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Reducing unnecessary radiation exposure from X rays: the role of the Bureau of Radiological Health

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The Bureau of Radiological Health is part of the Food and Drug Administration, Public Health Service, Department of Health and Human Services. Its overall goal is to minimize unnecessary exposure to radiation in the United States population. There are a number of federal agencies involved in various aspects of radiation protection. The Bureau's role is to assure the safety of consumer products, such as television sets, microwave ovens and sun lamps, and medical and dental products, such as X-ray machines. As I will discuss later, we carry out this responsibility through both regulatory and educational programs.

A large part of governmental activity with respect to radiation control is carried out not at the federal level, but by individual states and municipalities. All 50 states have radiation control programs, and their activity generally compliments the Bureau's.

In discussing our approach to controlling medical and consumer products, it is important to distinguish between what might be called incidental exposure to radiation and purposeful exposure. When a consumer buys a television set or a microwave oven, any radiation he or she receives in using the product is incidental. That is, it is not required that the operator be exposed to radiation in order for the product to accomplish its intended purpose; whatever exposure is received is incidental. We approach these kinds of products with an all or nothing frame of mind. Our goal with a television set or a microwave oven, or with X-ray baggage inspection systems in airports, is simply that the operator of the equipment should not be exposed to any significant amount of radiation.

With medical sources, on the other hand, we are dealing with purposeful radiation. After all, one cannot make a radiograph without exposing a patient to radiation. So the objective in this case is not to eliminate exposure, but to optimize that exposure to be sure that it is as low as possible commensurate with getting a good diagnostic image. Although this differentiation between incidental and purposeful radiation is a simple concept, it is important in setting a sound strategy for dealing with radiation-emitting products.

There is a triad of potential problem areas that we associate with the possibility of unnecessary exposure from diagnostic X rays. The first area involves equipment, the second technique, and the third judgment. The Bureau has the authority to regulate only the first of these.

The Radiation Control for Health and Safety Act (Public Law 90-602), passed in 1968, requires the government to set performance standards, imposed on manufacturers, for radiation-emitting electronic products. So if we in the Bureau are doing our jobs, X-ray equipment will leave the factory with a certain minimum standard of safety built in.

In addition to a standard for X-ray machines, the Bureau has performance standards for such things as microwave ovens, television sets, lasers, and sunlamps. The X-ray standard went into effect in 1974. For dental machines, it provides limits on tube housing leakage, and sets standards for: reproducability, for the proper amount of aluminum filtration in the beam, and for collimation to restrict the size of the beam.

What about older equipment that was manufactured prior to the X-ray performance standard? The Bureau has been working with the various states for a long time to upgrade and retrofit old machines that are obviously subpar. Many thousands of kits were sent by states to dental offices to equip old machines with proper collimation and filtration. The Federal standard helps to assure that this kind of retrofitting will no longer be necessary.

The best-designed and best-manufactured X-ray machine can still be used in such a way that the patient receives needless radiation. This brings us to the second source of unnecessary exposure: poor technique. Although we do not regulate technique, the Bureau has a number of voluntary educational

programs to help radiation users improve their practices. There have been several studies which helped us to pinpoint the kinds of technique improvements that are most needed. One such survey was supported by the Bureau at the Vanderbilt University Dental School in Nashville in the 1970s, and it is often referred to as the Nashville Study. Dental students were recruited to survey essentially all of the dental offices in the community to study X-ray equipment, machine settings and film processing. They found that about one-third of the dentists surveyed were still using sight development. That is, instead of using time and temperature according to the film manufacturer's recommendations, they were under-developing the film and compensating by overexposing it, a practice which also results in overexposing the patient. It was also found that 25% of the facilities weren't changing their developing solutions often enough, a problem that can also lead to overexposure of the patient.

In the mid 70s we also had the opportunity to look at a number of X-ray films in the state of Pennsylvania through the Pennsylvania Blue Cross/Blue Shield program. Two random surveys were made, each of about 1000 films, and both times about 25% of the films had problems serious enough to significantly compromise diagnostic information. Some films had cone-cuts, for example, and others were severely over- or underexposed.

To help improve dental X-ray techniques, the Bureau is engaged with 47 state and municipal radiological health agencies in a voluntary educational program called Dental Exposure Normalization Technique, or "DENT". The program begins with a thermoluminescent dosimeter (TLD) imbedded in a small card. The card is mailed out by the state to all of the dentists or dental facilities in its jurisdiction, with instructions to expose the card as though it were a bitewing and to fill out certain information about the characteristics of the machine and the image receptor. The card is mailed back and the radiation exposure received by the dosimeter is "read". Those facilities whose exposures are outside the normal range (the range having been determined by a panel of dental radiologists) are scheduled for an educational consultative visit.

A radiation specialist from the state agency visits the dentist and asks him to go through his usual procedures in making a radiograph. The surveyor then demonstrates how improved image quality and lower exposure can be achieved. What is generally found in the high-exposure facilities is that there are processing problems, such as old developer, or the use of sight development, or severe light leaks in the darkroom. We have found that the DENT program is able to reduce overall exposure by 40%, and even among the states that are now coming into DENT, we are still seeing a reduction of exposure of this magnitude. This voluntary program continues to provide encouraging evidence that dentists are willing to work with us and with the states to optimize radiation exposure.

The third source of unnecessary patient exposure is unnecessary X-ray procedures. Even with the finest equipment and the best techniques, any X-ray examination that doesn't provide needed diagnostic information or doesn't affect patient management or outcome, will give the patient needless radiation.

The American Dental Association has repeatedly stated that the calendar should not be the primary criterion for determining when to radiograph a patient. Statements such as this are what might be called "frame-of-mind guidelines." They provoke the practitioner to ask the important question, "Is this exam really needed?" But admonitions of this kind are often too general to provide much help. How is the practitioner to know when a radiograph is appropriate, and under what clinical circumstances, and how often?

What is called for now are specific guidelines, based on scientific data, as to when radiographs are most efficacious. We call these guidelines "referral criteria," and we have been encouraging medical and dental organizations to develop such criteria to give more specific guidance to clinicians than simply the advice to take only "needed" radiographs. What we hope will come out of this referral criteria process is a stronger scientific basis for selecting patients for radiographic examinations.

Referral criteria take two forms: they may either be statements of good practice, in which a consensus has developed about the use of a particular radiographic procedure; or they may consist of a constellation of signs and symptoms and patient history which warrants a radiographic examination.

Referral criteria can be developed by an expert group of clinicians in a particular specialty who try to develop a consensus about the indications for a specific X-ray procedure. As an example, the Bureau recently convened a panel made up of obstetricians and radiologists in order to consider the issue of routine pelvimetry in pregnant women. The panel was able to develop a statement of good practice about this procedure which was subsequently approved by the American College of Obstetricians and Gynecologists and the American College of Radiology.

There is another way to develop referral criteria that is more expensive and time-consuming. This process involves research, often involving thousands of patient records, in which the goal is to find out in retrospect that extent to which radiographs actually

affected patient management or ultimate outcome. The Bureau is presently supporting two research grants in dentistry using this process. One of these, under Dr. White at UCLA, is investigating panoramic radiographs; another is at the Eastman Dental Center in Rochester under Dr. Jensen, in which patient history and characteristics are being correlated with the outcome of dental bitewing exams. This kind of work won't be finished overnight, but it can give the kind of hard scientific data the professions need to develop sound guidance on when radiographic examinations are indicated.

Another area of Bureau activity is in educating patients about radiographs. Our goal here is to allay the anxiety of patients who may be unduly fearful of radiation, as well as to educate patients who may insist on having radiographs taken. To help accomplish this, we recently developed a brochure in cooperation with the ADA informing patients about dental X rays. The initial demand for this publication among dentists has been very encouraging.

I hope this brief overview has given you a picture of how the Bureau's programs affect the practice of dental radiology, and that it will provide a useful backdrop for your work during this Conference.

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