the treatments at any of the periods (all  $p$ -values  $\geq 0.0914$ ).

**Hypothesis six (H<sub>6</sub>) There will be a statistically significant difference in the fear, learner performance scores and blood pressure readings by gender.**

The hypothesis indicated that there would be statistically significant *Fear of Pelvic Examination Scale* score differences between genders, important differences in the learning performance scores of medical students by gender, and statistically significant blood pressure reading differences between males and females. Males reported significantly more fear than females ( $t = -2.06$ ,  $df = 164$ ,  $p$ -value = 0.0408). There was not a

statistically significant difference in the mean learner performance scores between males and females ( $t = -1.25$ ,  $df = 166$ ,  $p$ -value = 0.2122). Neither was there a statistically significant difference in the mean MAP scores between males and females ( $t = .08$ ,  $df = 148$ ,  $p$ -value = 0.9334).

#### Application to the Literature

The current research builds on prior work by focusing on simulation training of psychomotor skills, in this case pelvic examination skills, which is known to be effective (AHRQ, 2001). The study follows the best simulation-based medical education model by utilizing simulation technology, teachers prepared to use the technology to maximum advantage and curriculum integration (Issenberg, 2006). The major flaws of current simulation-based medical education, lack of prepared teachers and curriculum isolation, were avoided.

In the past, literature on pelvic examination skill development focused on the use of the genital teaching associate as a method proven to reduce anxiety and improve student performance (Holzman et al., 1977). The current study utilized both the mechanical mid-fidelity pelvic examination simulator and the genital teaching associate to teach medical students how to conduct the pelvic examination. Using two simulation methods avoided one of the previous mistakes in simulation research, which was to focus on a single simulation method.

The current study adds to the understanding of pelvic examination skill development of medical students. This study demonstrates the importance of the human

interaction with the GTA in order to decrease fear of the pelvic examination. It also demonstrates that learner performance during the simulator session is higher for participants who have already had the GTA experience. After the GTA experience, participants can engage more fully with the psychomotor skills.

This study also adds to the understanding of pelvic examination skill development by identifying specific areas of anxiety. The *Fear of Pelvic Examination Scale* breaks the pelvic examination down into seven distinct steps and students rated their fear at performing each individual step of the exam. Overall, the highest mean fear scores were for Step 3: inserting the fingers into the vagina, Step 7: bimanually palpating the ovaries, and Step 6: bimanually palpating the uterus. Clearly, students are most fearful of the more invasive steps in the pelvic examination procedure. Understanding specific student fears may be helpful in optimizing the GTA experience.

The current study has implications for medical ethics, funding medical education, and quality/patient safety. Use of simulation in medical education reduces ethical concerns. When there are no patients involved during the teaching of the pelvic examination, there are no issues regarding consent or privacy. The pelvic exam simulator poses no ethical concerns. Genital teaching associates are trained educators and their participation in teaching and in educational research is part of an agreement for services, in this study with Eastern Virginia Medical School. Interactions between students and GTAs could be an ethical concern. One item in the learner performance evaluation asked if the student attended to the modesty and dignity of the GTA. The mean LPERF score for the



GS group on that item was 4.83 and for the SG group 4.93 (out of possible 5). Note that both the faculty teaching with simulators and the GTAs are trained to teach not only the psychomotor skills, but also the demeanor and communication skills appropriate to the professional role. Thus, simulation-based learning addresses potential ethical issues in the examination of actual patients.

Teaching the pelvic examination with simulators and GTAs optimized limited resources. GTAs taught pelvic exam skills on themselves and NPs were employed to teach pelvic exam skills on the simulator. The resources were optimized in three ways. First, use of GTAs and NPs to teach pelvic exam skills utilized fewer resources than physicians teaching the same skills using actual patients. Physician time for teaching is a costlier resource than GTAs and NPs. Physicians are able to see fewer patients when supervising trainees, especially the most novice learners. Using GTAs and NPs to instruct novice learners in the simulated setting, physician faculty teaching time can be focused with more advanced learners in the actual clinical setting.

Second, cost savings in the simulated setting can be achieved by teaching in groups of three. In the actual clinical setting, one teacher is usually limited to one learner in order to protect patient comfort and because of limited space in the exam room. When students learn in small groups, there is an opportunity for additional learning while observing peers.

Third, the cost of the simulator is a onetime cost and provides the extra benefit of additional practice. The opportunity cost is also less since the simulator can be used at any time and doesn't require the scheduling of an actual patient in an office or clinic.

The use of simulation to teach the pelvic examination reduces patient safety issues. Students have the opportunity to acquire and practice pelvic exam skills on the simulator without negative consequences for patients. Students are allowed to make mistakes during the training in a safe environment with expert feedback. Students can stop, ask questions, review part of the exam and continue practicing without worrying about injuring an actual patient. There also is a reduction of potential emotional harm because with the GTA the inexperienced examiner has the opportunity to improve hand placement and pressure and to practice verbal phrasing. As a new learner, it is difficult to attend to both psychomotor skills and communication skills simultaneously. The simulation setting permits practice with both skills sets and with their integration.

Today, patients have an increased awareness of medical errors. Learning through patients or while caring for actual patients is no longer an option when there are practical, safer alternatives, such as simulation (Watcher, 2008). Preparing for professional practice will always require the use of actual patients; however, simulation provides a transition to learn basic skills.

#### Limitations – Threats to Internal and External Validity

One of the study limitations was the unequal number of evaluators between the genital teaching associates and the nurse practitioners who taught the students. There were five GTAs who evaluated student performance and ten nurse practitioners (NPs). One nurse practitioner was responsible for training all the other NPs in an attempt to decrease variability and increase inter-rater reliability. Each GTA was trained by a full time

simulated patient trainer. Both trainings were based on the same pelvic examination checklist. Inter-rater reliability was unknown and not measured as part of the study.

The results do not adjust for the different time periods between the two training sessions. Training began in January and ended in April. It is likely that the variation in time between the groups affected the groups equally since the subjects were randomized. There was not expected to be a difference between groups.

All students in the study performed pelvic examinations with blood pressure cuffs attached to their non-dominant arms. This may have produced anxiety and/or discomfort in individuals, but it is unknown how this actually affected performance. Effects of wearing blood pressure cuffs while conducting pelvic examinations was not measured as part of the study.

Another possible limitation of the study was the blood pressure readings from the students aged 20-24. The study participants aged 20-24 had a significantly higher MAP mean than the U.S. population of the same age. It is not known why the students had increased blood pressure readings, therefore higher mean arterial pressures. One might hypothesize that these higher pressures reflect the participants' stress. The setting for blood pressure measurement was more stressful (pre-pelvic exam) than the usual setting where blood pressure is measured.

Possible threats to external validity include results based on the medical students at one point in time at one institution: a large, public, urban academic medical center. The results may not generalize to all medical students across the country or to medical students

in other countries; however, they do represent our institution at that point in time. The participation rate in the study was high - more than 90% of the second year medical students were participants. It is likely that the results represent the student body of medical students at VCU. The gender mix of participants was 48.2% female, 51.8% male; this was similar to the overall gender mix for the class, 50.8% female and 49.3% male.

Another possible threat is that the *Fear of the Pelvic Examination Scale* was validated with medical students in Sweden, not those in the United States. There may be differences due to training, as well as cultural or gender mix.

#### Conclusions and Recommendations for Future Research

Prior experience with mechanical pelvic exam simulators did not appear to reduce anxiety among medical students when first conducting pelvic exams with humans. Completion of pelvic exam training with a genital teaching associate may reduce fear substantially and thus make the sequence of GTA followed by practice with the pelvic exam simulator the optimal first experience. The human simulator (GTA) appears superior to a mechanical simulator, possibly because of increased interaction and feedback from the GTA. Learner performance scores of students working with the simulator overall were higher after an initial GTA training session.

Because anxiety is a barrier to learning, the cost of GTAs is justified. Replacing GTAs entirely with mechanical pelvic exam simulators is unlikely to provide the training necessary for students to acquire these skills.

Use of secondary providers (NPs) to teach pelvic exam skills on the simulator yielded high student performance scores. The cost of using NPs to teach medical students is justified. It is unlikely that unsupervised practice with the simulator would be an effective learning experience for novice students.

Pelvic exam simulators should be made available, however, for medical education as they provide additional cost effective opportunities for students to practice pelvic exams, which provide the ability to begin working toward mastery of the skill.

Areas for future research include continued administration of the *Fear of Pelvic Examination Scale* during third year clerkships, perhaps before and after the Obstetrics and Gynecology clerkship. Students participate in the Ob/Gyn clerkship throughout the academic year, so this would predict what effect clinical experience in general had versus pelvic exam experience.

Another area for possible exploration with third year medical students would be pelvic examination training using GTAs versus actual patients. The cost of using additional GTAs for training would have to be justified and the possible harm to actual patients considered.

Medical students at Virginia Commonwealth University come from many cultural and religious backgrounds. Future research calls for an investigation of how cultural and religious barriers might affect pelvic exam training. A qualitative or mixed method study might reveal interesting details on such barriers.

Further investigation of gender differences and how they might affect skills is also indicated. A corollary study of simulation in learning the male genital/rectal examination would be useful in designing curriculum. The gender of the learner conducting the male exam might be questioned as to his/her fear before conducting the examination.

Genital teaching associates who teach pelvic examination skills on themselves might have a unique perspective on student learning. Their perceptions might be useful in refining the curriculum for medical student learners.

Another possible area for investigation includes interprofessional education. A study might explore the way nurse practitioner students versus medical students learn to conduct the exam and also compare their FEAR scores using the *Fear of Pelvic Examination Scale*.

The study proposes a change in the current medical school curriculum at VCU School of Medicine. Currently, both the pelvic examination simulator and genital teaching associate are being used to teach pelvic exam skills to second year medical students, but in the wrong sequence to maximize learning and reduce fear. A recommendation for change will be made to the course faculty.

There is no perfect model for teaching medical students pelvic examination skills. Medical educators must continue to explore new models, taking into account what has been learned about fear, anxiety, and working with simulators and actual patients.

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U.S. Senate: *Stop All Frequent Errors (SAFE) in Medicare and Medicaid Act of 2000*, 106<sup>th</sup> Congress, 2<sup>nd</sup> session. S. 3672.

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an opportunity to learn from errors. *Medical Teacher*, 27, 193-199.

## Appendices

## Appendix A

# VCU Memo

Virginia Commonwealth University

Office of Research Subjects Protection  
BioTechnology Research Park  
BioTech One, 800 E. Leigh Street, #114  
P.O. Box 980568  
Richmond, Virginia 23298-0568  
(804) 828-3992  
(804) 827-1448 (fax)

DATE: January 7, 2008

TO: Rita Willett, MD  
General Medicine  
Box 980102

FROM: Ann Nichols-Casebolt, PhD *ANC*  
Chairperson, VCU IRB Panel B  
Box 980568

RE: **VCU IRB #: HM11380**  
**Title: Pelvic Examination Skills Taught with a Pelvic Exam Simulator and with Genital Teaching Associates**

On January 3, 2008, the following research study was approved by expedited review according to 45 CFR 46.110 Categories 4 and 7. This approval reflects the revisions received in the Office of Research Subjects Protection on January 3, 2008. This approval includes the following items reviewed by this Panel:

**RESEARCH APPLICATION/PROPOSAL:** None

**PROTOCOL (Research Synopsis):** Pelvic Examination Skills Taught with a Pelvic Exam Simulator and with Genital Teaching Associates, received 1/3/08, version date 1/3/08

- Measures, received 12/18/07

**CONSENT/ASSENT (attached):**

- Research Subject Information and Consent Form, received 1/3/08, version date 11/26/07, 3 pages
- For Genital Teaching Associates: All four conditions for waiver of consent have been met. See §45 CFR 46.116(d). The IRB Panel has waived all elements of consent.

**ADDITIONAL DOCUMENTS:** None

**This approval expires on December 31, 2008.** Federal Regulations/VCU Policy and Procedures require continuing review prior to continuation of approval past that date. Continuing Review report forms will be mailed to you prior to the scheduled review.

The Primary Reviewer assigned to your research study is Thomas Eissenberg, PhD. If you have any questions, please contact Dr. Eissenberg at [teissenb@vcu.edu](mailto:teissenb@vcu.edu) and 827-4617; or you may contact Jennifer Rice, IRB Coordinator, VCU Office of Research Subjects Protection, at [jrice@vcu.edu](mailto:jrice@vcu.edu) or 828-3992.

Attachment – Conditions of Approval

***Conditions of Approval:***

In order to comply with federal regulations, industry standards, and the terms of this approval, the investigator must (as applicable):

1. Conduct the research as described in and required by the Protocol.
2. Obtain informed consent from all subjects without coercion or undue influence, and provide the potential subject sufficient opportunity to consider whether or not to participate (unless Waiver of Consent is specifically approved or research is exempt).
3. Document informed consent using only the most recently dated consent form bearing the VCU IRB "APPROVED" stamp (unless Waiver of Consent is specifically approved).
4. Provide non-English speaking patients with a translation of the approved Consent Form in the research participant's first language. The Panel must approve the translated version.
5. Obtain prior approval from VCU IRB before implementing any changes whatsoever in the approved protocol or consent form, unless such changes are necessary to protect the safety of human research participants (e.g., permanent/temporary change of PI, addition of performance/collaborative sites, request to include newly incarcerated participants or participants that are wards of the state, addition/deletion of participant groups, etc.). Any departure from these approved documents must be reported to the VCU IRB immediately as an Unanticipated Problem (see #7).
6. Monitor all problems (anticipated and unanticipated) associated with risk to research participants or others.
7. Report Unanticipated Problems (UPs), including protocol deviations, following the VCU IRB requirements and timelines detailed in [VCU IRB WPP VIII-7](#).
8. Obtain prior approval from the VCU IRB before use of any advertisement or other material for recruitment of research participants.
9. Promptly report and/or respond to all inquiries by the VCU IRB concerning the conduct of the approved research when so requested.
10. All protocols that administer acute medical treatment to human research participants must have an emergency preparedness plan. Please refer to VCU guidance on <http://www.research.vcu.edu/irb/guidance.htm>.
11. The VCU IRBs operate under the regulatory authorities as described within:
  - a) U.S. Department of Health and Human Services Title 45 CFR 46, Subparts A, B, C, and D (for all research, regardless of source of funding) and related guidance documents.
  - b) U.S. Food and Drug Administration Chapter I of Title 21 CFR 50 and 56 (for FDA regulated research only) and related guidance documents.
  - c) Commonwealth of Virginia Code of Virginia 32.1 Chapter 5.1 Human Research (for all research).

RESEARCH SUBJECT INFORMATION AND CONSENT FORM



TITLE: Pelvic Examination Skills Taught with a Pelvic Exam Simulator and with Genital Teaching Associates

VCU IRB PROTOCOL NUMBER:

INVESTIGATORS: Rita Willett, MD and Brenda Seago, MLS, MA

This consent form may contain words that you do not understand. Please ask the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

PURPOSE OF THE STUDY

The purpose of this research study is

1. To assess M2 students anxiety in performing a pelvic examination before and after practice with a genital teaching associate (GTA) and the pelvic exam simulator (SIM).
2. To assess M2 students readiness to perform a pelvic examination before practice with a GTA.
3. To determine whether order of performance (GTA then SIM or SIM then GTA) effects anxiety in, or readiness for performing a pelvic examination.

DESCRIPTION OF THE STUDY

All students learn the pelvic examination on the SIM and with the GTA as a curriculum requirement for M2 Foundations of Clinical Medicine course. Students who provide consent will complete The Fear of Pelvic Examination Scale (F-PEXS) before practicing with the pelvic exam simulator and before examining the GTA. Study participants will also have a baseline blood pressure and heart rate taken before working with either the SIM or GTA. Blood pressure and heart rate will be measured every five minutes during the SIM and GTA sessions. The GTA will rate the student's readiness to perform a pelvic examination after each GTA session.

Your participation in this study will last up to 3 months. Approximately 150 subjects will participate in this study.

Significant new findings developed during the course of the research which may relate to your willingness to continue participation will be provided to you.

PROCEDURES

If you decide to be in this research study, you will be asked to sign this consent form after you have had all your questions answered.

You will be randomly assigned to the group that completes the pelvic examination training either before or after the genital teaching associate training. Before learning the pelvic examination, you will be asked to complete a short demographic questionnaire, have your baseline blood pressure and heart rate recorded, and complete The Fear of Pelvic Examination Scale (F-PEXS). You will complete the F-PEXS again before your second set of training on either the simulator or GTA. Your heart rate and blood pressure will be monitored while you are learning the pelvic exam on the GTA and on the SIM.

APPROVED

1-3-08 / TE / JR



Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions. Additional information about participation in research studies can be found at <http://www.research.vcu.edu/irb/volunteers.htm>.

#### CONSENT

I have been provided with an opportunity to read this consent form carefully. All of the questions that I wish to raise concerning this study have been answered.

By signing this consent form, I have not waived any of the legal rights or benefits, to which I otherwise would be entitled. My signature indicates that I freely consent to participate in this research study. I will receive a copy of the consent form once I have agreed to participate.

\_\_\_\_\_  
Subject Name, printed

\_\_\_\_\_  
Subject Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name of Person Conducting Informed Consent  
Discussion / Witness <sup>3</sup>  
(Printed)

\_\_\_\_\_  
Signature of Person Conducting Informed Consent  
Discussion / Witness

\_\_\_\_\_  
Date

\_\_\_\_\_  
Investigator Signature (if different from above)

\_\_\_\_\_  
Date <sup>4</sup>

APPROVED

1-3-08 / TE / JTL

# VCU Memo

Virginia Commonwealth University

Office of Research Subjects Protection  
BioTechnology Research Park  
BioTech One, 800 E. Leigh Street, #114  
P.O. Box 980568  
Richmond, Virginia 23298-0568  
(804) 828-3992  
(804) 827-1448 (fax)

DATE: April 8, 2008

TO: Rita Willett, MD  
General Medicine  
Box 980102

FROM: Ann Nichols-Casebolt, PhD *ANC*  
Chairperson, VCU IRB Panel B  
Box 980568

RE: **VCU IRB #: HM11380**  
**Title: Pelvic Examination Skills Taught with a Pelvic Exam Simulator and with Genital Teaching Associates**

On April 8, 2008, the changes to your research study were approved in accordance with 110 (b) (2). This approval includes the following items reviewed by this Panel:

**PROTOCOL (Research Synopsis):** Pelvic Examination Skills Taught with a Pelvic Exam Simulator and with Genital Teaching Associates, received 4/1/08, version 2

- Pelvic Examination Workshop Using the Pelvic Exam Simulator (Measure), received 4/1/08
- Pelvic Examination Workshop with Genital Teaching Associate (Measure), received 4/1/08
- M3 Pelvic Exam Simulator (Measure), received 4/1/08

**CONSENT/ASSENT (attached):**

- Research Subject Information and Consent Form, received 4/1/08, version date 3/7/08, 3 pages
- For Genital Teaching Associates: All four conditions for waiver of consent have been met. See §45 CFR 46.116(d). The IRB Panel has waived all elements of consent.

**ADDITIONAL DOCUMENTS (attached):**

- High Baseline Blood Pressure Form, received 4/1/08
- Reporting of Baseline Blood Pressure Form, received 4/1/08

**As a reminder, the approval for this study expires on December 31, 2008.** Federal Regulations/VCU Policy and Procedures require continuing review prior to continuation of approval past that date. Continuing Review report forms will be mailed to you prior to the scheduled review.

The Primary Reviewer assigned to your research study is Thomas Eissenberg, PhD. If you have any questions, please contact Dr. Eissenberg at [teissenb@vcu.edu](mailto:teissenb@vcu.edu) and 827-4617; or you may contact Jennifer Rice, IRB Coordinator, VCU Office of Research Subjects Protection, at [jlrice@vcu.edu](mailto:jlrice@vcu.edu) or 828-3992.

RESEARCH SUBJECT INFORMATION AND CONSENT FORM



TITLE: Pelvic Examination Skills Taught with a Pelvic Exam Simulator and with Genital Teaching Associates

VCU IRB PROTOCOL NUMBER:

INVESTIGATORS: Rita Willett, MD and Brenda Seago, MLS, MA

This consent form may contain words that you do not understand. Please ask the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

**PURPOSE OF THE STUDY**

The purpose of this research study is

1. To assess M2 students anxiety in performing a pelvic examination before and after practice with a genital teaching associate (GTA) and the pelvic exam simulator (SIM).
2. To assess M2 students readiness to perform a pelvic examination before practice with a GTA.
3. To determine whether order of performance (GTA then SIM or SIM then GTA) effects anxiety in, or readiness for performing a pelvic examination.
4. To compare M2 and M3 anxiety levels before performing the pelvic exam on the pelvic exam simulator using the Fear of Pelvic Examination Scale.

**DESCRIPTION OF THE STUDY**

All M2 students learn the pelvic examination on the SIM and with the GTA as a curriculum requirement for M2 Foundations of Clinical Medicine course. Students who provide consent will complete The Fear of Pelvic Examination Scale (F-PEXS) before practicing with the pelvic exam simulator and before examining the GTA. Study participants will also have a baseline blood pressure and heart rate taken before working with either the SIM or GTA. Blood pressure and heart rate will be measured every five minutes during the SIM and GTA sessions. The GTA will rate the student's readiness to perform a pelvic examination after each GTA session.

Your participation in this study will last up to 3 months. Approximately 150 subjects will participate in this study.

All M3 students learn the pelvic examination of the SIM during the Ob/Gyn Clerkship. Students who provide consent will complete The Fear of Pelvic Examination Scale (F-PEXS) before practicing with the pelvic exam simulator. They will also complete the form asking about prior experience and demographic information.

Significant new findings developed during the course of the research which may relate to your willingness to continue participation will be provided to you.

**PROCEDURES**

If you decide to be in this research study, you will be asked to sign this consent form after you have had all your questions answered.

You (M2's only) will be randomly assigned to the group that completes the pelvic examination training either before or after the genital teaching associate training. Before learning the pelvic examination, you will be asked to complete a short demographic questionnaire, have your baseline blood pressure and heart rate recorded, and complete The Fear of Pelvic Examination Scale (F-PEXS). You will complete the F-PEXS again before your second set of training on either the simulator or GTA. Your heart rate and blood pressure will be monitored while you are learning the pelvic exam on the GTA and on the SIM.

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**APPROVED**

4-8-08 / TE / JR

3/7/08

1

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions. Additional information about participation in research studies can be found at <http://www.research.vcu.edu/irb/volunteers.htm>.

**CONSENT**

I have been provided with an opportunity to read this consent form carefully. All of the questions that I wish to raise concerning this study have been answered.

By signing this consent form, I have not waived any of the legal rights or benefits, to which I otherwise would be entitled. My signature indicates that I freely consent to participate in this research study. I will receive a copy of the consent form once I have agreed to participate.

\_\_\_\_\_  
Subject Name, printed

\_\_\_\_\_  
Subject Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name of Person Conducting Informed Consent  
Discussion / Witness  
(Printed)

\_\_\_\_\_  
Signature of Person Conducting Informed Consent  
Discussion / Witness

\_\_\_\_\_  
Date

\_\_\_\_\_  
Investigator Signature (if different from above)

\_\_\_\_\_  
Date

3/7/08

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4-8-08 / TE / JTR

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#### RISKS AND DISCOMFORTS

There is minimal risk to potential subjects, as all identifying information will be removed from the research database before being analyzed in this study. All data will be de-identified before analysis and kept in a secure location.

#### BENEFITS TO YOU AND OTHERS

This research will further our understanding of pelvic examination skill development of medical students at Virginia Commonwealth University, School of Medicine. The study should be useful to a wider audience interested in identifying areas of anxiety for students conducting pelvic exams. It should also provide valuable information regarding the order of performance (genital teaching associate, then simulator or simulator then genital teaching associate) and how it effects knowledge of, confidence in, or readiness for performing a pelvic exam.

#### PAYMENT FOR PARTICIPATION

You will receive a \$5 gift certificate to Alpine Bagel at the conclusion of the study (M2's only)

#### CONFIDENTIALITY

Potentially identifiable information about you will consist of study questionnaires, blood pressure and heart rate data. Your data will be identified by ID numbers not names, and stored separately in a locked research area. All personal identifying information will be kept in password protected files and these files will be deleted at the conclusion of the study. Other records will be kept in a locked file cabinet for 12 months after the study ends and will be destroyed at that time. None will be kept indefinitely. Access to all data will be limited to study personnel. A data and safety monitoring plan is established.

You should know that research data or (medical information if applicable) about you may be reviewed or copied by the sponsor of the research or by Virginia Commonwealth University.

#### COMPENSATION FOR INJURY

Virginia Commonwealth University has no plan for providing long-term care or compensation in the event that you suffer injury as a result of your participation in this research study.

#### VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this study is voluntary. You may decide to not participate in this study. Your decision not to take part will involve no penalty or loss of benefits to which you are otherwise entitled. If you do participate, you may freely withdraw from the study at any time. Your decision to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled.

#### QUESTIONS

In the future, you may have questions about your study participation. If you have any questions, complaints, or concerns about the research, contact:

If you have questions about your rights as a research subject, you may contact:

Rita Willett, School of Medicine, [rwillett@mcvh-vcu.edu](mailto:rwillett@mcvh-vcu.edu); Brenda Seago, School of Medicine, 1217 E. Marshall St., Box 980496 Richmond, VA [blseago@vcu.edu](mailto:blseago@vcu.edu); 828-3914

Office of Research  
Virginia Commonwealth University  
800 East Leigh Street, Suite 113  
PO Box 980568  
Richmond, VA 23298  
(804) 827-2157

You may also contact this number for general questions, concerns or complaints about the research. Please call this number if you cannot reach the research team or wish to talk to someone else.

153 APPROVED

4.8.08 / TE / JR

3/7/08

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High Baseline Blood Pressure Form

Your blood pressure today is \_\_\_\_\_.

This single reading doesn't establish a diagnosis of hypertension, but since your baseline blood pressure **may be** of medical significance, a clinician will be available to discuss this with you. Please contact Dr. Rita Willett or a back up physician at 828-6791 or 828-7451. We recommend that you postpone your session today and reschedule.

According to the U.S. Preventive Services Task Force recommendation normal blood pressures are lower than 140 mm Hg systolic and lower than 90 mm Hg diastolic.<sup>1</sup>

<sup>1</sup> Wolff T, Miller T. Evidence for the reaffirmation of the U.S. Preventive Services Task Force recommendation on screening for high blood pressure. Ann Intern Med. 2007 Dec 4;147(11):787-91. Review. Summary for patients in: Ann Intern Med. 2007 Dec 4;147(11):143.

APPROVED

4-8-08/TE /JK

Reporting of Baseline Blood Pressure Form

Your blood pressure today is \_\_\_\_\_.

According to the U.S. Preventive Services Task Force recommendation normal blood pressures are lower than 140 mm Hg systolic and lower than 90 mm Hg diastolic.<sup>1</sup>

<sup>1</sup> Wolff T, Miller T. Evidence for the reaffirmation of the U.S. Preventive Services Task Force recommendation on screening for high blood pressure. *Ann Intern Med.* 2007 Dec 4;147(11):787-91. Review. Summary for patients in: *Ann Intern Med.* 2007 Dec 4;147(11):143.



APPROVED

4-8-08 / TE / JR



## Appendix B

11/19/2007 11:41 AM

From: "Siwe Karin" <Karin.Siwe@lio.se>  
To: "Brenda L Seago/HSC/VCU" <blseago@vcu.edu>  
[Dear Brenda,](#)  
[I sent you my thesis last week. You should get it this week!](#)

[Best,](#)  
[Karin Siwe](#)

-----Ursprungligt meddelande-----

**Från:** Brenda L Seago/HSC/VCU [mailto:blseago@vcu.edu]

**Skickat:** den 19 november 2007 14:50

**Till:** Siwe Karin

**Ämne:** Re: SV: Request for Questionnaire

Dear Dr. Siwe,

I'm sorry to bother you again, but could you please send me the questionnaire referenced below?  
Thanks so much.

Brenda L. Seago, M.L.S., M.A., AHIP  
Administrative Director,  
Center for Human Simulation and Patient Safety  
Associate Professor and Director,  
Computer Based Instruction Lab  
School of Medicine  
Medical College of Virginia Campus  
Virginia Commonwealth University  
1217 E. Marshall St. Box 980496  
Richmond, VA 23298  
804-828-3914 phone  
804-828-6144 fax  
[blseago@vcu.edu](mailto:blseago@vcu.edu)

11/12/2007 11:41 AM

From: "Siwe Karin" <Karin.Siwe@lio.se>  
To: "Brenda L Seago/HSC/VCU" <blseago@vcu.edu>

[Dear Brenda L. Seago,](#)

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I am sorry I haven't answered your letter earlier: I have been very busy finishing my thesis. In the article you are referring to, the questionnaire was not validated at that time. Since then we have performed a validation study. This latter study is not presented in a paper yet but the results are presented in my thesis.

You may use our scale as long as you are referring to the source, my thesis. After the validation study the scale got the name Fear of Pelvic Examination Scale F-PEXS. If you are interested I can send you the thesis by mail tomorrow.

Best,  
Karin Siwe MD

-----Ursprungligt meddelande-----

**Från:** Brenda L Seago/HSC/VCU [mailto:blseago@vcu.edu]

**Skickat:** den 12 november 2007 15:18

**Till:** Siwe Karin

**Ämne:** Fw: Request for Questionnaire

Dr. Siwe,

I sent you an email earlier this month, but I realize that I may have asked you the wrong question. The article says that the GyExDQ was not validated at the time of the study, but that a validation study was in progress with 120 participants. When you first refer to the assessment instrument you refer to an article by Louis Vontver, MD. Is he the one who is validating the GyExDQ, and, if so, would you know how I could reach him?

Thanks for your assistance.

Brenda L. Seago, M.L.S., M.A., AHIP

----- Forwarded by Brenda L Seago/HSC/VCU on 11/12/2007 09:12 AM -----

Brenda L Seago/HSC/VCU

11/02/2007 10:22 AM

To karin.siwe@lio.se  
cc  
Subject Request for Questionnaire

Dear Dr. Siwe,

I've read your recent article on medical students learning the pelvic examination with interest. We use standardized patients to teach pelvic exam skills to our second year medical students. This year we'd also like to include the pelvic exam simulator before and after (randomized) the standardized patients. We would like to measure the anxiety level of our students. Would it be possible for me to get a copy of your Gynaecologic

Examination Distress Questionnaire (GyExDQ)? I would really appreciate it. I'm doing research towards my doctoral degree in health policy and administration and am trying to demonstrate the use of simulators and standardized patients as more than skills trainers, but also as important to patient safety efforts. Thanks for your consideration.

Brenda L. Seago, M.L.S., M.A., AHIP  
Administrative Director,  
Center for Human Simulation and Patient Safety  
Associate Professor and Director,  
Computer Based Instruction Lab  
School of Medicine  
Medical College of Virginia Campus  
Virginia Commonwealth University  
1217 E. Marshall St. Box 980496  
Richmond, VA 23298  
804-828-3914 phone  
804-828-6144 fax  
blseago@vcu.edu

## Appendix C

### Prior Experience and Demographics

#### M2 Pelvic Exam Simulator

Last 6 digits VCUCard: \_\_\_\_\_  
Blood pressure \_\_\_\_\_ Heart rate \_\_\_\_\_

#### I. Prior Experience

1. Have you had previous experience performing pelvic exams?
  - No
  - Yes, please explain \_\_\_\_\_  
If Yes,  
Approximately how many pelvic exams have you performed?
    - 5 or less
    - 6-10
    - 11-15
    - 16-20
    - more than 20
2. Have you had prior experience with the METI pelvic exam simulator?
  - No
  - Yes, please explain \_\_\_\_\_
3. Have you had prior experience with any medical simulator?
  - No
  - Yes, please explain \_\_\_\_\_
4. Are you taking any medication that might affect your blood pressure or heart rate?
  - No
  - Yes, please explain \_\_\_\_\_

#### II. Demographics

1. My age is: \_\_\_\_\_
2. My gender is
  - Female
  - Male

## Appendix D

### The Fear of the Pelvic Examination Scale (F-PEXS)

Instructions: Rate your feelings for each of the steps below at the prospect of the pelvic examination you will perform by giving a score between 0 and 6 (0 = “not at all,” 6 = “extremely strong/intense”). Each box should have a number in it.

Step in the PE	Global fear	Impulse to avoid the situation	Disturbing thoughts/ associations	Discomfort	Stress
1. Turn light on. Inspecting external genitalia.					
2. Separating the labia minora.					
3. Inserting fingers into the vagina.					
4. Placing the outer hand on lower abdomen.					
5. Pushing the outer hand deep in the abdomen.					
6. Bimanually palpating the uterus.					
7. Bimanually palpating the ovaries.					

## Appendix E

### Pelvic Examination Workshop With Genital Teaching Associate

	5 Met Expectations	4	3 Neutral	2	1 Expectations Unmet
1	Familiar with pelvic exam procedure (ready to practice)		Familiar with some aspects of procedure		Not familiar with pelvic exam procedures (lack of preparation hinders learning)
Evaluate >					
2	Active participant		Participates with prompting		Fails to participate
Evaluate >					
3	At ease while practicing skills		Uncomfortable but does not hinder learning		Anxiety hinders learning
Evaluate >					
4	Actively supports group learning		Allows all group members to participate		Dominates or disrupts group
Evaluate >					
5	Attends to GTA modesty and dignity		Does not violate modesty or dignity		Disregards GTA modesty and dignity
Evaluate >					
6	Seeks feedback		Accepts feedback		Defensive or argumentative
Evaluate >					

## Appendix F

### Pelvic Examination Workshop Using the Pelvic Exam Simulator

	5 Met Expectations	4	3 Neutral	2	1 Expectations Unmet
1	Familiar with pelvic exam procedure (ready to practice)		Familiar with some aspects of procedure		Not familiar with pelvic exam procedures (lack of preparation hinders learning)
Evaluate >					
2	Active participant		Participates with prompting		Fails to participate
Evaluate >					
3	At ease while practicing skills		Uncomfortable but does not hinder learning		Anxiety hinders learning
Evaluate >					
4	Actively supports group learning		Allows all group members to participate		Dominates or disrupts group
Evaluate >					
5	Palpates ovaries independently		Palpates ovaries with assistance from instructor		Unable to palpate ovaries
Evaluate >					
6	Seeks feedback		Accepts feedback		Defensive or argumentative
Evaluate >					

## Appendix G

### Pelvic Examination Checklist

Introduces self.
Explains to patient what to expect with pelvic exam.
Washes hands.
Wears gloves.
Avoids contaminating surfaces of table, equipment, and specimen containers.
Palpates inguinal regions bilaterally for tender or enlarged nodes.
Touches and moves vulvar tissues as needed to be able to see between folds.
Palpates Bartholin glands at 4:00 and 8:00 between forefinger and thumb.
Inserts speculum correctly.
Finds the cervix. (Give up to 3 attempts – If unable to locate, observe will place speculum and allow student to continue.)
Inspects the cervix for color, size, surface characteristics, discharge, size and shape of os.
Obtains specimen for wet prep. (If indicated)
Obtains specimens for gonorrhea and chlamydia screens.
Obtains specimens for cervical cytology – spatula.
Obtains specimens for cervical cytology – brush.
Inspects vaginal walls before and during speculum removal for color, surface characteristics, discharge.
Removes speculum, maintaining control of closure of blades.
Deposits speculum in proper container.
Informs patient of what to expect during the bimanual examination.
Changes gloves if appropriate.
Applies lubricant.



Inserts two fingers into pt's vagina slowly and places the other hand on the abdominal midline.
Palpates the cervix with intravaginal fingers and assesses for tenderness with lateral motion.
Palpates the uterus with both hands for location, size, and tenderness.
Palpates the ovaries and adnexa areas through the vaginal fornices for masses and tenderness.
In preparation for the rectovaginal exam, changes glove on hand that will be inserted.
Informs patient of what to expect.
Applies lubricant.
Inserts index finger into vagina and middle finger through anal opening into rectum.
Palpates rectovaginal spectrum between fingers for thickness and nodules.
Attempts to palpate posterior surface of uterus.
Palpates rectal wall circumferentially for masses.
Removes gloves disposes of them properly.
Wash hands again.
Conveyed to patient relevant findings.

Comments: \_\_\_\_\_

**Eval:**

- Passed       Needs Improvement       Failed

**Evaluator**

**Date**

## VITA

Brenda Lynn Seago was born on May 16,1953 in Rockford, Illinois and is an American citizen. She earned her baccalaureate degree in Spanish and Elementary Education from Augustana College in 1975and her master's degree in English from Virginia Tech in 1983. She earned her master's degree in Library Science from the University of Maryland in 1986. During her doctoral studies, she worked as the Director of the Computer Based Instruction Lab and as Administrative Director of the Center for Human Simulation and Patient Safety, both in the School of Medicine at Virginia Commonwealth University. She served as a Governor's Fellow in the Kaine Administration in 2006. Brenda was inducted into Phi Alpha Alpha, the honor society for Public Administration, in 2008.