NATIONWIDE EVALUATION OF X-RAY TRENDS (NEXT)

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Abstract

The impact of efforts by government agencies to minimize and control unnecessary patient exposure in medical x ray has been difficult to assess. Population exposure studies, such as those conducted in 1964 and 1970 of the United States Genetically Significant Dose, are expensive. Reports of the number of x-ray machines in compliance with equipment standards, such as for filtration and collimation, are traditional but are difficult to relate to patient or population exposures. Furthermore, such reports are limited to machine parameters and do not reflect other factors influencing patient dose such as operator training, film and screen selection and film processing.

A Task Force of State and Bureau of Radiological Health representatives, created in 1971, has applied the "standard man" concept as a method of evaluating the impact of government control efforts on medical x-ray exposure.

A limited number of randomly selected medical x-ray facilities are visited. The operator of an x-ray unit is requested to set the technique factors for a selected examination of a patient whose anthropometric characteristics have been standardized. Exposure data is collected using standardized procedures and equipment. Organ Dose Index values are generated for selected critical organs.

By eliminating patient size variation, the wide range of exposure technique factors currently employed in medical radiography has become readily apparent, together with the wide range of gonad doses encountered by a standard patient. It is expected that these can be correlated with governmental agency activities in radiological health and can be modified by their efforts.

The methodology of the NEXT Organ Dose Index System is simple. Fifty local, State and Federal radiological health programs in the United States are participating or planning to participate in the system which began operation in October, 1972. Some results of the first nine months of its operation are presented. The system appears to be far more efficient in assessing the impact of governmental program efforts in medical x ray than previously used methods. It avoids the complexity and cost of population exposure studies but can relate program impact in terms of patient exposure and dose.

Radiological Health Efforts in the United States

Historically, regulatory radiological health efforts in the United States trace their origins to the state and local levels, particularly as they affect medical x-ray use. Currently 50 States and the District of Columbia conduct radiation control programs under either general public health laws or specific enabling legislation.[1] Technical details of regulatory control are usually not included in authorizing legislation but are delegated to a radiological health agency or advisory group. More recently, under authority of Public Law 90-602, Federal performance standards for medical x-ray equipment have been prepared.[2]

In 1962 the Council of State Governments, in cooperation with the United States Public Health Service and the United States Atomic Energy Commission, developed Model Regulations for Radiation Control which included a section on the "Use of X rays in the Healing Arts."[3] The original regulations have been updated twice and are undergoing further revision. Most States which have adopted regulations in the area of medical and dental x ray have followed this guidance thus providing some measure of uniformity. The Council of State Governments' regulations have been based upon the recommendations of various standard-setting bodies, particularly those of the National Council on Radiation Protection and Measurements.[4]

The major thrust of radiological health agencies' activities in the United States, to date, has been directed at upgrading the x-ray equipment used in the diagnostic healing arts to meet minimum regulatory standards. Consequently, the primary purpose of most medical x-ray inspection programs has been to determine that the equipment requirements of the regulations are being followed. However, advantage is frequently taken of the personal contact during an inspection of a medical or dental facility to discuss with personnel other items related to the use of the equipment.

For example, exposure technique and film processing may be reviewed with the operator. In such cases, the inspection visit becomes a mini-training program. As a result, in addition to a report of items which do not meet regulatory requirements, recommendations may also be provided to the user which, if followed, can improve the overall radiological health aspects of an x-ray facility.

Regular training courses are offered by many radiological health agencies, usually in conjunction with, or using the resources of, various Federal agencies. The Bureau of Radiological Health of the Food and Drug Administration has developed training packages for use by State and local agencies. Many of these agencies routinely offer the services of their staff to provide lectures for ongoing formal training programs in hospitals or other schools.

Many State and local radiological health agencies review and approve x-ray facility plans and specifications. Items such as adequacy of radiation barriers, film handling and processing facilities, type and location of radiation machines, and adequacy of ancillary equipment are subjected to critical review.

Radiological health agencies realize that ensuring that proper equipment is provided is only one parameter in the equation of optimizing the benefit of an x-ray exposure of a patient. With this in mind, three States and the Commonwealth of Puerto Rico have approved specific laws which establish minimum standards for education, training and experience for certain user groups that apply x rays to humans for diagnostic or therapeutic purposes.[1] The United States Public Health Service has developed guidelines for the establishment of

licensing programs for x-ray users in the healing arts.[5]

All of these programs are directed toward minimizing exposure in the environs of an x-ray installation and optimizing the benefits of patient radiation. But how do these agencies determine their program effectiveness? National X-ray Exposure Studies such as conducted by the United States Public Health Service in 1964 and in 1970 can and do provide information to answer this question.[6,7]

However, such x-ray exposure studies require considerable investments of time, money and personnel at local, State and Federal levels. This time interval - 6 years - is too long for use by agencies requiring the kind of information which is necessary to justify budget requests, to plan program priorities and to evaluate past program effectiveness. These activities are performed on an annual basis and information must be available on an annual basis.

The usual information resources available to agencies are limited to reports of inspection programs such as the number of x-ray machines in compliance, the number of x-ray machines with deficient filtration, etc. Increasingly, such data has been found unsuitable for identifying specific problem areas, for justifying existing radiological health programs and budget requests, and for program planning. Such terminology is not meaningful to many public officials responsible for planning fiscal and personnel resource allocations to the various technical programs under their jurisdiction. Instead, program effectiveness or needs must be reported in people-related terms.

Nationwide Evaluation of X-ray Trends (NEXT)

In May 1971 the Conference of Radiation Control Program Directors called for the formation of a Task Force to design a uniform program for surveys of x-ray facilities.[8] The Task Force, co-sponsored by the Bureau of Radiological Health of the Food and Drug Administration, Department of Health, Education and Welfare, was appointed in July 1971 and consisted of equal representation from State and Federal radiological health agencies.

The Task Force adopted the project name of "NEXT", an acronym for Nationwide Evaluation of X-ray Trends. In reviewing its charge, the Task Force identified four specific objectives[9] it wished to meet:

1. Design a system to measure the effectiveness of radiological health programs,
2. Design a system which would enable program priorities to be assigned on a rational, documentary basis,
3. Identify the optimum componentsof a radiation survey, and
4. Provide for the uniform collection of data related to radiological health.

The development of an Optimum Survey Procedure Manual would partially satisfy these objectives. This is currently under revision and will not be discussed here.

While the production of a manual of optimum survey procedures will fulfill a long sought need by local and State radiological health programs, the NEXT Task Force recognized that additional parameters were required to meet the objectives of providing a system to measure program effectiveness and to assign program priorities. The Organ Dose Index System (ODIS) was devised to meet these objectives.

The Organ Dose Index System (ODIS)

The Organ Dose Index System is based on an annual survey of a statistically representative sample of the x-ray tubes within an agency's jurisdiction. The results are intended to provide the agency with a measure of its effectiveness in reducing unnecessary radiation exposure during diagnostic radiography. The system was not designed to replace compliance survey procedures now in use but is intended to be an adjunct to these procedures. The system provides specific organ doses called Organ Dose Indexes for selected x-ray procedures applied to a standard sized patient.

The term "Index" has been appended to "Organ Dose" because the calculated dose values are not an "average", nor representative of the population dose. They are the organ doses only for an individual who fits the physical characteristics of the"standard patient". (This patient was subject number 16 of the group who participated in the Johns Hopkins study to determine scatter to primary x-ray beam exposure ratios.[6]) Organ Dose Index, is therefore, a people-related quantity. Since it reflects a "standard patient" it removes the variable of patient size. It has the potential for evaluating variations of organ dose by type of facility, technique, operator training, beam size and shape, etc. The methodology of calculating radiation doses to the gonads used in the Organ Dose Index System is that used in the X-ray Exposure Studies of the United States in 1964 and 1970, with modifications.[6] Other organs have been identified by the Task Force for which calculated radiation doses are desired. These are the thyroid, lens of eyes and bone marrow. Organ Dose Indexes for these organs are awaiting development of suitable dose models.

Twelve common diagnostic radiographic examinations are included in the Organ Dose Index System:

Projection	Body Part of Interest	Body Part Thickness (centimeters)
Chest (P/A)	Thorax	23
Skull (Lateral)	Head	15
Abdomen (KUB) Scout Film (A/P)	Abdomen	23
Retrograde Pyelogram Scout Film (Cysto Units) (A/P)	Abdomen	23
Thoracic Spine (A/P)	Thorax	23
Cervical (A/P)	Neck	13
Lumbo-Sacral Spine (A/P)	Abdomen	23
Full Spine (A/P) (14"x36" film size only)	Chest and Abdomen	23
Feet (Weight Bearing) (D/P) (Podiatrists Only)	Foot	8
Dental Bitewing (Posterior)	Left Biscuspids and Molars	-
Dental Periapical	Central Incisor (Maxillary)	-
Dental Cephalometric (Lateral)	Head	15

These projections were selected to provide a useful cross-section of x-ray examinations encountered in private and institutional medical care facilities.

To obtain Organ Dose Indexes, a statistically representative sample of the healing arts x-ray facilities within a participating agency's jurisdiction is drawn by the participating agency on an annual basis.

During the inspection of a selected x-ray facility, the inspector determines which of the twelve selected examinations are performed most frequently on the machine being inspected. The inspector asks the operator to set the technique (milliamperage, kilovoltage, exposure time, target-to-film distance, collimation, etc.) that would be used for this standard patient. For example, if a Chest P/A is the most frequent examination performed with the machine in question, the operator is asked to set the technique that would be used for a patient having a 23 centimeter chest. Appropriate measurements of x-ray beam exposure, quality and beam size are made utilizing standardized procedures and equipment.[9] A Mean Ovarian Dose and a Testicular Dose are then calculated from the measurement data using computer programs.

Preliminary Results

The NEXT Organ Dose Index System began October 1, 1972. At the end of the first nine months operation, 32 States and 3 Federal agencies were participating. Additionally, NEXT data has been processed for one foreign government and for an international health agency. At the end of nine months of operation (June 30, 1973), data for 3,431 projections had been collected in the United States and submitted for processing. Pre-edit and quality control checks designed to eliminate erroneous data are applied to all submitted data. 2,316 projections passed these checks and were entered upon the NEXT ODIS master file

The present data pool is not yet complete. Many participating agencies have not completed surveying their annual representative sample. Not only is it too early to attempt an identification of trends, but the baseline has not yet been established.

Nonetheless, preliminary analysis of existing data does seem to validate some of the concepts, and expectations of the system.

For example, data is available for 291 cases of the Lumbo-Sacral (A/P) projections. Registered radiologic technologists performed 129 of these projections, the others being performed by practitioners or other persons. For these 291 applications of this projection to our standard patient:

1. The reported kVp ranges from 50 to 110,
2. The reported mAs ranges from 10 to 400,
3. The measured tube target-to-film distance ranges from 30 to 72 inches,
4. In view of the ranges in the above 3 categories it was not surprising to find the calculated exposure at skin entrance varied by 2 orders of magnitude.
5. X-ray Field Size at the film varied from well collimated beams limited to the spinal column, e.g., 5"x16" to large circular beams, e.g., 49", and even large rectangular beams, e.g., 22"x47",
6. In consequence of these variations, the Mean Ovarian Dose Index ranged fror 4 mrad to 951 mrad and the Testicular Dose Index ranged from $<$0.5 mrad to about 2,300 mrad.

This kind of variation is not unique to the Lumbo-Sacral Spine examination. A another example, 42 cases of the Retrograde Pyelogram Scout (Cysto only) (A/P) were collected. This is a specialized projection rarely performed outside a hospital or major private practice facility. The x-ray machine operator in 34 of the 42 cases was a registered radiologic technologist.

1. The reported kVp varied from 68 to 90,
2. The reported mAs varied from 20 to 250,

3. The measured tube target-to-film distance varied from 31 to 59 inches,
4. The calculated exposure at skin entrance varied from 205 mR to 1,200 mR,
5. Beam size at the film varied from a 25"diameter circular beam to a 10"x13" rectangular beam,
6. The mean Ovarian Dose Index varied from 45 mrad to 507 mrad and the Testicular Dose Index varied from 1 mrad to about 1,000 mrad.

It is evident that the range of variation for this projection is smaller than for the Lumbo-Sacral Spine, but it is still quite large. As noted earlier, this projection is a specialized procedure restricted to a limited number of facilities. In comparison to the Lumbo-Sacral projection, a larger proportion of the operators were registered radiologic technologists and one may speculate on the influence of this factor.

Even so it is perplexing to find such wide variation in technique for the same examination for the same standard patient.

NEXT, Now and Future

These preliminary results suggest that opportunity does lie ahead for reducing unnecessary diagnostic x-ray exposure by identifying facilities using high exposure techniques. The NEXT Organ Dose Index System, by eliminating patient size variation and utilizing standard survey techniques, provides an objective method of accomplishing this.

Presumably, a radiological health agency effort, directed at identifying the high exposure facilities, followed by efforts to change their techniques, if successful, should be reflected by a trend, over time, to lower average organ dose indexes. The NEXT Organ Dose Index System will monitor these trends.

The NEXT Organ Dose Index System will not provide estimates of population dose, nor will it provide per capita dose information. It will provide information that can be used to effect changes in population dose. It will monitor changes in medical diagnostic x-ray application and trends in medical x-ray exposure.

REFERENCES

1. Lois A. Miller. Federal/State Radiation Control Legislation 1972, DHEW Publication (FDA) 73-8035 (1973), National Technical Information Service, Springfield, Virginia 22151.

2. Federal Register of August 15, 1972 (37 FR 16461, Office of the Federal Register, Washington, D.C. 20408.

3. Council of State Governments. Suggested State Regulations for Control of Radiation, Revised June, 1970.

4. National Council on Radiation Protection and Measurements. NCRP Report 33, Medical X-ray and Gamma Ray Protection for Energies up to 10 MeV- Equipment Design and Use (1972) and other NCRP reports, NCRP Publications, Washington, D.C. 20014.

5. Model Legislation for Users of Ionizing Radiation in the Healing Arts, BRH/ORO 70-8 (1970), National Technical Information Service, Springfield, Virginia 22151.

6. Population Exposure Studies Section, Bureau of Radiological Health, Population Dose from X-rays U.S. 1964, Public Health Service Publication No. 2001 (1969) U.S. Government Printing Office, Washington, D.C. 20402.

7. Joseph N. Gitlin and Philip S. Lawrence. Population Exposure to X-rays U.S. 1964, Public Health Service Publication No. 1519 (n.d.) U.S. Government Printing Office, Washington, D.C. 20402.

8. 3rd Annual National Conference on Radiation Control, DHEW Publication (FDA) 72-8021, BRH/ORO 72-2 (1971) National Technical Information Service, Springfield, Va. 22151.

9. 4th Annual National Conference on Radiation Control, DHEW Publication (FDA) 73-8003, BRH/ORO 73-3 (1972) National Technical Information Service, Springfield, Va. 22151.