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## Benefits of Medical Radiation Exposures

**Pat Zanzonico, PhD, and Michael G. Stabin, PhD, CHP**

### Background

We frequently receive questions on the Ask the Experts (ATE) feature of the Health Physics Society website from people who have received one or more diagnostic medical exams. These people express concern about the risks of the radiation exposure(s) from these exams.

We always encourage people to become well informed about the risks and benefits of all uses of radiation, and in the case of medical exposures, it is good to be an active participant in the process. This includes an understanding of the procedures involved and the possible risks associated with them.

We routinely answer this kind of ATE question with as much information taken from various standard published data sources as we can provide about typical radiation doses for the procedure. However, only the physician, physicist, and other professionals from the institution where the procedure is performed can provide specific radiation dose information for the particular exams and techniques employed.

We usually add a statement that "any theoretical risks of the radiation exposures that you received were far smaller than the direct benefits of the study." We say "theoretical" because all risk information is based on the so-called "linear no-threshold" (LNT) theory, which assumes that risks (mostly of cancer) observed in populations exposed to high doses of radiation can be extrapolated to the much lower doses that we deal with in diagnostic medical procedures, radiation-worker situations, and other circumstances. By "extrapolation" we mean that a straight line is drawn through the risk-versus-dose data available at higher doses (typically at least 10-fold higher than diagnostic or occupational doses) and this line is then extended down to zero dose.

No one knows if this extrapolation is valid, but it is used to set radiation dose limits for workers, make general evaluations about risks and benefits of medical exposures, and estimate risks in other applications.



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Some have used this model to state as fact that thousands of excess cancer deaths will occur in populations exposed to low doses of radiation, but this is not supported by the available science—we don't know for a fact that low (that is, diagnostic and occupational) levels of radiation are associated with increased risks of developing cancer. Many believe that the LNT approach overestimates the actual risks at such low doses and some even believe that there is evidence for a threshold for such effects, that is, that there may be a non-zero radiation dose below which there is NO increased risk of cancer. Others believe that the best explanation of available data is given by an LNT model. Importantly, the data upon which the LNT model is based begin at doses above 100 mSv (10 rem).

### Quantitative Estimate of Benefits

Until now, we have never had a **quantitative estimate of the benefits** of the exposures to go along with our quantitative estimates of risk. Pat Zanzonico, PhD, of the Memorial Sloan-Kettering Cancer Center in New York, analyzed the benefits of a number of medical procedures in order to provide quantitative estimates of these benefits so they can be compared with the theoretical risks of the procedures. With his permission we summarize this information here to provide some understanding of this important issue. One should understand that while the data which Zanzonico used in his analysis have already been published in the peer-reviewed scientific literature, his analysis has not yet been published nor peer-reviewed.

### Radiogenic Cancer Risk

First, let's define the radiogenic risk of cancer. It is finite and quantifiable—the excess number of cancers in a population using the LNT approach is:

$$\# \text{ persons exposed} \times \frac{\text{effective dose (rem or mSv)}}{\text{person} \cdot \text{procedure}} \times \frac{\text{excess relative risk}}{\text{effective dose (rem or mSv)}} .$$

The excess relative risk (ERR) gives the number of excess fatal cancers (excess above the naturally occurring rate) predicted by the model in a large population of people exposed to radiation. One value that is widely cited is from the National Council on Radiation Protection and Measurements Report No. 115, "Risk Estimates for Radiation Protection." It is  $5 \times 10^{-5}$  per person mSv ( $5 \times 10^{-4}$  per person rem).

What this number means, for example, is that if each person in a population of a **million** were to receive a dose of 1 mSv, the expected number of excess cancer

fatalities observed in this population would be  $5 \times 10^{-5}$  per person mSv  $\times 1 \times 10^6$  person mSv (collective dose) = **50**. It is important to remember that, even if we accept the tenets of the LNT model, any calculated risk numbers should be applied to populations, never individuals.

### Benefits of Radiological Procedures

The benefit of a radiological procedure has not been previously quantified. The number of lives saved may be quantified as the number of lives lost by not performing the procedure or the number of lives lost by performing an alternative, invasive procedure. Zanzonico has now attempted to quantify this for four important medical procedures using information gleaned from the literature about actual rates of complications and lives lost *when the radiological procedures are not performed*.

#### 1. Use of $^{18}\text{F}$ FDG PET in Preoperative Assessment of Suspected Non-Small-Cell Lung Cancer (NSCLC)

With a conventional preoperation evaluation of the disease, a thoracotomy is ordered in 81 percent (78/97) of the cases, with 41 percent (39/78) of these being futile (meaning that the procedure is not successful in removing the diseased tissue and therefore cannot possibly be curative) (van Tinteren et al. 2002).

If a  $^{18}\text{F}$ FDG PET (2-[ $^{18}\text{F}$ ] fluoro-2-deoxy-D-glucose positron emission tomography scan) study is done, however, thoracotomy is ordered in only 65 percent (60/92) of cases, with only 21 percent (19/60) futile interventions. Surgical-related mortality is reported as 6.5 percent.

With the use of PET, 20 percent of futile surgeries are avoided. There are 174,470 new lung cancers diagnosed in the United States every year (2006 data). The expected rate of futile surgery deaths without a PET examination is estimated as 3,766 per year, whereas with the PET study the level would be only 1,574 per year, representing a gross benefit of lives saved through use of the PET studies of 2,192 per year.

Assuming an effective dose of 7 mSv (0.7 rem, from a typical administration of 370 MBq, or 10 mCi), due to the study, the LNT model would predict 61 excess cancer deaths each year.

Thus the net benefit in terms of lives saved is  $2,192 - 61 = 2,131$  per year. It is important to recall that the lives saved are actual lives saved, whereas the lives lost from the 7 mSv exposure are theoretical lives lost, only true if the LNT model accurately predicts fatal cancer incidence down to this low-dose level. Data for the LNT model

begin at doses above 100 mSv.

### 2. Use of Multislice Computed Tomography (MSCT) versus Conventional Coronary Angiography (CCA)

The effective dose from the use of MSCT is about 14 mSv (1.4 rem) (Coles et al. 2006). Using the LNT model, this would suggest an excess radiogenic cancer death risk of 0.07 percent. The effective dose from CCA by comparison is about 6 mSv (0.6 rem) (Coles et al. 2006), suggesting an excess radiogenic cancer death risk of 0.03 percent. The nonradiogenic, noncontrast mortality risk from CCA is 0.11 percent, according to Noto et al. (1991). The U.S. population of individuals aged 50 to 55 years (2006) is 18.8 million. The number of excess cancer deaths due to the use of MSCT screening for CAD (coronary artery disease), if such screening were done, can be estimated as 13,160 for a single exam. The number of excess cancer deaths would be 39,480 or 2,627 per year when an exam is given every five years to age 70.

The potential gross benefit of MSCT CAD screening is estimated at 33,500 per year. The number of lives saved is 10 percent of ~335,000 sudden cardiac deaths per year (American Heart Association 2005). For an individual having a first myocardial infarction at age 68 (American Heart Association 2005) more than 90 percent had greater than 75 percent stenosis in more than one vessel (Liberthson et al. 1974), which is detectable by MSCT. Conservatively, therefore, the net benefit of MSCT is seen to be 30,873 lives saved per year.

### 3. Use of Sentinel Node Biopsy versus Standard Axillary Therapy in Operable Breast Cancer

In a multicenter randomized trial, comparing quality-of-life outcomes in clinically node-negative invasive operable breast cancer, the number of sentinel node biopsies was 515 and the number of standard axillary therapies was 516. Total biopsies that indicated breast cancer were seven, with either sentinel node biopsies or standard axillary therapies. The incidence of lymphadema and sensory loss at 12 months for sentinel node biopsy is only 37 percent of that for standard axillary therapy risk (Mansel et al. 2006).

The use of  $^{99m}\text{Tc}$ -labeled sulfur colloid for breast imaging results in an effective dose of about 0.92 mSv (0.092 rem). The use of the LNT model with this dose level predicts a number of excess cancer deaths in the 515 subjects of 0.024, which is approximately zero.

Thus, the net benefit of the use of sentinel node biopsy is equal to the **gross** benefit, namely a 63 percent reduction in the incidence of lymphadema and arm-

sensory loss.

#### 4. Use of Scintigraphic Perfusion Imaging to Predict Cardiac Events in Noncardiac Surgery

The most important cause of perioperative cardiac mortality and morbidity is myocardial infarction (MI) due to occult CAD (coronary artery disease). The incidence of the event during vascular surgery is 13 percent and the mortality is 40 to 70 percent. The rate of perioperative cardiac events with the use of dipyridamole  $^{201}\text{Tl}$  imaging of the perfusion defect (3,600 patients, 26 studies) (Gojer and Williams 1995) is 2 percent for a severity level of 0 and an extent of 0 and 100 percent for a severity level of 3 and an extent of 5-6. Twenty-two percent of patients have reversible perfusion defects. The number of vascular surgeries (data from the VA database) is about 9,500 per year. The number of perioperative deaths (fatal MIs) is thus estimated as 494 per year. Therefore the gross benefit of preoperative perfusion imaging with  $^{201}\text{Tl}$  is 109 per year (predictable perioperative deaths [fatal MIs] avoided). The effective dose from the  $^{201}\text{Tl}$  study is about 24 mSv (2.4 rem).

The LNT model would predict 11 excess cancer deaths, but the net benefit of preoperative perfusion imaging remains at  $109 - 11 = 98$  lives saved per year.

#### **Conclusion**

These four examples above are only representative examples from the literature. The analysis could be extended to other studies and agents. But the conclusion is immediately clear—**the use of radiation in medicine saves hundreds to thousands of lives every year, while the entirely theoretical risks predicted by the LNT model are orders of magnitude smaller.**

Thus, our focus on the use of radiation in medicine should be on whether the study is indicated by the physician to obtain important, often lifesaving information for the patient and not on the small and theoretical risks that may be suggested by the LNT model.

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