BACKGROUND REPORT

RECOMMENDATIONS ON GUIDANCE FOR DIAGNOSTIC X-RAY STUDIES IN FEDERAL HEALTH CARE FACILITIES



ENVIRONMENTAL PROTECTION AGENCY INTERAGENCY WORKING GROUP ON MEDICAL RADIATION SUBCOMMITTEE ON PRESCRIPTION OF EXPOSURE TO X RAYS

RECOMMENDATIONS ON GUIDANCE FOR DIAGNOSTIC X-RAY STUDIES IN FEDERAL HEALTH CARE FACILITIES

Report of

Subcommittee on Prescription of Exposure to X rays

Interagency Working Group on Medical Radiation U.S. Environmental Protection Agency Washington, D.C. 20460

March 1976

PREFACE

The Administrator of the Environmental Protection Agency formed an Interagency Working Group on July 5, 1974, to develop guidance to reduce unnecessary radiation exposures from the use of x rays in the healing arts in Federal health care facilities. The consensus of this group was that it is desirable and possible in Federal facilities to reduce exposure from diagnostic uses of x rays by: 1) eliminating clinically unproductive examinations, 2) assuring the use of optimal techniques when examinations are performed, and 3) requiring appropriate equipment to be used. As a result of this consensus a Subcommittee on Prescription of Exposure to X rays (SPEX) was established to examine factors to eliminate clinically unproductive examinations and consider the feasibility of reducing radiation exposure in productive studies. Another Subcommittee on Techniques of Exposure Prevention was formed to examine the second and to some extent the third subject areas. The third area is being regulated by the U.S. Food and Drug Administration which has recently issued x-ray equipment performance standards.

The mission of SPEX was to examine diagnostic radiology procedures and develop recommendations which have immediate applicability in Federal facilities. The members of SPEX were especially mindful that their recommendations should not preclude necessary uses of x rays in diagnostic medicine. Serious efforts were made, however, to formulate recommendations that would eliminate the prescription of unwarranted examinations and eliminate the taking of unproductive radiographs. This approach has recognized the need for expert diagnosticians, principally radiologists, to be involved in medical decisions involving the prescription of diagnostic x-ray examinations.

The SPEX recommendations basically result from two considerations: 1) the clinical decision to order a particular examination, and 2) the optimization of the number of radiographic views required in an examination. Fortunately, a reduction in unproductive radiation exposure to the patient and the goals of good diagnostic radiology are directly related in that elimination of unproductive diagnostic examinations achieves both. We believe the recommendations represent consensus judgment of appropriate prescription of x-ray examinations in Federal health care facilities. It should be recognized that the body of knowledge on both the radiation exposure and efficacy of x-ray examinations is rapidly changing and the recommendations will, of necessity, need periodic review and appropriate revision.

Charles W. Ochs, MC, USN

Charles W. Ochs, MC, USN Chairman, Subcommittee on Prescription of Exposure to X rays

MEMBERS

Department of the Navy Captain Charles W. Ochs, MC, USN, CHAIRMAN Captain James Dowling, MSC, USN* Captain William Bottomley, DC, USN Commander James Spahn, MSC, USN Commander Peter Kirchner, MC, USN

<u>Veterans</u> Administration Leonard Bisaccia, M.D., VICE CHAIRMAN Donald Knoeppel, D.D.S. James Smith, M.D.

Department of the Army Lt. Col. Robert Quillin, MSC, USA

Department of the Air Force Colonel John Campbell, MC, USAF Colonel Charles Mahon, MC, USAF

Environmental Protection Agency James E. Martin, Ph.D. DeVaughn R. Nelson, Ph.D. Harry Pettengill, Ph.D.

Consultants

Otha Linton, M.S.J. Director of Governmental Relations American College of Radiology

S. David Rockoff, M.D. Chairman, Department of Radiology George Washington University Medical Center

William S. Cole, M.D. Associate Director - Bureau of Radiological Health U.S. Food and Drug Administration

John Doppman, M.D. Chief of Radiology National Institutes of Health

*Deceased

CONTENTS

PREFACE	Page ii
MEMBERS	iii
INTRODUCTION AND RECOMMENDATIONS	1
BACKGROUND	7
Administrative Control or Convenience	
Criticism and Legal	
Intellectual Curiosity	
Inexperience	
Public Health Screening	
PRESCRIPTION CONSIDERATIONS	10
Qualifications to Prescribe X rays	
Screening and Administrative Programs	
Mammography	
Dental Radiography	
Self-referral Examinations	
PROCEDURAL CONSIDERATIONS	21
General Considerations and Review Plans	
Minimum Number of Examinations and Views	
Patient History and Physical Condition	
EQUIPMENT CONSIDERATIONS	25
Equipment Use Policy	
General Radiographic Equipment Policy	
Fluoroscopic Equipment Policy	
REFERENCES	32

INTRODUCTION AND RECOMMENDATIONS

One of the most significant aspects of good medical care is the use of x rays to diagnose and define the extent of disease or physical injury. The per capita use of x rays in medicine and dentistry has expanded rapidly in the United States due to wider availability of services, new equipment, and an increase in sophisticated diagnostic examinations. Although many procedures now produce less exposure per film, the increased number of procedures has increased the radiation exposure to the population. A number of medical and scientific groups generally agree that there is unproductive radiation exposure from xray uses that could, and should, be reduced and research efforts are in progress by several organizations such as the American College of Radiology to determine the efficacy of certain radiographic examinations.

The most important factor in reducing radiation exposure is to eliminate clinically unproductive procedures. factors involved The in accomplishing this goal were examined by the Subcommittee on Prescription of Exposure to X rays which was made up of physicians, physicists from the three military services, the dentists, and Veterans Administration, and the Environmental Protection Agency. The Subcommittee had consultants from George Washington University, the Public Health Service, the Food and Drug Administration, and the American College of Radiology (see list on page iii).

Appropriate prescription of x-ray examinations involves two major categories: the clinical decision to order a given examination, and the choice of the number and type of views required to conduct it within the principles of good radiological practice. Establishment of routine examinations either for administrative non-medical reasons or efficiency of clinic operation tends to be counterproductive to minimizing exposure. In the first category the qualifications and demonstrated proficiency of those who order diagnostic procedures largely determine whether the procedure will be productive. The same factors are also important in the second category with equipment, technician training, and administration of x-ray examinations also playing important roles. within this framework, the Subcommittee has made the following recommendations for guidance in the prescription of diagnostic x-ray examinations in fixed Federal and contractor installations:

1. Privileges to request general radiographic or fluoroscopic examinations should be limited to Doctors of Medicine or Osteopathy who are eligible for licensure in the United States or one of its territories or commonwealths; exception should only be granted for properly trained physician-supervised individuals such as physician assistants, nurse practitioners, and persons in post-graduate training status or for life-threatening situations.

2. Privileges to request dental x-ray examinations should be limited to Doctors of Dental Surgery or Dental Medicine who are

eligible for licensure in the United States or one of its territories or commonwealths; exception should be granted only for persons in post graduate training status under the supervision of a person meeting such requirements.

3. Privileges to request specialized radiographic or fluoroscopic examinations such as angiography, pneumoencephalography, tomography, or other complex studies requiring many exposures should be restricted to physicians and dentists meeting recommendations of credentialing committees for prescription of general radiographic procedures and who have had advanced training in the medical specialty involved in order to determine the need for and to fully evaluate the results of such special examinations for definitive medical care.

4. Routine chest x-ray examinations should not be performed for tuberculosis screening, as a Federal requirement for employment, or as an established part of periodic physical examinations except in epidemiologically determined high-risk groups; performing such examinations with photofluorographic equipment is not advised because of high radiation exposure. Chest x-ray examinations should generally not be done merely for hospital admission on patients under the age of 40, or as part of routine prenatal care, unless a clinical indication of chest disease exists.

5. Mammography examinations should not be used to screen asymptomatic women under the age of 35; for asymptomatic women between age 35 and 50 the screening policy should be based on an annual review

of current data on yield, radiation risks, and economic and social factors. Screening of women above age 50 appears justified at this time.

6. Radiographic examinations obtained for the evaluation of cancer patients should be reviewed for their efficacy both for the initial evaluation and required followup care. Existing protocol studies should be evaluated periodically to establish the appropriate studies for evaluating the various types of malignancy and its metastatic spread.

7. Dental x-ray examinations should be prescribed only on the basis of a clinical evaluation by a dentist; neither a full-mouth series nor bitewing radiographs should be part of routine preventive dental care. Exceptions may be made for certain groups for forensic purposes.

8. The use of self-referral x-ray examinations should be limited to studies unique and required by the specialty of the physician performing them and be consistent with a peer review policy. The examination should be performed only by physicians qualified to supervise, perform, and interpret examinations unique to that specialty.

9. A current document listing the standard views for defined examinations should be provided for all x-ray equipment operators and tailored to the department and equipment available. The number, sequence, and types of standard views tor an examination should be

problem-oriented and kept to a minimum; additional views should only be authorized by the supervising diagnostician.

10. Follow-up x-ray examinations should be done only at time intervals long enough to make proper decisions concerning continuation or alteration of treatment.

11. Requests for x-ray examinations should be considered as medical consultations between the clinician and the diagnostician and should state the diagnostic objective of the examination and detail relevant medical history including results of previous diagnostic x-ray examinations. The radiologic diagnostician should have the authority to direct the examination to obtain) the diagnostic objective through the addition, substitution, or deletion of prescribed views; this should be done in consultation with the requesting clinician whenever practicable.

12. Operation of medical and dental x-ray equipment should be permitted only under a policy which is established and reviewed annually by the responsible authority; this policy should specify the amount of training required for x-ray equipment operators and whether authorization to operate x-ray equipment is limited or general.

13. Equipment used in Federal and contractor health care facilities should conform to the Federal Diagnostic X-Ray Equipment Performance Standard (21 CFR Subchapter J) as soon as practicable; in the interim all equipment should conform with parts F.4, F.5, F.6, and F.7 of the 1974 "Suggested State Regulations for Control of Radiation"

where applicable. A plan which is reviewed annually should exist for timely replacement of diagnostic x-ray equipment used by Federal agencies.

14. All fluoroscopy units in Federal and contractor health care institutions should provide image-intensification; non-radiology specialists such as orthopedists, neurosurgeons, gastroenterologists, cardiologists, chest surgeons, etc. who are determined by the responsible authority to require fluoroscopy, and are qualified to use it, should be limited to the use of units with electronic image-holding features when practicable.

15. These recommendations, which are intended for fixed health care facilities in the United States or its territories and possessions, should be reviewed at timely intervals to accommodate advances in radiological practices and changing levels of technological sophistication.

BACKGROUND

The ideal circumstance in which to order a diagnostic x-ray examination is for a physician or dentist qualified in his speciality to have determined that sufficient clinical symptoms or history necessitate the examination to either establish disease or injury or its extent. Many x-ray examinations are prescribed, however, that do not necessarily satisfy such clinical-historical prerequisites. The major factors involved in ordering unnecessary x-ray examinations appear to be:

Administrative Control or Convenience

Once an x-ray facility is established a minimum amount of use may be required to justify its existence. A small health care unit may tend to perform x-ray examinations because of location and "convenience to the patient" rather than to refer him to a more appropriate radiology facility. Patient, facility, and physician "convenience" may be interrelated and difficult to separate in determining proper medical care.

Criticism and Legal

Many x-ray examinations may be ordered principally to preclude criticism that everything that could be done for the patient was not done or that the established practice was not followed. This consideration probably exists in all medical practice. In some cases fear of criticism may be manifested in actions to provide a legal

record that good practice was followed even though the physician's course of treatment would not be altered by the result. Unfortunately, such factors lead to established routines which eventually lead to usual practice and unnecessary radiation exposure. Other routine x-ray examinations may be decreed by local, state, or Federal laws for pre-employment physicals for various occupations, workmans compensation, and disability compensation. These examinations may be of economic importance to the patient in deciding his compensation, yet have minimal value for his medical care. Certain high risk groups require survey studies for medical purposes; however, they should be evaluated periodically.

Intellectual Curiosity

Physicians, from time to time, obtain extra radiographic studies to determine the presence, progress, or exact nature of some entities, the knowledge of which has little immediate or long-term implication in the care of the patient.

Inexperience

Medical students, interns, residents, and some non-physician practitioners may not have developed medical judgment as to which test would be most efficacious. Because of such inexperience, examinations may not be ordered in the best sequence and may even interfere with the next test to be done. Also, practitioners with inadequate training in radiological techniques and interpretation may supervise both the taking and interpretation of radiographic examinations. An extensive

series of examinations is sometimes performed to rule out various conditions for which there are no clinical indications.

Public Health Screening

Certain groups may be examined in large numbers by screening programs for diseases such as tuberculosis, pneumoconiosis, or breast cancer. Frequently the decision to take such an examination is made by the patient without physician consultation. In an attempt to provide comprehensive bill-of-health physicals, unnecessary x-ray studies may be conducted as a routine part of the physical examination.

These five factors influence the number of x-ray examinations and add to the radiation exposure received by the population. In addition to the number of examinations, the number and type of radiographic projections used in each examination, whether clinically indicated or determined for other reasons, also influences the radiation exposure. These factors, as well as other aspects of eliminating unproductive xray exposure were examined by the Subcommittee on Prescription of Exposure to X rays on the basis of three considerations: Prescription, Procedure, and Equipment. The Subcommittee's recommendations were developed from considerations directed toward health care in Federal and contractor facilities and their implementation should promote a reduction in patient exposure.

PRESCRIPTION CONSIDERATIONS

Clinicians who prescribe an x-ray examination have a dual responsibility to assure that requisite diagnostic information is obtained and that the radiation administered is done so only with commensurate benefit. The benefits derived from the use of x-ray examinations in medical diagnosis are very high and account for its widespread use. In 1970 the number of radiographic procedures per capita was estimated to be increasing at rates varying from 1-4% per annum (1). Since 1970, the rate is most likely higher due to new and improved developments in radiological diagnostic modalaties and procedures such as mammography, angiography, and computerized axial tomography. Because of this upward trend in x ray use and the importance of minimizing the aggregate population exposure, it is quite important to insure that the prescription of any x-ray examination is necessary.

Qualifications to Prescribe X rays

The qualification of medical personnel authorized to prescribe diagnostic x-ray examinations is the most important factor in limiting the prescription of unproductive examinations. Requests for x-ray examinations in general radiography or fluoroscopy in Federal health care facilities should be made only by a person possessing a M.D. or D.O. degree who is eligible for licensure or licensed where required by statute. Properly trained and physician-supervised individuals such

as physician assistants, nurse practitioners, and persons in postgraduate medical training status do not have to meet the above requirements but they must be under the supervision of one who does.

Any requests in specialized radiography and fluoroscopy such as angiography, pneumoencephalography, computerized axial tomography, or other complex studies requiring many exposures should be made by a person who meets the above requirements, and who, in addition, has special training or expertise to evaluate the indications of the examinations.

In addition to the privileges for which broad qualifications are needed, there are a number of specialties which require only limited types of x-ray examinations. For example, a D.D.S. or D.M.D. may request appropriate examinations of the head, neck, and chest, although such requests are normally confined to the oral region. Podiatrists who have been granted clinical privileges may request x-ray examinations appropriate to their specialty.

It is recognized that medical students, interns, residents, and some non-physician practitioners may not have developed medical judgment as to which test would be most efficacious. Such lack of experience is remedied by work under conditions where there is sufficient expert supervision to monitor the prescription of examinations and to provide appropriate medical assistance.

Variances to the above qualification requirements should occur only for emergency or life-threatening situations. Non-peacetime

operations in the field and aboard ship would generally require such variances wherein equipment designed for field use would need to be operated by personnel available to perform necessary medical services. <u>Screening and Administrative Programs</u>

Many x-ray examinations are the result of screening programs or administrative decisions, the reasons for which may no longer be justifiable. In general, such examinations are not preceded by clinical evaluation by a physician to determine their need. All screening programs should be under the auspices of an appropriate medical staff committee which annually reviews and affirms the need to continue the program. The annual review should eliminate all routine or screening examinations which are not clinically justified.

Chest x-ray examinations to screen for tuberculosis are not justified except for certain high risk population groups (2,3). The U.S. Public Health Service, the National Tuberculosis and Respiratory Disease Association (now the American Lung Association), the American College of Chest Physicians, and the American College of Radiology have publicly opposed such screening programs. A review board should establish that the expected incidence of tuberculosis is sufficiently high in a population before a screening program is started. The radiation exposure and economic considerations suggest that the primary screening examination for tuberculosis should be a tine or tuberculin test even in populations exhibiting a higher than average incidence of

the disease (4); radiological examinations should be used only to followup clinical indications derived from such methods.

Where chest x-ray screening has involved large numbers of persons, it has been common practice to employ photofluorographic techniques to save time and expense. This technique uses a fluoroscope to produce an image of the chest which is then photographed on 70 mm film. Whereas the procedure is relatively fast and adaptable to examining patients quickly at mobile stations, the exposure per examination is considerably higher than an x-ray examination performed on general purpose equipment which produces standard-sized radiographs. Also, the size and quality of the 70 mm film is such that only gross abnormalities can be diagnosed. Although the technique was perhaps justified a few decades ago when there was a high incidence of tuberculosis in the United States, the relatively higher exposure and lower diagnostic yield of this technique make its use generally unjustified even when chest x-ray screening may be justified. Whenever possible, Federal agencies should not use photofluorographic equipment to perform x-ray examinations.

A routine chest examination for hospital admission is not suggested or presently required by the guidelines of the Joint Commission on Accreditation of Hospitals. A chest examination is currently not justified as a routine requirement for hospital admission due to the low yield of abnormalities diagnosed. A recent study of routine screening in a hospital population indicated that routine chest

examinations, obtained solely because of hospital admission or scheduled surgery, are not warranted in patients under the age of 20 and the lateral projection can generally be eliminated in patients under age 40 (5). Careful evaluations should be made of the need for existing admission x-ray examinations and, of course, should precede the institution of new ones.

Other routine or screening x-ray examinations which should be carefully evaluated are pre-employment lower back studies and routine physical examinations which involve routine upper GI, barium enema, gall bladder, and IVP examinations. Examinations required by legislation €or certain high risk populations in order to establish worker disability compensation should be evaluated carefully to determine their continuing necessity.

X-ray examinations which result in exposure of the fetus should be avoided for pregnant women whenever possible (6). Examples of exposures of pregnant women which may not be justified include routine prenatal chest and routine pelvimetry examinations. When such women have not received adequate prenatal care such examinations may well be indicated.

Mammography

Breast cancer is recognized as one of the significant causes of cancer death in the United States. Because of the importance of early detection in control and survival, an increased emphasis on the use of mammography has occurred. This technique has improved considerably,

especially with respect to lowering exposure per examination with the development of low-dose mammography and xeroradiography; however, even at the current state of the art these techniques result in a dose of several rads to each breast for a typical examination. Whereas the technique is justified to examine symptomatic women at any age, the use of mammography to screen asymptomatic women is still being seriously examined by several groups, in particular the National Cancer Institute and the American Cancer Society. Asymptomatic women are defined as those without complaint, without history, without physical findings, and without a strong family history of breast cancer. Symptomatic women are those who exhibit a palpable breast mass, have skin changes, have a significant genetic or endocrinologic predisposition to or carcinoma of the breast.

The American College of Radiology formed a committee on mammography which recently evaluated mammography data accumulated from the Health Insurance Plan in New York and the National Cancer Institute. On the basis of this evaluation, the Committee recently made recommendations on mammography screening to the U.S. Food and Drug Administration's Medical Radiation Advisory Committee for women in three age categories (7).

On the basis of the ACR findings, it is recanmended that mammography should not be used routinely to screen asymptomatic women under the age of 35 for breast cancer. It is further recommended that mammographic technique continue to be evaluated to obtain procedures

that represent an appropriate balancing between low exposures and diagnostic accuracy.

Current data on the effectiveness of mammographic screening for breast cancer in asymptomatic women between the ages of 35 and 50 is insufficient at this time to determine if such screening is justified. The efficacy of routine mammographic examinations for this age group is presently being studied through a joint screening project of the American Cancer Society and the National Cancer Institute. Because of the continuing development of new information on mammography, Federal agencies should periodically evaluate data from this study and others in developing screening policies for this age group.

Screening in asymptomatic women over 50 years of age appears justified at this time.

Cancer Patient Evaluations

In many health care facilities it is common practice for cancer patients to receive extensive x-ray studies as part of their treatment planning and followup. Bagley, et. al., have reported the effectiveness of several studies in managing the treatment of cancer patients admitted to the National Institutes of Health (8). Their findings indicate that once the primary diagnosis was made and confirmed for some cancers, the results of routine x-ray studies such as a barium enema and an upper GI series were found to have little influence in the treatment of the patient. These findings also suggest that the yield of certain x-ray examinations is too low to justify their use as a general screening tool for cancer evaluation. Although any study that would assist in the control of cancer in a patient can be justified, such examinations should be generally productive in the care and followup of a patient. For this reason, Federal facilities should periodically evaluate existing protocol studies to establish those that are appropriate for evaluating patients with carcinomas. In this respect, the American College of Surgeons recently recommended that tumor committees be established to periodically review cancer evaluations and management (9).

Dental Radiography

One of the most common radiographic procedures an individual is likely to receive as a part of health care is a dental x ray. A large portion of the U.S. population visits a dentist one or more times each year for routine checkups and associated dental care. The 1970 X ray Exposure Study estimated that 661 million radiographic films were produced in 1970 and of this number 279 million were dental films (1).

A patient presenting himself to a dentist has a good chance of receiving a dental x ray even though he may have no immediate dental problems. A study of dental radiography in Nashville, Tennessee indicated that 57 percent of the facilities surveyed routinely do interproximal examinations each year on regular patients and 21 percent do a full-mouth series every 1 to 3 years; on new patients 58 percent routinely do interproximal examinations and 64 percent selectively do a full-mouth series (10). The mean exposure per film in the Nashville

study was 542 mR in 1972; after an educational program the mean dropped to 340 mR per film, indicating the value of carefully controlled procedures in reducing patient exposure due to dental radiography. Because of the increased use of dental radiography in the U.S. it appears reasonable to conclude that every effort should be exerted to optimize the exposure per film and the number of films per examination.

The proper decision to use x-ray studies in dental examinations should be based on a requirement for proper diagnosis or definition of disease and the number of radiographs should be the minimum necessary to obtain the essential diagnostic information (11). It is recommended that dental radiographs be taken only after a dentist has examined the patient and established by clinical indication the need for the x-ray examination; neither a full mouth series nor a bitewing series is justified as part of periodic preventive dental care. This recommendation is consistent with those of the American Dental Association which also decidely disagrees with any requirement to provide postoperative radiographs as proof of services rendered (12).

Dental radiography may be justified for forensic purposes for certain high risk groups such as military personnel. In such circumstances it may be desirable to obtain a full mouth radiograph of the teeth and jaw structure.

Self-referral Examinations

A 1970 study indicates that approximately 30% of the medical x-ray examinations in the U.S. were performed by non-radiologic clinicians

(1). Some examinations performed by non-radiologists may occur because of the convenience of having the x-ray unit and the patient in the same location, or, in the case of civilian contract services, need to justify the equipment purchased or maintenance costs. Self-referral examinations are frequently performed by equipment operators lacking adequate training and physician supervision by clinicians with inadequate radiologic experience.

Patients are sometimes referred to another health care facility for medical care and previous x-ray examinations conducted at the first facility will be repeated. In a primary care facility, only the studies needed for appropriate referral should be performed. When examinations have been conducted prior to referral, these x-ray films should accompany the patient to minimize the need for additional diagnostic x-ray examinations and resulting patient exposure (13).

Unnecessary radiation exposure caused by self-referral practices generally need not occur in Federal health care installations where facilities staffed by radiologists are normally provided. Exceptions could be small operational units such as ships, field units, or isolated stations where the normal work load does not justify a staff radiologist. Thus, the conduct of self-referral x-ray examinations should be permitted only for a physician whose qualifications to supervise, perform, and interpret diagnostic radiologic procedures have been demonstrated to the appropriate authorities.

It is recognized that limited self-referral type examinations are performed in Federal medical centers in certain clinical specialties. In such situations, the examinations performed should be unique to the specialty. Such examinations should be performed only by qualified personnel and peer review policies should exist to assist in eliminating unproductive practices.

Self-referral practices in contract civilian facilities should be prohibited since such practices have been shown to lead to overutilization (14). Exception may be made in remote areas where no practicable alternative exists. Although the largest reduction in radiation exposure is to prevent the ordering of an unproductive x-ray examination, patient exposure can also be reduced by the diagnostician by careful consideration of the numbers and types of radiographs to be taken during the examination (15). These considerations can also be classified as prescription decisions. In conducting x-ray examinations, therefore, the diagnostician should be capable of making the best diagnosis possible and be aware of the quantity and potential risk of the radiation he is administering.

General Considerations and Review Plans

Each x-ray examination should be as objective-related as possible to accomplish the diagnosis with the minimum amount of exposure. Most x-ray departments establish a set of standard examination procedures which specify the number and types of radiographic views to be taken when the procedure is performed. A periodic review of all standard examination procedures should be performed to determine if the established routine is achieving the objectives and whether modifications are warranted. Continuation of a standardized examination procedure should be predicated on satisfying the following criteria: a) the efficacy of the examination is sufficiently high to assure that the diagnosis could not have been made with less risk by other non-radiologicalmeans or a lower number of views, b)

consideration of the previous similar examinations performed with multiple views established that in a significant number of the cases all views were necessary for the diagnoses rendered, and c) the yield of the examinations offsets the radiation exposure delivered.

A periodic review of standard operating procedures should be made at least annually by the appropriate medical or dental staff committee with the advice of referring physicians. Such reviews should consider the consensus and advice of professional societies concerning the efficacy of radiologic exams.

Minimum Number of Examinations and Views

A written outline containing the minimum number of views to be obtained for each requested examination should be made available to each clinician and equipment operator in every radiology facility. Beyond the specified minimum views, the examination should be individualized according to a patient's needs.

All examinations should be tailored to the individual department taking into account the equipment available. In some instances, certain examinations should be done only on certain types of equipment.

The outline of procedures should indicate who may authorize deviations from the standard set of views for any examination. Every effort should be made to reduce to a minimum the number of standard views for any examination. The necessity of additional views, such as comparison views, should be determined by the radiological diagnostician. Follow-up for examinations should be done at reasonable

time intervals so that significant changes in clinical information are obtained for making proper decisions on continuation or alteration of the management of the patient.

Patient History and Physical Condition

whenever possible a radiologist should review all examination requests requiring fluoroscopy or multiple film studies, especially those associated with tomography or scanning techniques, before the examination is given and preferably before it is scheduled (16). For this reason, it is important that a thorough and accurate patient history be included with each examination request. Based upon a review of the history and previously documented studies, the radiologic diagnostician should direct the examination to obtain the diagnostic objective stated by the referring clinician through the addition, substitution or deletion of views. It is preferable that changes in the examination be done in consultation with the requesting clinician.

Another means by which the radiologic diagnostician may reduce patient exposure is to avoid any repeat examinations due to improper patient preparation for contrast media studies. Miller has reported that poor bowel preparation is a frequent cause of marginal or repeated contrast media studies of the lower GI tract (17). The radiology department can minimize the number of marginal studies by instituting appropriate pre-examination procedures (13). These procedures should include assuring that patients have had the appropriate laxatives and enemas prior to performing contrast media studies of the lower GI

tract. It may also be advantageous to place bedridden, elderly, or constipation-prone patients on low-residue diets several days before scheduling the studies. Determination that a patient has had previous surgery before GI tract examinations could also help minimize the number of marginal studies. Similarly, the prior determination that a patient had taken any prescribed oral contrast media would prevent unnecessary retakes of such studies.

EQUIPMENT CONSIDERATIONS

Once the physician or dentist determines that the prescription of an x-ray examination is warranted for diagnostic purposes, other factors become important in limiting patient exposure. These factors are the design of good x-ray equipment, equipment use, and the assurance that equipment operators have received adequate training to perform the examination without unnecessary exposure to himself or the patient.

Equipment Use Policy

The utilization and supervision policy of medical and dental x-ray equipment should be approved by the responsible facility authority upon the recommendations of medical and dental staff.

Criteria for the supervision of medical x-ray equipment should also be established in each facility in a written policy. The formal policy should be reviewed annually by medical staff committees and by those departments whose members have privileges in radiology. The definition of privileges in radiology should be made in terms of the needs of the patients served by that facility, recognizing that the availability of optimally trained physicians and the varying levels of service and training will make each circumstance different.

Types of medical personnel eligible for utilization of x-ray equipment may be classed as physicians, ancillary personnel, and radiological technologists. Eligible physicians include radiologists

and other physicians granted privileges in radiology. Such privileges might include the use of x-ray equipment by cardiologists for cardiac catheterizations and by dentists or podiatrists as part of their practice. Before physicians and dentists are granted radiology privileges they should have received adequate training in equipment use and radiation protection. However, specific protocols establishing the limit of radiology privileges to specified types of physicians or dentists should be part of the written policy statement.

The use of x-ray equipment by ancillary personnel such as radiation physicists and repairmen should be limited to testing and evaluating equipment performance.

Radiographic technologists are by far the largest group to directly utilize x-ray equipment. Eligibility to operate general purpose x-ray equipment should be granted only to registered (ARRT) technologists or those with equivalent training. Technologists in training should be eligible to utilize equipment only while under the supervision of a registered technologist. "Limited privilege" technologists not having registration, equivalent training, or supervision by a registered technologist may perform selected examinations under the direct supervision of physicians granted radiology privileges. "Limited privilege" technologists include those who perform single or limited studies such as operating a photo-timed chest unit.

The utilization of dental x-ray equipment should be under the supervision of a licensed dentist. Dental care personnel such as dentists, dental hygenists, dental assistants, and dental technologists should only perform dental x-ray examinations after proper training. The training should include proper tube positioning and film placement, technique selection, film processing techniques, and a thorough review of radiation protection principles, The training in film processing is to be stressed since a common error in dental radiography is to overexpose and underdevelop a film, thus leading to excessive patient exposure.

Other medical personnel such as nurses and laboratory technologists should not be eligible to operate x-ray equipment. Their use of such equipment could be warranted only in a life saving or threatening situation during which qualified personnel as specified above are not available to perform the examination.

General Radiographic Equipment

The Nationwide Evaluation of X-ray Trends survey has demonstrated that the same technique factors used with different x-ray generators may produce widely varying patient exposures. Thus, the performance of x-ray equipment utilized for diagnostic x-ray procedures is an important factor in limiting patient and operator exposure. The Federal Diagnostic X-Ray Equipment Performance Standard (21 CFR Subchapter J) requires that x-ray equipment manufactured after August 1, 1974, be certified by manufacturers to comply with performance

standards issued by the U.S. Department of Health, Education, and Welfare pursuant to the Radiation Control for Health and Safety Act of 1968 (PL 90-602).

All Federal health care facilities which perform diagnostic x-ray examinations should, as soon as readily achievable, utilize medical and dental x-ray equipment that conforms to the requirements of 21 CFR Subchapter J. It is possible to obtain variances for special medical and dental x-ray equipment purchased after August 1, 1974; however, Federal use of this variance should be minimized.

All existing, non-certified equipment being used is not necessarily substandard. In order to preclude substantial economic costs involved with large-scale replacement or retrofit of all noncertified equipment, while still providing for the elimination of equipment which is determined to be sub-standard with reference to currently accepted radiation safety standards, it is recommended that all non-certified medical and dental x-ray equipment meet the criteria in parts F.4, F.5, F.6, and F.7 of "Suggested State Regulations for Control of Radiation (18)." Whereas the above criteria do not meet the rigid requirements for certification according to the Federal performance standard, they provide adequate conformance with those parameters which affect radiation protection of the patient and operator. Assurance that the x-ray generator meets the "Suggested State Regulations for Control of Radiation" can be demonstrated with test equipment considerably less complex than that required to demonstrate compliance with the equipment performance standards for xray equipment required by 21 CFR Subchapter J.

Certain sections of the x-ray equipment performance standard provide for planned obsolescence, such as the provision which permits the use of non-certified components as replacement items in equipment manufactured before August 1, 1974. Although such use of non-certified replacement components is permitted until August 1, 1979, their use should be justified. Stockpiling of either x-ray equipment or components should also be minimized, since the technological advances in x-ray equipment tends to preclude its use.

To insure that x-ray equipment used is justifiably representative of present day technological advances, authorities should develop and periodically review a planned replacement schedule for all types of diagnostic x-ray equipment used in their programs. Fluoroscopic Equipment Policy

x-ray equipment should not exceed the medical mission of the facilities, i.e., fluoroscopy should not be available in facilities where qualified medical personnel are not assigned. This will serve to deter one source of unproductive radiation exposure.

Although the aggregate population dose is larger from the use of general purpose diagnostic equipment, the highest exposures to individuals are generally associated with fluoroscopic examinations. Fluoroscopic examinations require large exposure rates for periods of time long enough to observe dynamic changes; thus, it is of utmost

importance that Federal health care facilities give particular attention to minimization of fluoroscopic examinations.

Because the reduction of patient exposure is considerable and the additional cost of image-intensified units is justifiable, fluoroscopic units which do not contain image-intensification systems should not be used. The retention of older non-image intensified units for the reason that they may not be used with great frequency should not be permitted because the patient exposure rates are an order of magnitude greater than intensified units. If the medical mission requires fluoroscopy, only image-intensified units operated by those with demonstrated competence should be permitted.

Specialized procedures (hip replacements, transphenoid hypophysectomy, biopsy and cannulizations via fibro optic scopes) may In order to provide fluoroscopic require fluoroscopic assistance. assistance for such special procedures and to minimize patient exposure, non-radiological specialists such as orthopedists. neurosurgeons, gastroenterologists, cardiologists, chest surgeons, etc. should where practicable only use equipment with electronic image holding features such as pulsed video-hold or equipment with similar low-exposure features. The advantage of such units is that the radiation exposure is about one-twentieth of that from continuous fluoroscopy and yet the image is adequate.

Non-radiologists who operate a special fluoroscopic unit should take a course of instruction in radiation safety which meets guidelines

established by responsible authority and demonstrate competence in the use of this equipment. Such courses of instruction should be considered as a standard part of the training program for physicians who may have occasion to use such equipment in their practice. Use of pulsed video-hold or similar dose-saving special equipment should be approved by a senior radiologist in order to prevent use of such units for studies other than those for which they were designed.

REFERENCES

- 1. <u>Population Exposure to X rays U.S.</u> <u>1970</u>, DHEW Publication No. (FDA) 73-8047, November 1973.
- 2. <u>The Chest X-ray as a Screening Procedure for Cardiopulmonary</u> <u>Disease</u>, Policy Statement, DHEW Publication No. (FDA) 73-8036, April 1973.
- 3. "Chest X-ray Screening Recommendations for TB-RD Associations," NTRDA Bulletin, October 1971.
- 4. Ochs, C.W., "The Epidemology of Tuberculosis", JAMA, Vol. 179, pp. 247-252, January 27, 1962.
- 5. Sagel, F., et. al., "Efficacy of Routine Screening and Lateral Chest Radiographs in a Hospital-BasedPopulation," N. Engl. J. Med., Vol. 291, No. 19, November 7, 1974.
- 6. <u>Protection Against Ionizing Radiation From External Sources</u>, International Commission on Radiological Protection, Pergamon Press, p. 19, 1969.
- 7. Minutes, 13th Meeting of Medical Radiation Advisory Committee, U.S. Food and Drug Administration, Bureau of Radiological Health, Rockville, Maryland, May 1975.
- 8. Bagley, D.H., et. al., "Barium Enema, Proctosigmoidoscopy, and Upper Gastrointestinal Series in the Preoperative Evaluation of the Cancer Patient," Surgery Branch, National Cancer Institute, Bethesda, Maryland (To be published).
- 9. <u>Position Statement on Cancer Patient Care Evaluation</u>, American College of Surgeons, Chicago, Illinois, December 1, 1975.
- 10. Crabtree, C.L., et. al., <u>Nashville Dental Project</u>: <u>An Educational</u> <u>Approach for Voluntary Improvement of Radiographic Practice</u>, DHEW Publication No. (FDA) 76-8011, July 1975.
- 11. Chamberlain, R.H., <u>A Practical Manual on the Medical and Dental</u> <u>Use of X-ray with Control of Radiation Hazards</u>, The American College Of Radiology, Chicago, 1958.

- 12. Council on Dental Materials and Devices, "Recommendations in Radiographic practices," JADA Vol. 90, pp. 171-172, January 1975.
- 13. "Memorandumon Implementation of the Second Report of the Adrian Committee on Radiological Hazards to Patients," Brit. J. Radiol. Vol. 37, pp. 559-561, 1964.
- Childs, A.W., and Hunter, E.D., <u>Patterns of Primary Medical Care</u> -<u>Use of Diagnostic X-ray by Physicians</u>, Working Paper No. 10, Committee on Health Economics and Administration, Institute of Business and Economic Research, University of California - Berkley (1970).
- Payne, F.W., "Physicians, Radiologists, and Quality Control," Proceedings of the 1972 Radiological Health Section, American Public Health Association, DHEW Publication No. (FDA) 74-8002, Bureau of Radiological Health, Rockville, Maryland.
- 16. Abrams, H.L., "Observations on the Manpower Shortage in Radiology," Radiology, Vol. 96, pp. 671-674, 1970.
- 17. Miller, R.E., "The Clean Colon," Gastroenterology, Vol, 70, No. 2, pp. 289-290, 1976.
- <u>Suggested State Regulations for Control of Radiation</u>, prepared by The Conference of Radiation Control Program Directors in cooperation with the U.S. Atomic Energy Commission and the U.S. Food and Drug Administration, Published by FDA-Bureau of Radiological Health, Rockville, Maryland, October 1974.