The Ultrasound Practitioner

A Proposal

Response to the SDMS for the Development of A Middle Care Provider in Ultrasound Imaging

Ultrasound Practitioner Commission

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Introduction

The Changing Milieu of Medicine

The societal need for change in the domestic healthcare system has been debated and documented. The debate has created dynamic tensions between cost accountability and traditional unlimited access to care between primary and specialized clinicians, between acute treatment and managed care and prevention, and between individual physician and team providers.[1] Patients, providers, and payers are continuously seeking alternatives that provide quality, community, and patient-centered care.

Medical technology increased knowledge, and interventions have created the need for highly specialized health care personnel other than doctors, nurses, pharmacists, and dentists. These groups of personnel known collectively as *"allied health providers"* are now estimated to comprise 60% of the health care workforce worldwide.[2] In the United States, Allied Health is one of the fastest growing occupational groups as evidenced by a 144% growth rate from 1970-1990.[3] Change within these allied health groups parallel those in other segments and will include increased responsibility for patient management, increased need and opportunity for critical thinking and decision making, and increased involvement on healthcare teams.[4]

The Traditional Role of the Sonographer

Practice of Ultrasound

The art and science of *ultrasonography* has been *practiced* in the United States for more than thirty years. Traditionally, clinical ultrasonographic examinations have been performed collaboratively by both physicians, *or sonologists*, and non-physicians, *or sonographers.* The technical component of the examination (production of images) has been considered the responsibility of the sonographer and the professional component (interpretation of the images) has been the purview of the sonologist. Some argue that the interpretation of the ultrasound image is the practice of medicine. The American Institute of Ultrasound in Medicine (AIUM) has affirmed:

> "Ultrasound studies shall be supervised and interpreted by a physician with training and experience in the specific area of ultrasonography. Findings must be recorded and results communicated in a timely

fashion to the physician responsible for care. Although a sonographer may play a critical role in extracting the information essential to deriving a diagnosis, the rendering of a final diagnosis of ultrasound studies represents the practice of medicine, and, therefore, is the responsibility of the supervising physician.[5]"

The Sonographer

According to the Society of Diagnostic Medical Sonographers, the sonographer[6]:

". . .utilizes high frequency sound waves and other diagnostic techniques for medical diagnosis. The professional level of this health care service requires highly skilled and competent individuals who function as integral members of the health care team. The Diagnostic Sonographer must be able to produce and evaluate ultrasound images and related data that are used by physicians to render a medical diagnosis. The Diagnostic Sonographer must acquire and maintain specialized technical skills and medical knowledge to render quality patient care."

The number of health professionals who specialize in ultrasound has increased exponentially since the 1970's. Currently there are over 34,000 sonographers and vascular technologists registered in at least one of eight specialty examinations by the *American Registry of Diagnostic Medical Sonographers* (ARDMS).[7] These registrants represent a minority of the healthcare personnel actually performing ultrasound examinations. Education, experience, and expertise within the groups of non-physician and physician health professionals practicing sonography vary widely. The need for ultrasound imaging professionals with standardized education and enhanced expertise to apply this technology to patients in a cost-effective and quality manner is essential.

Problems with the Current Model of Practice[10]

The *Diagnostic Medical Sonographer* or *sonographer* is the health care professional responsible for the administration of the diagnostic ultrasonographic examination. In 1970 when the profession was founded, the role of the Sonographer (then known as the *Ultrasound Technical Specialist)* in health care was envisioned to be exclusively technical. Generally, the sonographer exercised limited judgement in diagnosis and patient assessment. The relationship between the sonographer and physician required that both partners be educated, well trained, and experienced.

As ultrasound became an accepted medical procedure, the lack of physician training and development in the field became significant problem. Over the course of time, it became obvious that sonography was highly operator-dependent, and the talent and experience required to interpret sonographic images by the physician was underestimated. Many

incorrectly assumed physicians could easily acquire the skill within the limited duration of their medical education. This was not to be the case.

In the 1970's and 1980's, as the deficiencies in physician training became apparent, the role of the well-trained and experienced sonographer expanded. Because of the daily analysis of hundreds of sonographic images by many sonographers and the close working relationship with subspecialist physicians, their expertise grew in the acquisition and interpretation of these images. These sonographers developed keen interpretive skills that were relied upon by physicians. Chan et. al. stated, *"The functional level of sonographers will vary with their natural talents, their levels of training, and experience, and their ability to integrate their sonographic experiences on the job."*[8] Indeed, many physicians with less time devoted to obtaining the skills necessary to analyze the image became dependent on what the sonographer *"could see"* and the sonographer's description of both normal and abnormal anatomy. This *"non-classical"* approach to sonographic interpretation, not historically envisioned early on, is now common practice in the United States.

In the past thirty years, a variety of problems are known with the current system of clinical practice. While this system is not inherently flawed and it functions well in many regions of the United States, a variety of problems are known to exist. These include, but are not limited to:

- *Logistic limitation*s - The number of patients that can be examined on a daily basis is limited. Large blocks of time are required for sonograms to be reviewed, and sometimes reexamined by a physician.

- *Latency of interpretation* - The final interpretation, for even emergency examinations, often occurs long after the examination has been performed. Thus, the referring clinician does not obtain the diagnosis in a timely manner. The physical distance between sonographer and interpreting physician may contribute to this problem.

- *Deficiencies in physician ultrasound training* – Many sonographers may have more experience and better interpretation skills than their physician counterparts. Sonographers have, through continuing medical education, adapted to new technologies. Physician supervision and interpretation, while an ideal and theoretical goal, may not be universally achievable.

- *Advanced Sonographer Training and Experience* - The clinical demands and diversity of ultrasound practice have fostered an evolution of sonographers practicing beyond the scope of the traditional definition. Some sonographers have achieved both a medical and technical understanding equivalent to that of a physician, nurse practitioner, or physician's assistant. Many sonographers

currently both supervise clinical ultrasonography and interpret ultrasonography studies.[9] Depending on the application of ultrasonography, diagnosis and the rendering of a final report by the non-physician has become commonplace. Unfortunately, no advanced standards of training or practice exist to define this type of practice. This has resulted in the somewhat ill defined, but nonetheless widely accepted *advanced practice of sonography* by the sonographer.

The Commission is concerned that real-life circumstances have led to conditions in which many sonographers are functioning beyond their defined Scope of Practice. Common sonographic practices may put the public at risk because of the lack of both standards of practice and standards of education. We believe that these issues must be clarified and a structure of accountability established. It is with that intent that we propose the new profession of the ***Ultrasound Practitioner***.

The Ultrasound Practitioner

First suggested in 1993 as the Advanced Practice Sonographer[10], the current document has been constructed to propose formally the profession of ***Ultrasound Practitioner.*** In 1996, a Task Force commissioned by the Board of Directors of the Society of Diagnostic Medical Sonographers was charged with investigating the feasibility of this type of practitioner. In 1998, the **Ultrasound Practitioner Commission** was established to develop this profession.

The Ultrasound Practitioner Commission defines the Ultrasound Practitioner as:

Definition

> The Ultrasound Practitioner is a health care professional who autonomously performs and interprets ultrasound procedures in primary or specialty care settings. As part of the interdisciplinary team, the Ultrasound Practitioner will provide services based upon clinical competency obtained by advanced education and clinical experience.

The Ultrasound Practitioner will function as part of a healthcare team with primary responsibility to manage or perform ultrasound examinations. This professional will assess and use critical thinking to contribute to clinical decisions based on the ultrasound results and other primary assessments. The Ultrasound Practitioner may function within radiology, obstetrics, urology, cardiology, vascular surgery and/or other specialty and primary care areas. The Ultrasound Practitioner will work within a healthcare team and in association with a primary care provider or specialty physician. As computer networking and telemedicine evolves, it is likely that some Ultrasound Practitioners may function at a distant

location. The Ultrasound Practitioner will be capable of clinical assessment, patient counseling, and cost-effective patient referrals as well as primary ultrasound imaging assessment. The Ultrasound Practitioner may also be a contact for patients in some team care situations.

These responsibilities have been determined in accordance with the recommendations by the Institute of Medicine that primary care services be provided by a broad array of individuals. Working as a primary care team member, these individuals will have the latitude to structure the division of duties and responsibilities.[11]

Role of the Ultrasound Practitioner

The following is a description of the professional role of the Ultrasound Practitioner:

> The Ultrasound Practitioner is a health care professional who autonomously performs and interprets ultrasound procedures in primary or specialty care settings. As part of the interdisciplinary team, the Ultrasound Practitioner will provide services based upon clinical competency obtained by advanced education and clinical experience. The professional Ultrasound Practitioner certification requirement establishes a qualifying standard in credibility for this practitioner.

The responsibilities of the Ultrasound Practitioner would include the interpretation of the ultrasonographic images and production of a written report. This report must be consistent with the guidelines provided by the AIUM.

Education of the Ultrasound Practitioner

The following is a general statement regarding the education of the Ultrasound Practitioner. A detailed description of proposed educational requisites is provided in Chapter 4 of this document.

> The Ultrasound Practitioner will participate as an integral part of the health care team and will have a standard educational background with all other Ultrasound Practitioners. Guidelines for education are defined by the profession to be completed through a formal educational program. Broad didactic and clinical assessment training will be required regardless in which specialty area the Ultrasound Practitioner ultimately practices. Stringent continuing medical education essentials will be necessary.

Accountability of the Ultrasound Practitioner

The Ultrasound Practitioner, as a member of the health care team, has both accountability and responsibility. Each must be clearly defined.

The Ultrasound Practitioner provides quality services in the best interest of the patient. As a member of an integrated health care team, the Ultrasound Practitioner seeks to improve the patient's clinical outcome. This requires certification and maintenance of clinical skills through in-service, continuing medical education, advanced competency, research and graduate study. The Ultrasound Practitioner consults with physicians as necessary, follows the code of ethics for advanced practice and functions within safe, accepted levels of service. In general, the Ultrasound Practitioner will be accountable for high-quality, holistic patient care that will be ensured by the processes of continuing education, peer review, maintenance of clinical skills and outcome assessments.

The Ultrasound Practitioner accepts responsibility for their individual actions. This role will evolve in response to the changing health care environment. As the Ultrasound Practitioner implements roles of imaging clinician, researcher, administrator and educator to both patients and other medical professionals, adequate didactic instruction and clinical training will be essential when implementing new techniques of practice. Knowledge of the legal boundaries of practice will be required. The Ultrasound Practitioner provides cost effective care and serves as the patient's advocate. The evolving role of the Ultrasound Practitioner will require professional organizational involvement and promotion of the profession among sonographers, physicians, and other health care providers.

Models of Nonphysician Medical Practice

Two models of non-physician clinical practice exist; the *Nurse Practitioner* (NP) and the *Physician Assistant* (PA). Both practice models have unique features that vary from state to state depending on their respective Scope of Practice documents and state regulations. The main differentiation between state Scopes of Practice for these professions is the level of autonomous practice and prescription ordering, and the role of physicians in their practices. Withstanding the need for a licensed physician to prescribe some medications or review patient care plans, a physician is not required to be a part of a NP model. The PA model requires a supervising physician in place to meet most state practice requirements. Depending on state, region, institution, or personal agreements, the PA can and does essentially act as a totally autonomous clinician, using the supervising physician as a consultant.

Nurse Practitioners (NP) have evolved within the functional autonomy model. "Functional autonomy" allows critical thinking and independent decision making within defined boundaries documented by medical professionals as their Scopes of Practice. Today nurse practitioners are accepted nonphysician providers of primary care in pediatrics, obstetrics, gynecology, dermatology, anesthesiology, and a myriad of other specialties. Nurse practitioner practice is grounded in its functions related to patient care and comfort and is respected by consumers for that framework.

Physician Assistants (PA) developed a revolutionary model of autonomy allowing practice flexibility to assume any function as long as clinical competency could be demonstrated provided a supervising physician approved the function. This model of "competency-based autonomy" differs from a standardized scope of practice and allows flexibility to assume a variety of medical services traditionally reserved for physicians. Physician assistants, like nurse practitioners, serve in primary and specialty areas including surgery, pathology, and radiology. Interaction between physicians and physician assistants has been a fundamental tenet in the development of this profession.

The Ultrasound Practitioner Commission has elected to develop this profession as one having attributes similar to both the Physician Assistant and Nurse Practitioner, using a *"competency-based autonomy"* model. Responsibilities and functions are to be defined by clinical competency, integrated with physician interaction and supervision. The emphasis on patient care and comfort and the defined educational standards from the nurse practitioner model will be incorporated. The Commission envisions a relationship with physicians, which will be grounded in competency-based team interaction. Ultrasound Practitioners will assume positions as team members under the general supervision of the primary care provider or specialty physician.

Chapter
2

Why Propose the Ultrasound Practitioner?

Increasing Need for Ultrasound-Related Health Care in the United States[1]

The population of the United States will be changing dramatically over the next 50 years with corresponding changes in healthcare resources to meet population demands. The demographics of a population can be very useful information for the sonographic community. The clinical specialties that sonography serves such as cardiology, vascular surgery, obstetrics and gynecology, and other primary care specialties are directly impacted by supply and demand of the population being served. Thus, the supply of quality medical professionals should meet population demands in normal markets.

The short term general demographic trends show a 4.5 % increase in population from 1995 to 2000. Long term projections suggest an American population of 300 million people by the year 2010, and the possibility of 394 million by 2050 which is a 50% increase from 1995. Median age within the United States will steadily increase throughout the 21st century. In 1995, the median age of the American population was 34.3 years, the highest ever recorded and projected to increase to 35.7 years in the year 2000, and peak in 2035 to 38.7 years. Median age is projected to decrease, slightly, to 38.1 years in 2050. This increase in median age is largely based on the aging of population born between 1946-1964, and presently consists of 30 % (80 million people) of the present population (baby boomers). Thus, the first wave of the baby boomers will reach age 65 in the year 2011 and peak in year 2029. Simultaneously, the population of 25 to 34 year olds will increase at a slower rate in relation to older age ranges, with 37.2 million in 2000 and maximizing to 190 million in 2035.

The older age groups (65 years and older) are estimated to increase well into the 21st century. In 1995, 12.8% of the population was 65 and older and by 2030 will increase to 20 % of the total population (69.4 million people). Of interest, the increases in the 65 and older group after the year

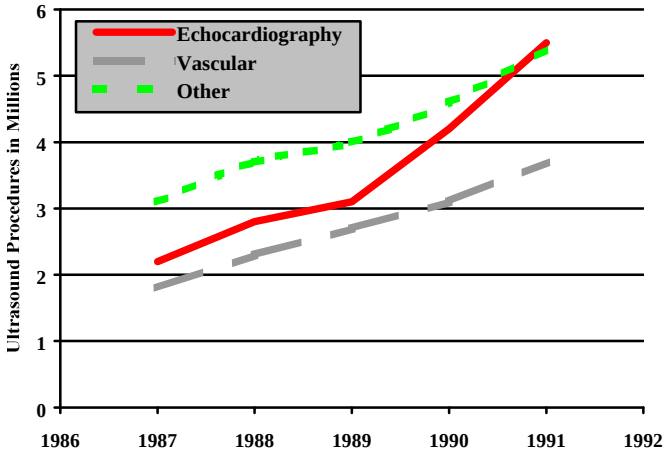
[1] All data in this section based from: Population Projection of the United States by Age, Sex, Race, and Hispanic Origin 1995-2050. U.S. Dept. of Commerce, Economics and Statistics Administration, Bureau of Census, 1996.

2030 will be attributed to the increasing number of the 75-year-old and over cohort. Conversely, the number of births in the United States is expected to remain stable at 4 million per year through 2005. After the year 2011, the number of births would surpass the highest annual birth rate achieved in the 20th century (4.5 million).

Since it has been shown that many pathologic states are age related, including cardiovascular disease and cancers, it is conceivable with the aforementioned data that an increase in sonographic services will be required. This also holds true for the impending increase in birth rates in the second decade of the 21st century.

Increasing Need for Services in the Global Marketplace

Diagnostic ultrasound products sold to physician's offices, hospitals, and clinics have been estimated to be $ 2.5 billion, worldwide. This figure includes the purchase of new equipment as well as upgrades and accessories. The diagnostic ultrasound market accounts for approximately 30% of the total worldwide medical imaging market that includes x-ray, CT and MRI equipment. The North American market (U.S. and Canada) constitutes approximately 34% ($850 million) of the worldwide market. Europe is the largest market with 35% ($ 875 million) of world market share. Japan and Asia Pacific / Latin America have 11% and 20% of the world ultrasound market, respectively.



• Figure 1 Ultrasound procedures paid by Medicare, 1987-1991. Source: Technology Marketing Group, Des Plaines, IL

Diagnostic ultrasound has four primary clinical application areas; radiology, cardiology, obstetrics and gynecology (OB/GYN), and non-invasive vascular diagnostics (Figure 1). Radiology-based ultrasound, which is also referred to as general imaging, is the largest market with half of total worldwide market ($ 1.25 billion). Cardiology, with 30% of the worldwide market ($825 million) is the second largest market, with OB/GYN capturing approximately 15% ($375 million). Non-invasive vascular diagnostics is the smallest market with an estimated 7% ($175 million of the world market). There are also emerging markets within the ultrasound industry such as mammography, musculoskeletal, and intraoperative applications. The growth rate and actual marketshare of

these emerging markets is presently not well known since all major market players are incorporating these applications into pre-existing practices.

Increasing Need for More Economic Health Care

As patient care moves towards outpatient settings, there is a simultaneous decrease of inpatient days. This cause and effect relationship has increased healthcare provider competition and patient/consumer demands forcing the traditional practice of medicine to change. These changes in medical practice methods offer unique opportunities for patient and physician needs be met through quality sonographic care. Although logistical limitations of traditional ultrasound practices can be improved with telemedicine technology, physical limitations still exist. For instance, improvement in time management of normal examinations and the ability to meet patient expectations of high quality, timely, and the convenience of located sonograms cannot not be met unless more non-traditional examining hours are engaged and more human resources are used (sonographer and physician). Strict capital and cost structures imposed by medical practices and institutions from decreasing reimbursement rates require ultrasound professionals to work harder with less resource than in previous years to maintain traditional practices.

To meet these new challenges in healthcare, *"out of the box"* practices must be developed. These practices will have to maintain high quality care, but deliver their particular services using new methods, personnel, and technologies. The demands of healthcare consumers, which are continuously changing, not only allow healthcare services to meet present day market issues, but address the future demographic trends that will occur in the United States, and in fact around the world. Without question, more sonograms will need to be performed as the population gets older which will simultaneously demand high quality at low cost. Private industry is also aware of these demographic needs and is developing new technologies. For instance, the trend in ultrasound equipment manufacturing is the development of multi-modality machines that offer examinationflexibility with high quality imaging characteristics at much lower costs. In fact, these attributes are being met with smaller sized equipment. Hand-held sonographic units with high quality imaging capabilities will be on the market by the year 2000. Recent trends in equipment purchasing have seen mid and low range priced machines drive corporate sales over the last few years, with no change in future trends.

Increasing Physician Services

A shortage of physicians, especially in rural and underserved areas, has been a longstanding and serious problem. National and state policymakers and educators continue to face the challenge of finding

effective ways to increase the supply of rural physicians. In 1999, Rabinowitz *et. al.* investigated this condition to determine the direct and long-term impact of a concerted effort to impact physician shortage in rural areas. [12] The Ultrasound Practitioner would aid in alleviating this problem.

Decreasing Patient Care Costs

The high cost of medical technology does include ultrasound examinations. Although parallel increases in the use of MRI and CT will occur, the inherent advantages of ultrasound, low cost and portability, combined with advances in electronic miniaturization and technology, will ensure continued growth in the use of sonography. The Ultrasound Practitioner's enhanced role will streamline patient care, increasing accessibility, while providing the technical and professional components of ultrasound practice at a lower rate than physicians will provide. The wide variety of experience of sonographers and physicians currently practicing in the field of ultrasound increases costs where inexperience leads to incorrect or ambiguous examinations**.** The Ultrasound Practitioner can reduce costs by providing less ambiguous exams and better quality through defined education and professional entry standards.

Development of the Ultrasound Practitioner is a marketable and quality approach within the evolving health care system. The Ultrasound Practitioner Commission agrees with the American College of Physicians that the scope of practice by non-physician providers should be evidence-based.[20] The Commission will facilitate well-designed clinical trials that will evaluate the role and effectiveness of the Ultrasound Practitioner.

Chapter
3

Effectiveness of Nonphysician Practitioner Services

***Historical*[13]**

In the early 20th century, physicians held a virtual monopoly as the exclusive providers of patient care services. The position of the physician was secured through state licensure and training of large numbers of additional physicians. However, many feel that there is an expanding role for the nonphysician clinician in patient care because:

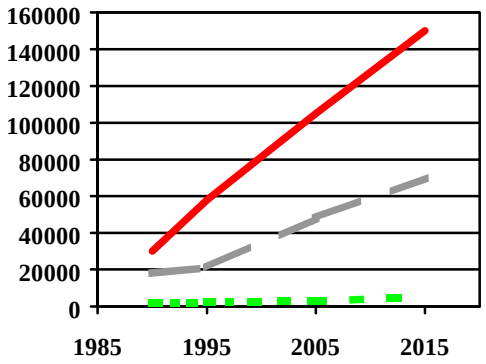
(1) of favorable changes in state and regulations enhancing the practice prerogatives of nonphysician clinicians,

(2) the market is creating new opportunities for these professionals to engage in clinical practice, and

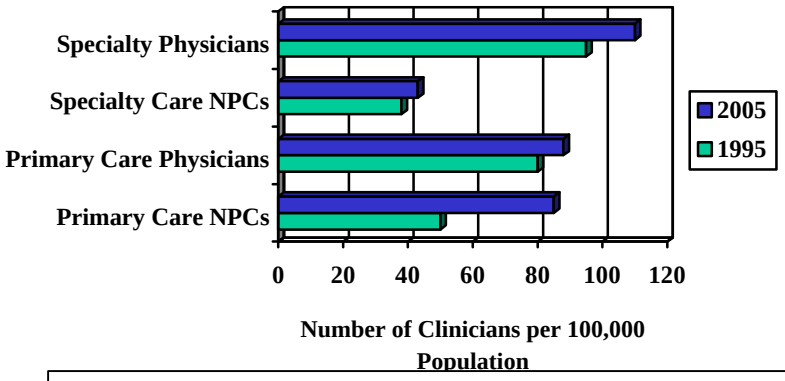
(3) the number of nonphysician clinicians being trained is increasing.

Nonphysician clinicians are recognized because their scope of practice strongly overlaps with the scope of medical and surgical practice provided by physicians (often referred to as *physician services*). These disciplines include nurse practitioners, physician's assistants, chiropractors, acupuncturists, naturopaths, optometrists, podiatrists, nurse anesthetists, and clinical nurse specialists. Practitioners in each of these disciplines are authorized to assume the principle responsibilities for patient care under some circumstances.[14]We expect the Ultrasound Practitioner to be another nonphysician clinician.

Analysis of workforce projections for nonphysicians revealed that the number of these care providers doubled between 1992 and 1997. Further growth of 20% is projected by 2001. It is expected that the total of all nonphysician clinicians (listed above) will grow from 228,000 in 1995 to 384,000 in 2005.[13] It



- Figure 2 Supply and projected supply of number of nonphysician clinicians, 1995-2015[13]. Solid line is *Nurse Practitioners*; large broken line is *Physicians Assistants*; small broken line is *Certified Nurse Midwives*



- Figure 3 Primary and Specialty Physicians and Primary and Specialty Nonphysician Clinicians (NPCs) in 1995 and 2005.[13]

is expected to continue to grow at a similar rate thereafter (Figure 2). This growth is projected to be double that of physician growth for the same period. Growth in the number of nonphysician clinicians serving in specialty areas is expected to be less than that in primary care areas (Figure 3).

As mentioned earlier, there is a significant shortage of physicians in rural and under served areas, there is an oversupply in urban areas. This oversupply is expected to continue for the next decade. How the expanded role of the nonphysician clinician will affect the demand for physicians in the future is uncertain.

Ultrasound Diagnosis and the Nonphysician Clinician

Multiple studies have demonstrated the ability of well-educated and competent non-physician personnel to perform procedures. For example, published studies have found that properly trained, evaluated, and supervised physician assistants or radiological technologists interpreted mammograms with equivalent sensitivity and specificity to trained radiologists.[11,15] In the Netherlands, a large ongoing cancer project uses radiological technologists to perform the clinical examination and palpation on patients and to screen the mammograms with excellent outcomes.[16] In the United States, Physician Assistants and Nurse Practitioners have been shown to provide care indistinguishable in quality from care provided by physicians.[17,18] Patient satisfaction measures were favorable. The Institute of Medicine[11] and the American College of Physicians[19] both support expanded roles for non-physician extenders within a collaborative system that includes a physician who is responsible for the care provided.[20] Many sonographers currently function in an expanded role, as demonstrated by the ARDMS task analysis, suggesting that credentialed sonographers discuss preliminary results with referring physicians 85-96% of the time.[34] Given the wide variety of education and experience within the profession of sonography, the support of a diagnostic role in the current workforce is highly positive for the acceptance of an expanded professional role.

Competence of Ultrasound Services

The precedent for non-physician performance of ultrasonographic examination has been established by sonographers, advanced practice nurses, and physician's assistants.[21,22,23,24,25,26,27,28,29,30,31,32,33] The ability of sonographers to assume expanded roles in the provision of ultrasound services as been documented by both Persutte, *et. al.*[34] and Bates, *et. al.*[35]. Many physicians support an expanded role for credentialed sonographers.[36,37] In the former report, the efficacy of advanced practice sonographer interpretation was compared with that using the traditional sonographer-sonologist model in obstetrical sonography. The authors found no significant advantage to the traditional model in any outcome variable. This represents the only study evaluating the semi-autonomous model of sonographer practice in the United States. These studies can be used to suggest that quality of care is not compromised by the use of well-educated and competent physician extenders.[7,38] In contrast, cost-effectiveness, flexibility, and enhanced communication is provided by a team that include nonphysician providers.

Anticipated Problems with Ultrasound Practitioner Practice

A variety of problems is anticipated with the introduction of a new allied health profession. We considered the evolution of other nonphysician clinicians in order to identify potential difficulties. These problems include:

a) Resistance from sonographers who may feel antagonism for the development of a professional level of sonographic practice. The opportunity to become an Ultrasound Practitioner must be available to all sonographers wishing to advance their career.

b) Resistance from physicians who may be threatened by the medical and economic implications of Ultrasound Practitioner practice. The Ultrasound Practitioner is not intended to be a *substitute for*, but a *supplement to*, the physician who interprets ultrasound examinations.

c) Resistances from referring physicians who may feel that their patients are receiving lesser quality examinations from the Ultrasound Practitioner compared with those evaluated by the sonographer and the interpreting physician. Rigid standards of education and practice will exist in defining the boundaries of the Ultrasound Practitioner and in reassuring patients.

d) The potential for increased liability, discussed later in this document, may discourage collaboration with medical care providers. Current medical imaging assessment in patient care will not be altered by these providers and may, in fact, be improved.

e) Difficulties anticipated concerning reimbursement for Ultrasound Practitioner services. Savings in reimbursement by third party payers will likely support this professional.

f) Difficulties anticipated concerning the resistance by clinical care providers from perceived or presumed direct competition for services to patients. Conversely, support for an Ultrasound Practitioner service may evolve in the form of:

1. care for patients who are socially and economically disadvantaged or non compliant,

2. teaching the role of diagnostic ultrasound practice and medical care,

3. improving diagnosis and care for patients in remote geographic areas or the inner city, and

4. preparatory work for enhancing timely medical care.

Chapter
4

Educational Standards for the Ultrasound Practitioner

Background

Changes in health care in the 21st century will shape the roles of current and future health science practitioners, including the Ultrasound Practitioner. This is the result of changing patient demographics, needs and health care finances. Additionally, clinical guidelines developed by the Bureau of Health Professions Strategic Plan describe expectations of quality improvements in clinical practice within the health professions which developing professions must consider.[39] The Nurse Practitioner and Physician's Assistant roles as specialized members of the health care team are the models for the Ultrasound Practitioner professional.

Suggested educational background requirements for the Ultrasound Practitioner will compare to their and other health science professional educational models.[40,41] State laws mandate graduation from an accredited Nurse Practitioner or Physician's Assistant program as well as current national board certification in order to practice.[42,43] Pioneers in the Nurse Practitioner and Physician's Assistant fields obtained their additional education through various methods, such access to medical and pharmacy school open courses. Clinical internships with physicians provided the necessary clinical experience.

Since then, many schools dedicated to these specialties have developed accredited educational programs that have a standardized curriculum. This process was a lengthy one that has been changed and modified over the twenty-five year evolution of these professions to include courses deemed necessary and to eliminate those that were not. A similar process is anticipated for development of the Ultrasound Practitioner curriculum. As this professional role evolves, courses may be added or subtracted to meet the changing needs of this field and of the health care community. The didactic educational process for the Ultrasound Practitioner is viewed, therefore, as ongoing and dynamic. Additionally, clinical practice guidelines will be specified and standardized in order to meet the required attributes suggested by the Institute of Medicine.[44]

Definition

The Ultrasound Practitioner is a health care professional who autonomously performs and interprets ultrasound procedures in primary or specialty care settings. As part of the interdisciplinary team, the Ultrasound Practitioner will provide services based upon clinical competency, obtained by advanced education and clinical experience. Therefore, the Ultrasound Practitioner will provide quality ultrasound examinations and interpretation, clinical correlation, and suggested follow-up. Although there are sonographers practicing who have many years of experience, the role of the Ultrasound Practitioner is not intended to be that of an advanced-level ultrasound imager providing a preliminary report. Nor is the intention for the Ultrasound Practitioner to be merely an individual who is legitimately compensated for the *"interpretive"* aspect of a sonographer's job. It is not the intention of this document to justify the current job responsibilities of sonographers and expected performance of their everyday duties.

The Ultrasound Practitioner will be required to function at a much higher level of clinical performance. This practitioner will have a more global understanding of the patient's clinical picture, and will participate as an integral part of the health care team. The profession will be standardized and sonography experience is a prerequisite. Added clinical decision-making responsibilities will require a diverse medical education. Broad clinical assessment skills, advanced coursework, a clinical internship and a national board examination will be required. This level of preparation creates a pathway to the practitioner level that is consistent with all other health professional models. Graduation from an accredited program AND certification through an advanced-level national board examination are necessary in order to practice.

The Ultrasound Practitioner will be responsible for obtaining a patient's medical history, performing a detailed sonographic examination, interpreting and reporting the results and suggesting further evaluation or clinical correlation. Whenever appropriate, follow-up will be suggested and performed by this professional. It is imperative that this professional has the medical knowledge and clinical skills to perform at this level.

Educational Requirements

In contrast to the wide latitude of education, clinical background, and clinical roles of the current population of sonographers, the clinical and didactic preparation for the Ultrasound Practitioner will be standardized.

As with the Nurse Practitioners and Physician Assistants, the educational programs will evolve within the defined standards in response to the demand for these new specialists. The goal for Ultrasound Practitioners is a Master's Degree. Future educational programs will be developed so that

this will be a degree with possible concentrations in General Practice, Women's Health, Vascular, and Cardiology. The first Ultrasound Practitioners will arrive at it by a circuitous route. For instance, regardless of one's specialty, the Ultrasound Practitioner will receive core didactic and clinical assessment education followed by specialized clinical and interpretation experience.

Standards of Ultrasound Practitioner Master's Degree

Following is the suggested curriculum for the Ultrasound Practitioner Master's Degree. The educational standards suggested would validate the level of increased responsibility for this professional. Most Master's Degree programs require 30-45 semester credit hours. Prerequisites usually include a Bachelor's Degree with a specific minimum Grade Point Average, usually a 2.5. Although most health science related Master's Degree eligibility requirements do not indicate that the Bachelor's Degree be in a specific science major, the prerequisite science courses are expected and well defined. Based upon the NP and PA models, a clinical internship of 900 hours is envisioned. This internship may be completed in the specialty area chosen by the individual.

Prerequisites for the Ultrasound Practitioner Masters Program consist of th following semester credit coursework:
General Biology (6 Credits W/Lab)
General Chemistry (6 Credits W/Lab)
General Physics
Physiology (6 Credits W/Lab)
Anatomy (3 Credits W/Lab)
College Algebra
Statistics
Psychology
Humanities (8 Credits)
English

Suggested Master's Degree Curriculum for the Ultrasound Practitioner Program should include Core and Concentrated courses:

- Recommended Master's Degree Core Courses:

    - Pharmacology
    - Biomedical ethics or health law
    - Patient history & physical assessment
    - Advanced human anatomy & physiology
    - Advanced pathophysiology & clinical correlation
    - Research methodologies & design
    - Biostatistics
    - Psychosocial aspects of medical care

- Concentration Area Courses - These courses will vary depending on the specialty area elected by the student and will be completed following the core courses. The following are suggested elective courses for each area:

    - General Practice: advanced abdominal imaging (to include other modalities):

        1. advanced abdominal pathologies
        2. non-imaging testing
        3. advanced hemodynamics and physiology
        4. clinical internship

    - Women's Health:

        1. prenatal diagnosis
        2. embryology
        3. prenatal testing and assessment
        4. pelvic examination techniques
        5. pelvic pathologies
        6. non-imaging testing
        7. fetal anomalies, syndromes, and aneuploidies
        8. advanced hemodynamics/physiology
        9. breast disease
        10. clinical internship

    - Vascular:

        1. advanced hemodynamics
        2. vascular testing (non-imaging) & interpretation

3. vascular pathologies
4. advance hemodynamics/physiology
5. clinical internship

- Cardiology:

1. advanced hemodynamics/physiology
2. congenital heart disease & corrective procedures
3. acquired heart disease
4. medical and surgical treatment
5. contrast agents
6. other cardiac testing (Holter monitors, treadmills)
7. electrophysiology
8. clinical internship

Completion of this Master's Degree will entitle the Ultrasound Practitioner to be eligible for the Ultrasound Practitioner National Board Exams. Successful completion of the Ultrasound Practitioner Board Exams will then allow them to practice in his/her chosen specialty area. Suggested designated credentials would be Ultrasound Practitioner-OB/GYN, Ultrasound Practitioner-C (cardiology), Ultrasound Practitioner-GP (general practice), and Ultrasound Practitioner-V (vascular).

National Board Certification

It is inconceivable that any health care provider would simply begin practicing because they have many years in the field at some level of patient health care or have completed the required coursework in a particular didactic program without a national certification or licensing examination. A standardized national board certification examination will be created. Examination development will include a comprehensive section for all candidates as well as specialty sections as listed above. Examination questions should include contributions from physicians and practitioners in the designated specialty areas. This certification examination would act as a means to practice. Whether or not individual states require separate licensure for this practitioner is a different issue and not addressed in this chapter.

Several agencies have national recognition for advanced certification examination development.

Continuing Medical Education

Continuing education will be mandatory for this individual to remain competent and current in his/her chosen specialty. According to the

principles set forth by the PEW Health Professions' Taskforce to develop health care reform and workforce regulation, recommendation was made that states require implementation to measure continuing clinical competency objectives in order to ensure competency of health care professionals.[45]

With the advent of additional developments in specialized ultrasound procedures and technologies, this professional will also be required to stay current in their field as these and other new procedures become a part of their everyday practice. A designated number of Continuing Medical Education units in AMA category 1 would be required. A suggested number of Continuing Medical Education credits is 20 per year, which is consistent with or less than the NP and PA Continuing Medical Education requirements.

Educational Development

The suggested educational requirements listed above attempt to allow for the various pathways by which sonographers may enter the Ultrasound Practitioner profession. As the educational backgrounds of these interested individuals become more standardized, such as a Bachelor's Degree for entry-level sonographers, the curriculum of the Master's Degree can be modified.

Temporary Tracts

Since there are currently no programs offering the above-mentioned education, the first individuals to pursue this degree will be required to take courses currently offered from a number of existing programs, thus developing a self-guided interdisciplinary curriculum and internship. As long as the suggested coursework closely parallels that which is recommended, this route will be satisfactory until a dedicated Ultrasound Practitioner Master's Degree can be implemented.

Until such time that the Master's Degree is available, arbitrarily set for 2010, temporary tracts by which a sonographer may prepare for eligibility to the Master's programs in Ultrasound Practice are as follows:

- TRACT 1: Pre-requisites are a two-year allied health Associate's Degree plus graduation from an accredited ultrasound educational program of no less than 12 months and ARDMS certification. Course work would include those liberal arts and additional science courses necessary for this individual to obtain a bachelor's degree on the way to this Master's Degree.

- TRACT 2: Pre-requisites are a two-year Associate's Degree in Diagnostic Medical Sonography from an accredited community or technical college and ARDMS certification. Course work would include those liberal arts and science courses necessary for this individual to obtain a Bachelor's Degree on the way to this Master's Degree.

- TRACT 3: Pre-requisites are a Bachelor's Degree in ultrasound or a related science, such as medical imaging, biology, genetics, kinesiology, or nursing. These individuals would then take only those courses necessary for the Master's Degree, provided that they had taken the prerequisite courses within their Bachelor's Degree. All individuals with a Bachelor's Degree in areas other than sonography must be ARDMS certified.
- TRACT 4: Those individuals who received their allied health education through hospital-based programs and/or on-the-job training and are ARDMS-certified sonographers, would be required to have taken those liberal arts and additional science courses to obtain a Bachelor's Degree before applying for the Master's Degree program. Course work would be the same as those individuals on TRACT 1.

In order to begin clinical practice, successful completion of a national board certification examination must occur.

The Commission has suggested the following qualifications for entry-level practice:

	Up to 2010	After 2010
Minimum Education for Entrance to Clinical Training	Bachelor's Degree (with basic science coursework as suggested)	• Bachelor's Degree (with basic science coursework as suggested) • Ultrasound Practitioner Master's Degree Core Curriculum
Minimum Certification	RDMS, RDCS, RVT or CCI certified	RDMS, RDCS, RVT or CCI certified
Suggested Master's Degree Clinical work and Boards	• 5 Years sonographer clinical experience • Completion of core curriculum • Post-graduate clinical training in Ultrasound Practitioner Program (18-24 months) • Successful completion of Ultrasound Practitioner national board certification examination	• 5 Years sonographer clinical experience • Post-graduate clinical training in Ultrasound Practitioner Program (18-24 months) • Successful completion of Ultrasound Practitioner national board certification examination

Chapter
5

Legal Implications of the Ultrasound Practitioner

The medicolegal consequences of advanced practice sonography are unique and of particular importance to the potential practitioner.

Medicolegal Liability for Medical Practitioners

Mid level providers have become integral parts of the health care delivery system. The role of the Ultrasound Practitioner is being developed as another mid level care provider or *"physician extender"* with similar responsibilities and medicolegal concerns as a nurse practitioner, physician's assistant, optometrist, podiatrist, or audiologist. The Ultrasound Practitioner must be aware of the risks for liability in this role. This section briefly discusses liability issues that may be encountered by an Ultrasound Practitioner and recommendations for coverage. Based on the Practitioner's expected required certification and or licensure, he will have an independent duty to the patient and will be, therefore, solely responsible for the well being of the patient while in his care. The burden of the Ultrasound Practitioner will be similar to that of the licensed nurse. As an example, the 1987 Georgia Appellate Court ruled that the failure of a Registered Nurse to take an accurate medical history of a patients serious condition (his responsibility to the patient) and convey that information to an physician, the individual nurse was liable.[46]

Medicolegal concerns for the Ultrasound Practitioner will extend beyond his or her own duties and will involve other health care providers. Sonologists and other physicians may be reluctant to collaborate with or supervise Ultrasound Practitioners because of the potential for their malpractice liability and insurance to rise. This may be relevant because of a statute from the Missouri Supreme Court decision of 1983. The Court ruled that if standing physician orders exist, that physician can be held liable if a care provider under his supervision incorrectly diagnoses or fails to diagnose pathology. [47]

All licensed, limited license, and unlicensed medical and nursing practitioners must comply with professional and technical standards established by their respective professions. No standards currently exist

for the Ultrasound Practitioner. This document introduces the foundation for the professional standards for the Ultrasound Practitioner. The Scope of Practice and standard of care for a medical professional is defined by their medical license, training, educational certification, and/or by state statute. Laws regulating the practice of mid-level care providers vary greatly from state to state. Relevant to all practitioners, however, is medical malpractice and the tort of negligence. This exists if the following conditions are violated:

- *Pre-existing duty*: The provider of care must agree to care for a patient.
- *Breach of duty*: The provider of care does not meet standard of care in the performance of their duties.
- *Damages*. The action or inaction of the care provider directly results in an injury or loss to the patient.
- *Proximate cause*: There must be causation between a negligent act or omission and damages suffered by the patient.

Common causes of liability in medical imaging include:

- Negligence
- Failure to diagnose
- Liabilities for procedural complications, or inadvertent or inappropriate procedure
- Improper treatment
- Negligence

The most common risk an Ultrasound Practitioner is likely to encounter is for a common *tort* in medical practice known as *"negligence"*. Negligence can be either in the form of omission or commission. An omission results when the practitioner fails to perform an action that a reasonable, prudent individual would do in a clinical situation. This individual, by education and training, may be liable for failure to know their role if a reasonably prudent individual (in a similar circumstance) would have known what to do or not do. This could be extended to performing certain procedures without adequate skills rather than referring the patient to a physician. Thus, the Ultrasound Practitioner at times may need to contact the physician for information and instruction in certain situations. Conversely, an act of commission occurs when the practitioner performs an act that a reasonable, prudent individual would not do in a clinical situation.[48]

The risk of negligence can be minimized when the Ultrasound Practitioner is aware of underlying clinical conditions of the patient, by performing a careful history and physical examination, and considering other relevant laboratory testing. Thus, *"foreseeability"* can be offset if the Ultrasound Practitioner is always aware of the patient's clinical status.[49]

Failure to Diagnose

False diagnoses in ultrasonography occur in the forms of both false positive and false negative diagnoses. The Ultrasound Practitioner must posses a clear understanding of both the potential and limitations of ultrasound in making accurate medical diagnosis. This is particularly the case concerning clinical conditions where the technology is used for diagnosis.

Accountability

The accountability of the Ultrasound Practitioner may be linked to both the patient, and physician or managed care organization. An Ultrasound Practitioner could be held also to the *"doctrine of respondent superior"* where negligence of another health care professional, with whom the Ultrasound Practitioner works (i.e. a physician), can place the Ultrasound Practitioner in a position for liability; particularly if there is failure to act in a given situation where the Ultrasound Practitioner has been involved in patient care.[50]

As professionals, any legal actions against an Ultrasound Practitioner should likely be based on theories of malpractice rather than negligence. Since an Ultrasound Practitioner will be rendering a diagnosis, statute of limitations must be established in any case of malpractice.[51] Actions in a medicolegal suit that involve an Ultrasound Practitioner will likely be compared to those of physicians, until the independent nature of the Ultrasound Practice is established.

An Ultrasound Practitioner will require liability insurance. Although the rates of malpractice premiums can not be predicted, they will likely be influenced by the Ultrasound Practitioner's practice discipline.[52] Typical insurance carriers could include both physician owned companies or commercial joint underwriting associates (i.e., state insurance commission). More than half of physicians in practice are insured through physician owned companies. Locations of practice will affect premiums and states with high litigation rates. For example, Florida, California, New York, and Michigan will likely require higher premiums. The Ultrasound Practitioner must be aware of the limits of liability and whether defense costs are included within the policy limit or provided in addition to the limit.

Standard of Care

Well-defined and documented standards of care and practice will be required for the Ultrasound Practitioner. Acceptable practices for the Ultrasound Practitioner will be established on a local, state, and national levels. National Standards will be developed by professional organizations or established from data presented in recognized publications. Local standards may include internal the policies/procedures of a specific health care organization (HCO).

Standards for the Ultrasound Practitioner should be systematically reviewed every 2-3 years to ensure that they comply with the referring physicians' guidelines or other guidelines of a health care organization. These standards must be flexible and address, for example, handicapped individuals' care and care provided in rural areas where medical facilities may not be specialized or advanced to render *"reasonable"* or *"proper"* care. It should be noted that the *"Standard of care"* is often abstract and a *"locality rule"* may apply. A locality role measures a practitioner's standards against the standards of others practicing in the same or similar community rather than a national standard.[50]

Credentials/Licensure

As a health care *"professional,"* the title of the Ultrasound Practitioner may be broadly defined, but will have several common factors. First, the Ultrasound Practitioner will have achieved a nationally recognized credential. Credentialing will occur through a testing process given by a non-governmental agency or association. This *"Board"* examination will be used to establish minimum knowledge or competence in a given practice area beyond a general level. The examination should be based on recognized standards, have rigorous entry requirements (i.e. bachelors or masters level education depending on professional development), and be psychometrically validated. The testing agency should be accredited by the National Commission for Certifying Agencies.

The Ultrasound Practitioner must complete a rigorous course of study in their field from an accredited educational program. The program should be accredited either though the United States Department of Education and/or the Commissions on Recognition of Post Secondary Accreditation. This will assure a program is validated and the curriculum meets specific content objectives and national standards. Programs meeting such standards of the United States Department of Education will be then eligible for federal funds (i.e. student financial aid). The educational organization should be licensed by the State Department of Health and be willing to undergo peer review validations.

As a health care professional, the Ultrasound Practitioner will, therefore, have a recognized credential and level of education. The Ultrasound

Practitioner will have a state license and registration with the state board of Health. The practitioner's name, address, location, nature and operation of service will be the required registration information. Licensure will ensure the public that the Ultrasound Practitioner has attained a minimal degree of competence to ensure public safety and welfare.

Since licensure of the Ultrasound Practitioner will be required, this profession will need to be added to the National Practitioner Data Bank (established with Health Care Quality Improvement Act of 1986 and the Medicare/Medicaid Patient and Protection Act of 1987).[53] If Ultrasound Practitioner functions in a hospital setting, with clinical privileges, it will be important that the organizations peer review panels are composed of Ultrasound Practitioners or similar professionals.

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