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ABSTRACT

Nurses are prime users of medical devices in patient care and must be aware of four safety issues: safety of the patient, the information, the personnel, and the device. Thus, nurses need to be able to understand and communicate in the language of technological devices. With formal coursework in the use of instruments being limited, agency in-service programs taught by biomedical technicians or manufacturers' representatives have become primary sources of information. As nursing care increasingly takes place in home settings, nurses have become both primary users of devices and primary teachers of patient users. Lack of formal education and experience regarding safe use of medical devices has led to development of the Abbey-Shepherd Device Education Model. The model is designed to be additive, be applicable to all medical devices, permit incorporation into ongoing curricula, allow for constant updating, and be based upon scientific principles. The model covers characteristics of each device, operating principles, common use errors, adverse patient reactions, device failures and their frequency, safety concerns, device function and safe use, and care of instrument. (19 references) (JDD)

PROCEDURAL, EDUCATIONAL AND CARING ASPECTS OF NURSING AND HEALTH CARE TECHNOLOGY

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INTRODUCTION

Technology first invaded health care with slow measured steps related to unique situations, such as, kidney failure, respiratory support, central line pressures, and cardiac monitoring. Concurrently, transistors allowed miniaturization of devices and promoted the development of high speed electronic computers.

The speed at which advances in technology pushed science and science-generated technology led to a logarithmic curve of invention and discovery, fed by the zest and rewards of successful innovation. Technological progress permitted and sustained increasingly "far out" intervention and more complex care. The new treatments required more sophisticated instruments and greater monitoring precision as technology furnished the means for testing science. Thus, the major outgrowth of the merging of technology and science is information, at once the essence of knowledge and the power of science.

With computerization and refinement of physiological sensors and monitors, technology afforded two major thrusts to science and health care. Two slaves, as it were, to provide information to the intellect: that of memory and that of extension of the sensors, or, respectively, the computers, and monitoring of subcutaneous events. The advantages of these technological information slaves are: replicability, information, precision, sharing of information through visual or print-out displays, and multiple simultaneous event recordings in real time. Thus, otherwise unmanageable and unattainable information for intellectual processing was attained and knowledge was generated and became available to medicine and health care.

In the mid-1960s, regional medical programs became the first nationwide effort to update both physicians and nurses in cardiac care and the use of electrocardiographs. Within a short time, clinical specialty organizations developed, led by the Association of Critical Care Nurses. Hospitals redefined themselves into acute, intermediate, and diagnostic centers. The technology used in each depends on the acuity level of care, purpose of stay, patient's condition, and diagnosis. The level of acuity of care within institutions rose concurrently with the introduction of the machines and materials of technology and the cost containment programs of Diagnosis-Related Groups (DRGs). As length of patient stay decreased with early discharge, the use of devices in the home became increasingly common.

SAFETY ISSUES

Safety of the patient

Safety of the information

Safety of the personnel

Safety of the device

A concern about safety and iatrogenic illness grew more apparent (Steel & Gertman, 1981). Nursing's contribution to the problem was, at first, rarely acknowledged. In 1984, however, investigation by the Food and Drug Administration revealed nurses to be a prime user of devices in hospitals. This finding is not surprising because there are almost one and a half million licensed practicing nurses in the United States and 60 percent work in acute care hospitals (American Nurses' Association, 1987).

Considering that nurses care for patients 24 hours per day, it is readily apparent that nurses are the primary user of medical devices in patient care. These activities require that attention be paid to four safety issues. Safety concerns of nursing, therefore, include that the instrument be safe to use on the patient, and that the information obtained be accurate and safe to use for care and in caring environments.

The device needs an informed user for protection from abuse and misuse who can determine and describe accurately the elements of malfunction for determining whether repair or replacement is necessary. The question then becomes: *Can nurses address these safety issues?*

DEVICE REQUIREMENTS

Stable without a tendency to fail or break

Reliable and accurate over long time periods without decreasing or interrupting service

Free from user hazzard, such as leakage of current or sharp edges

THE PROBLEM

The overall problem is complex and multifaceted. Health care, in all of its areas, has embraced advances in technology more than any other industry. The intrinsic and extrinsic changes have been quick, dramatic, and continuous. With technology feeding science and science generating technology the only visible constant is change. Yet, throughout the process, two stabilizing factors remain: (1) the common basic understandings of the involved scientific principles and (2) the need to understand the unique languages of the participants. Communication between and among disciplines is essential to insure successful attention to the four safety issues. Education of the participants in health care delivery depends upon these commonalities for communication. Nurses, as primary users of the technology, need to be able to understand and communicate in the language of devices.

Nursing Education

Nursing education as a whole was not prepared for the rapidity or constancy of change in the health care settings. Change built upon change as long-term plans became yesterday's bondage. Nursing education concentrated on developing clinical skills and nursing science. Technology entered most schools in the form of computers to be used as memory extenders in compiling and analyzing data. The sensor extenders (psychological monitors), by contrast, rushed into clinical settings, but not the schools. All schools, however, taught about intensive care, which included monitoring and sophisticated treatment devices, concentrating on the indicated nursing care.

Although this action was logical, and even commendable, it negated important aspects of care and understandings. In particular, the four issues of safety--safety of the patient, safe to use patient information, safety of the personnel, and safety of the device--were not addressed. The same pattern occurred at both undergraduate and graduate levels. A 1980 survey showed only four graduate programs offered courses in bioinstrumentation, and the remaining 254 responding collegiate programs expressed little interest in changing this situation. A more recent survey of accredited schools in 1986 (Abbey, DePalma, & Rome, 1986), showed change beginning at the baccalaureate level, with five of 299 schools reporting an elective course specifically in clinical instrumentation.

An additional 146 programs, 49 percent, noted a course that included an instrumentation component. Descriptive course materials (N=106), examined by three raters for inclusion of theoretical principles underlying the equipment, showed that emphasis remained on the information gathered, for example, critical

EKG interpretations or instrument-specific set-ups for hemodynamic monitoring. General principles on how the instrument worked or influenced the information obtained were lacking.

The survey of accredited graduate programs resulted in a 66 percent response (50 of 77 programs responded). Nine out of 15 schools stating that an instrument course was taught also sent course materials. Review by three raters showed that only two course descriptions included underlying principles basic to instrumentation and clinical devices. Four course descriptions, which supposedly addressed instrumentation, did not mention devices, equipment, monitors, or instruments. All course material did, however, emphasize nursing care, patient assessment, and the dependence of interpretation and evaluation of patient progress on the obtained information (Abbey, DePalma, & Rome, 1986).

The next question is: *Do the practicing nurses recognize a need for further formal coursework?* A small exploratory study was done to determine interest and support for a course that concentrated on overall principles of medical devices, how they worked, the purpose for use, operational procedures and safety concerns in hospitals, clinics, and home use (Abbey, DePalma, & Rome, 1986). The questionnaire was sent to 15 urban and suburban agencies for distribution to three nurses at each site. Twenty-six of the respondents worked in acute care or step down units; nine were nurses involved in home care delivery. The educational backgrounds included eight diploma graduates, 11 with baccalaureate degrees, and 14 with master's degrees. There were no associate degree nurses in this sample.

Formal coursework in the use of instruments was limited. Agency in-service programs taught by biomedical technicians or manufacturers' representatives were cited as the primary sources of information. The respondents named 77 different instruments used in patient care. Of the 35 returns (77.7 percent) 34 felt the need for a clinical instrumentation course. Fourteen out of the 15 agencies agreed to reimburse tuition fees and pay for time off to attend classes (Abbey, DePalma, & Rome, 1986).

The Settings and the Players

The interest of home care nurses and the support of their agencies with time and money to learn about the devices reflect the mounting changes in home care due to tightening hospital budgets, increasing average inpatient severity of illness, earlier discharge to home care or nursing homes, and development of treatment protocols that permit and facilitate the use of complex technology at home (Abbey, DePalma, & Rome 1986). According to the Secretary's Commission on Nursing (U. S. Department of Health & Human Services, 1988) a 52 percent and 47 percent increase in Medicare-supported home visits and skilled nursing units, respectively, occurred between 1980-1987.

Swanson (U. S. Department of Health & Human Services, 1988) reports that due to a growth in the use of complex technologies, a greater need exists for professional nurse care in ambulatory settings. The size of the market for home care equipment is estimated at $1 billion to $2.6 billion annually (Home Health Line, 1986). Reimbursement standards lagged behind introduction of the equipment into the home. The increasing financial expenditure and risk continues to emphasize the need for knowledgeable user evaluation of design and manufacturing reliability for home care.

Whether user or teacher of patient users, the nurse needs knowledge of principles, experience, and use of devices to incorporate technological advances into practice settings.

Nursing education no longer can depend upon the controlled, expert-saturated environs of hospital in-service to teach the use of devices because practice settings are also changing. Use of medical devices in either hospital or home settings involves many interarticulating groups in implementing safe care. A brief list

includes manufacturers, supply buyers, regulating agency personnel, bioengineers, biomedical equipment technicians, physicians, nurses, physical therapists, respiratory therapists, nutritionists, infusion therapists and, some would say, liability insurers (Home Health Line, 1986). These groups all depend upon the knowledge and skills of each other to "do right by the patient," that is, to use the device in compliance with all four aspects of safety in caring for the sick and infirm.

The nurse, as a primary user of the technology, needs to understand and communicate in the language of the devices.

At the interface between user-machine-patient, the acute care setting differs greatly from the home care setting. In the hospital, trained personnel use the equipment on very ill patients. In the home, the patient and family members govern use. In the hospital, malfunctioning instruments are replaced rapidly by experts. In the home, where failure can be just as life threatening, support services are not usually as readily available. The contrast becomes apparent when access to resources is compared. The hospital is a controlled environment with ready availability of a variety of knowledgeable, experienced professionals. The home lacks constant access to the widely experienced professional. In the hospital, nurses are a primary user of devices; in the home, nurses are the primary teacher of patient users. In either case, nurses require knowledge of principles, experience, and use of devices to be able to incorporate technological advances into both practice settings.

SAFE USE MEDICAL DEVICES

As medical devices for diagnoses, therapy, monitoring, and recording move into all health care settings, changes occur in the roles of the care-giving personnel. New responsibilities replace and/or are added to old. Patient responses and the expectations of society modify. Educational requirements alter upon reevaluation. The language of each discipline incorporates new terms from different perspectives, bias, knowledge base, interest, and purpose. "The solution to the problems caused directly or indirectly by the introduction of technology" as Dyro (1983) observes "are to be found in technology catching up to itself." The remark pertains with equal import to health care disciplines, which also must catch up with themselves as the incorporation of technology outdistances the care givers.

The use of devices is currently taught to health care professionals primarily by in-service training provided by the manufacturer's representatives, employers through biomedical technicians for use on specific, recently purchased equipment, or continuing education. The major difficulty in each of these methods is that the learners lack a comparable knowledge base. Experience, educational preparation, and goals are disparate even within a specific class. Yet, all participants have a serious intent and need to know how to use the devices correctly.

As creator of the device, the manufacturer develops information about its construction, performance, quality, purpose, design specifications. The manufacturer also performs the initial clinical testing and secures Food and Drug Administration approval. The manufacturer is thus the only source of information and is responsible for addressing the four safety issues. The labeling and instruction manuals must be understandable to all groups of users.

The sequence of introduction logically flows from manufacturer to his representative to, in some cases, a supplier, to technician, to user. The user can be anyone who uses the device for information or treatment, such as nurse, doctor, therapist, family member, or patient. The sequence is one of teacher-learner-teacher as one participant shares knowledge about the equipment with the next member in the chain. Each person possesses different knowledge, experience, purpose, and need. The language and communication, therefore, change as the information is shared and modified according to the knowledge base transition and the goals of the participant-teacher and the participant-learner. These content and purpose levels have not been

defined for all devices nor used by the manufacturers in instructional manuals.. To date, such delineation is not readily available for designing instruction.

Starting in the early 1980s more reports of iatrogenic effects of devices began to appear (Dyro, 1983; Agarwall, 1980; & Amundson, 1985). Lack of experience in the medical and nursing staff was found by Abramson et al (1980). The problem most often cited, however, was lack of formal education for nurses (Harton, 1982; Abbey & Shepherd, 1989; Lenihan & Abbey, 1978; Dyro, 71983; Smith & Brdlik, 1985). Thus, maximizing safe use of medical devices is predicated on:

1) Developing a means of device content organization that could be used by all members of the participant chain from manufacturer through maintainers and regulators to users;

2) Delineating levels of content appropriate to teacher's-learner's purpose and need to know;

3) Incorporating scientific principles into instructional design to afford a common language for communication and improved capability for understanding the omnipresent advances and change; and

4) Providing opportunity for practice with component parts of equipment to develop skills because use of technology is the use of tools.

DEVELOPMENT OF THE MODEL

The Center for Devices and Radiological Health of the Food and Drug Administration (FDA) began in 1984 to study the role that user-error played in the problem of safe use of devices. Upon reviewing the literature, Smith and Brdlik (1985) found a lack in academic preparation of the principal users of the devices to be a frequent factor. That same year, the National Student Nurses' Association passed a resolution to " . . . support the inclusion of basic principles of biomedical instrumentation and technology as part of the undergraduate curriculum in nursing . . . " (National Student Nurses' Association, 1985).

The FDA held an invitational meeting on Nursing and Medical Devices in March 1986 to develop an understanding of device-related injuries and deaths, to identify factors that interfere with safe and effective use of devices, and to develop strategies to address those factors. The meeting was attended by 50 representatives from nursing, medicine, home care, the hospital association, the medical device manufacturers' association, and other involved groups from the private and governmental sectors.

Develop an understanding of device-related injuries and deaths.

Identify factors that interfere with safe and effective use of devices.

Develop strategies to address these factors.

Steering and planning committees selected from attendees met throughout 1986 and 1987 to determine further activity in addressing the problems associated with safe and effective use of devices by nurses and other health care professionals. A second invitational meeting was held in 1988 to address the educational challenge to nursing by the movement of technology into health care. The FDA Nursing and Medical Device Committee identified the characteristics and defined criteria for an education model for devices. The model should address cost effectiveness and risk. It should facilitate learning specifics of the devices.

The Abbey-Shepherd Device Education Model, designed for the second conference, is based upon these criteria. It is intended to be used to introduce device-specific content into ongoing curricula in an orderly progression. As such, the model is a mechanism for content organization and integration into increasing

CRITERIA

Be additive, realizing that individual course content will vary according to the knowledge base of the user and purpose of the instruction.

Be applicable to all medical devices.

Provide structure for generation of specific information and content levels.

Allow for constant continued updating.

Permit incorporation into ongoing curricula relating to patient care.

Be based upon scientific principles.

LEARNING SPECIFICS

Characteristics of each device

Operating principles

Common use errors

Adverse patient reactions

Device failures and their frequency

Safety concerns

All factors related to device function and safe use

Care of instrument

levels of complexity according to purpose and need. A step-by-step use of the model is published in the Plant Technology and Safety Management Series of the Joint Commission on Accreditation of Health Organizations (Shepherd & Abbey, 1989). Examples of model development are also included in the FDA conference proceedings (U. S. Department of Health & Human Services, Food & Drug Administration, 1989). This model will need testing by all levels of nursing education, including in-service and continuing education.

By approaching the problem with the input and approval of representatives from the concerned, key organizations that deal with devices in health care delivery, the model, in fact, does address the interdisciplinary language problem directly. By recognizing that nursing is the prime user of this technology and, therefore, at risk of contributing to patient iatrogenic incidents through misuse and lack of knowledge, the parameters of the problem become visible. By defining what is necessary to support teaching the content and providing opportunity to develop skills in using the technology, the solution becomes possible.

The problem by its very nature demands action. Technology and science generate expectation and hope in both the receivers and the givers of health care. As such, resources flow toward promises and results, from both private and governmental sectors. Implosive and explosive changes occur within health care and in the market-place with ever-increasing speed. Nursing cannot maintain its position in health care without incorporating the visions and rules of science. Nursing will be crippled, indeed, if it does not fully access the information tools of technology as slaves for intellectual growth.

A paper presented at the 1990 annual meeting of the Southern Council on Collegiate Education for Nursing. The Southern Council on Collegiate Education for Nursing (SCCEN), in affiliation with the Southern Regional Education Board (SREB), engages in cooperative planning and activities to strengthen nursing education in colleges and universities in the South. Contact: Eula Aiken, Executive Director (592 Tenth Street, N. W., Atlanta, Georgia 30318-5790).

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