SIDE-EFFECTS FROM IONIZING RADIATION: ADVANCES IN ASSESSING THE RATE OF MALIGNANCIES PER UNIT OF DOSE

John W. Gofman, M.D., Ph.D., Professor Emeritus of Medical Physics,
102 Donner Lab, Univ. of California, Berkeley, CA 94720;
Lecturer in the Dept. of Medicine, Univ. of Calif., San Francisco.

1. • INTRODUCTION

Low-LET Radiations and Malignancies: In both internal medicine and in occupational medicine, the ionizing radiations of prime concern are the low linear-energy-transfer radiations (low-LET radiations). These include X-radiation, gamma-radiation, and the beta-particles emitted from a host of radionuclides used in nuclear medicine. We shall limit our discussion to the two main and delayed effects of exposure to such radiations, namely radiation-induced cancer and leukemia.

Dose-Units: The three dose-units commonly used in human exposures are the roentgen, rad, and rem. The roentgen refers to the energy in an X-ray beam measured at the surface of the body just before the beam enters the body. Inside the body, the traveling beam becomes weaker and weaker because internal organs are absorbing its energy. When the beam comes out the patient's opposite side, it carries only a few percent of its original energy. Energy deposited in body tissue is called an absorbed dose, and is expressed in rads or rems. For low-LET radiations, rads and rems are interchangeable units. One rad represents the deposition of 100 ergs of energy per gram of tissue.* When rads are used instead of roentgens to express an entrance dose, they refer to energy absorbed by the surface of the skin.

Current Controversies: There are some controversies in this field which every physician who orders either diagnostic or therapeutic radiation, or who practices occupational medicine, needs to recognize. I shall discuss the "hottest" current issues before we end. First, however, I plan to provide some practical information which is helpful in making everyday judgments about medical irradiation and occupational exposures. Such information is tied closely to three generalizations, which I will state in a moment.

* The Gray represents 100 rads; the Sievert represents 100 rems. These are recently introduced units.

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2. • THREE GENERALIZATIONS

In 1969, Gofman and Tamplin (Go69) presented three generalizations concerning radiation carcinogenesis in humans; their basis was the human epidemiologic evidence available at that time. The additional human data which have accumulated over the following 17 years continue to confirm the generalizations' validity. Today, almost no one in this field disputes the first and third ones. Concerning the second one, there is still a relative shortage of data, so it is not yet fully part of "mainstream" doctrine. The three generalizations are as follows:

First Generalization: "All forms of cancer, in all probability, can be increased by ionizing radiation, and the correct way to describe the phenomenon is either in terms of the dose required to double the spontaneous mortality rate for each cancer, or alternatively, of the (percent) increase in mortality rate of such cancers per rad of exposure."

Second Generalization: "All forms of cancer show closely similar doubling doses and closely similar percentage increases in cancer mortality per rad (at a given age at exposure)."

Third Generalization: "Youthful subjects require less radiation to increase the (cancer) mortality rate by a specified fraction than do adults."

Practical Results: These generalizations have made it possible to combine the worldwide epidemiologic evidence in a valid manner and to arrive at quantified risk-estimates for radiation-induced cancer. The hazard depends not only on the size of the dose, but on age at exposure and the frequency of spontaneous cancer. The chance of inducing cancer is highest when organs with high spontaneous rates (for instance breast, colon) are irradiated in youthful subjects.

Now it is time to present my own estimates of cancer risk from radiation (Go81), and then also to present estimates made by others.

3. • WHOLE-BODY RADIATION EXPOSURE

It is helpful to start with assessing the cancer consequences from uniform exposure of the whole body by radiation, before considering the lesser risks from exposing only part of the body. Presented in Table 1 are three types of information on whole-body exposure.

Whole-Body Cancer Doses By Age-Groups (Table 1, Column 2): The Cancer Dose is expressed in "person-rads," a unit which represents the

number of exposed persons receiving the same size of dose, multiplied by that dose. Thus 100 person-rads can be the result of only one person receiving 100 rads, or 50 persons each receiving 2 rads, or 100 persons each receiving 1 rad. Since person-rads can be added, the sum of those three examples would be 300 person-rads.

The Whole-Body Cancer Dose is defined as the dose in person-rads which will produce one fatal, radiation-induced cancer in the exposed group during its remaining lifespan. If the Cancer Dose has been distributed over a group containing several people, no one can predict who will be the unlucky one. But if the Cancer Dose is received by a "group" of only one person, the prediction is all too easy. In a few moments, we will consider individuals instead of groups.

Percent Increase In Fatal Cancers Per Rad (Table 1, Column 3): These entries are the percent increase in the spontaneous rate of fatal cancer per rad of whole-body exposure when the total remaining lifespan of the exposed persons is considered. Column 3 clearly reflects what was stated by Generalization 3: the younger the group is at exposure, the more severe is the cancer-effect per rad of dose.

Suppose that among a group of 100 newborn boys, the spontaneous cancer mortality over the group's lifespan is expected to be 20%, or 20 cases. Suppose, however, that soon after birth, each receives 2 rads of whole-body irradiation. Table 1 tells you that the exposure will increase the spontaneous rate, which is 20 cases, by (8.45% per rad) times (2 rads), or by 16.9%. Thus there will be an increase of 20 cases times 0.169, or about 3 cases of fatal radiation-induced cancer in this exposed group. Instead of 20 cases, this group will experience 23 total cases of fatal cancer.

As Table 1 shows, the higher the risk per rad (Column 3), the lower the Cancer Dose (Column 2). This inverse relationship must be kept in mind.

Average Loss of Life Expectancy (Table 1, Column 4): These entries are the number of years of lost life for those individuals who do develop a radiation-induced fatal cancer, on the average. It is not the lifespan loss for the entire group.

Illustrative Use of Whole-Body Cancer Dose: Suppose that 100,000 newborn males each receive 1 whole-body rad at age 0.

Radiation-induced fatal cancers = 100,000 person-rads / 64 person-rads per fatal cancer,
= 1,562.5 fatal cancers induced.

Illustrative Use of Percent Increase Per Rad: Suppose that 100,000 newborn males each receive 1 whole-body rad at age 0.
Spontaneous fatal cancers = 18.5% of 100,000 = 18,500 fatal cancers.
Percent increase per rad = 8.45% per rad (from Table 1, Column 3).
Radiation-induced fatal cancers = (spontaneous fatal cancers) x (0.0845)
= (18,500 cases) x (0.0845)
= 1,563.2 fatal cancers induced.

Comparison: Aside from differences from prior rounding-off, the results by the two methods agree, as they must if correctly used.

Risk-Values for the Individual (Table 2): If 100,000 newborns each receiving 1 whole-body rad yield 1,562.5 fatal cancers, then it follows that the risk per individual necessarily must be 1,562.5 per 100,000, which is equal to 1 chance per 64. One chance in 64 is the same as the individual's dose in rads over the Whole-Body Cancer Dose in rads.

Table 2 lists the risk-rates from 1 rad for all ages. Doses above and below 1 rad are handled the same way. Example: for a newborn boy receiving 3 whole-body rads, the risk is 3 per 64, or 1 chance in 21 of a later, fatal radiation-induced cancer. For a newborn boy receiving 0.2 whole-body rad, the risk of a fatal, radiation-induced cancer later in life is 0.2 per 64, or 1 chance in 320.

It must be noted that for every fatal cancer induced, there will be one additional non-fatal cancer induced. Therefore, the total cancer risk is twice that shown for fatal cancers in Tables 1 and 2. (Tables 3A,B include the non-fatal cancers.)

Exposure Of Entire Populations: When populations of mixed ages and both sexes are exposed to ionizing radiation, the cancer consequences are assessed by weighting the values in Table 1 by the number of persons in each age-group. Following are the results, based on age-distribution in the United States.

Group	Whole-Body Cancer Dose (in person-rads)	Percent Increase In Fatal Cancers Per Rad
Males	235	2.300
Females	300	2.083
Mixed Population . all ages, both sexes	268	2.163

Illustrative Use Of Cancer Dose: Suppose we have a mixed-age population of 1,000,000 persons each exposed to 1 rad of whole-body radiation, on the average. How many fatal cancers are produced? 1,000,000 person-rads / 268 person-rads per case = 3,731 fatal cancers.

Illustrative Use Of Percent Increase: For that same exposure, the corresponding percent increase in fatal cancers per rad is 2.163%. For a mixed U.S. population, we expect 17.25% to die of cancer, so for 1,000,000 persons, we expect 172,500 spontaneous fatal cancers. Radiation-induced cases = (0.02163) x (172,500) = 3,731 fatal cancers, the same result obtained by using the Cancer Dose above.

Leukemia Induction By Ionizing Radiation: The human evidence is very solid for leukemia induction by ionizing radiation, as it is for cancer induction. But for leukemia, a variation in risk according to age at exposure is less certain. Our best estimate is that the Whole-Body Leukemia Dose is in the neighborhood of 6,000 to 7,000 whole-body marrow-rads per leukemia, regardless of age at exposure (Go87).

4. • PARTIAL-BODY RADIATION EXPOSURE

Medical Procedures: In many settings, particularly the medical and dental use of X-rays and the internal administration of radio-nuclides in nuclear medicine, we are dealing with partial-body exposure. It is expected, of course , that partial-body radiation must yield fewer cancers per rad than does whole-body radiation, since many of the sites susceptible to cancer induction receive no dose at all, or exceedingly small doses from radiation scatter. Indeed, risk is lower.

How To Evaluate Risk: A simple rule converts the Whole-Body Cancer Dose into the appropriate Specific-Organ Cancer Dose. The cancer risk for a single exposed organ is the Whole-Body Cancer Dose by age-sex class, divided by the fraction of all spontaneous fatal cancers in that sex accounted for by cancers of that single organ.

Breast Cancer As an Illustration: Breast cancer accounts for 0.2 of the cancer death-rate in women. For 25-year-old women, the Whole-Body Cancer Dose is 252 person-rads. It follows from the rule that the Breast Cancer Dose at that age is 252 / 0.2, or 1,260 breast-rads (absorbed dose by each of two breasts) per fatal radiation-induced breast cancer. Thus the individual risk for a woman receiving a dose

of 3 breast-rads at age 25 is 3 per 1,260, or 1 chance in 420. The rate for every group of 420 such women is 1 fatal radiation-induced breast cancer per group, plus 1 non-fatal case.

Variation In Risk From Diagnostic X-Ray Exams (Tables 3A and 3B): The rates of radiation-induced cancer from common X-ray procedures, including CAT scans and mammography, have recently been evaluated by Gofman and O'Connor (Go85) in "cold dope" tables. These tables, of which Table 3A is a sample, are derived directly from the principles I have been explaining. The cancer risks from the lumbo-sacral spine exam do not come from bone cancer, which has a very low spontaneous rate. The risk-rates in Table 3A represent the combined risks from the stomach, bladder, large intestine, kidney, pancreas, rectum, prostate, uterus, and ovaries --- all of which develop an increased risk of cancer due to the radiation doses they receive during such an exam.

Table 3B, which summarizes results from ten such tables, shows that some examinations are characterized by very low cancer risks, particularly exams of the limbs and all exams in persons over 50 years of age at the time of exposure. Of course, the youngest have the highest risk from any particular X-ray exam.

Tables 3A and 3B are based on typical doses at institutes nationwide, as surveyed by the FDA. Such surveys also establish that some institutions achieve perfectly good X-ray films with doses 10, 20, and even 50 times lower than the doses given at other institutions. The facilities giving the excessive doses and unnecessary cancer-risks seldom know they are doing so. Most often, they have been depending on calculating their doses from manuals instead of actually measuring them. Measurements are far more reliable, and not expensive.

Facilities which measure their doses on a frequent schedule are able to recognize an overdose problem and to take corrective action. Some facilities achieve a 3-fold reduction in dose and risk just by better care in processing their films, a 6-fold reduction by careful choices in film-screen combinations, a 2-fold reduction by careful choice of filters (Ta83).

At the Mayo Clinic, Dr. Joel Gray and co-workers have developed techniques which achieve over a 50-fold reduction in dose to the breasts

from the upper spinal X-rays so often used during treatment of scoliosis (Gr83). Says Dr. Gray about facilities which won't tell you the doses they give: "My feeling is that if they won't tell you, they don't know, and if they don't know, they could be among the facilities delivering a hundred times the necessary dose" (Gr84).

The Benefits of X-Rays With One-Third the Risk: A conservative estimate by Dr. Kenneth Taylor, a real expert in dose-reduction, is that it would be easy to achieve a 3-fold reduction in average X-ray doses without any loss of image-quality (Ta79). A conservative estimate by myself and Ms. O'Connor (Go85) is that a 3-fold reduction in average X-ray doses would prevent 50,000 cases of cancer every year in the United States --- without anyone foregoing a single X-ray exam or its benefits. Aside from cessation of smoking, I have not seen evidence for any single cancer-prevention measure which would be as certain to work, and as simple, as avoiding X-ray facilities which are careless about their diagnostic doses.

5. • CURRENT ISSUE: DISPARITY IN RISK-ESTIMATES

Although diagnostic X-rays have been one of the most widely used procedures in medicine for decades, the cancer-risk per rad of dose remained virtually unquantified until 1969. The early attempts to quantify it (Go69, Go70a, Go70b, Go71) brought forth massive resistance and finally a report in 1972 from the BEIR-1 Committee (Beir72) under the umbrella of the National Academy of Sciences. Subsequently, there have been many committees, many estimates. The two most commonly cited committees are the United Nations' UNSCEAR and BEIR-3, which was chaired by Dr. Edward Radford in 1980.

Currently there is significant disparity in risk-estimates, as reflected in estimates of the Whole-Body Cancer Dose for populations of mixed ages:

Year	Source	Whole-Body Cancer Dose In Person-Rads	
1977	UNSCEAR Committee	10,000	(Un77)
1980	BEIR-3 Committee, Table V-4	4,400	(Beir80)
1981	Gofman, independent estimate	268	(Go81)
1982	UNSCEAR Committee	10,000	(Un82)
1985	Radford, independent estimate	1,000	(Ra85)
1987	Gofman, independent estimate, based on new human data (Pr86)	254	(Go87)

Obviously, some of the estimates must be very seriously in error and hence useless in medicine.

UNSCEAR, in its 1986 report (Un86), neither affirms nor repudiates its value of 10,000; it just offers no value at all, now. This omission suggests that the committee may be wishing to discard its value of 10,000 because the number simply bears no resemblance to the existing evidence.

BEIR-3's value of 4,400 is considered by its own chairman, Dr. Edward Radford, to be a 4.4-fold underestimate of cancer-risk (Ra85).

My own estimate in 1981 was based exclusively and directly on human epidemiology from over 20 separate series of exposed humans. Unlike the BEIR-3 Committee, I do not invoke in-vitro cell data, radiobiological hypotheses about what epidemiology ought to show, animal data, or elaborate mathematical manipulations of the observations. I try to let the actual observations of exposed and unexposed humans tell their own story.

In 1986, Preston and co-workers (Pr86) provided four years of additional data from the continuing follow-up of the atomic-bomb survivors of Hiroshima-Nagasaka. This series includes not only some high doses, but far more important, it includes nearly 29,000 persons who received an average absorbed gamma dose of only 1.27 rad, and another 15,000 persons who received an average of only 9.36 rads. These dose-levels are of direct relevance to medical practice. The suggestion that no human evidence exists for radiation-induced cancer below a dose of 50 rads (Br83) is pure misinformation.

Since the Hiroshima-Nagasaki series is the human study most favored by UNSCEAR and BEIR-3, I was eager to analyze the Preston data by themselves, unmixed with data from other series. The resulting Whole-Body Cancer Dose, based on the groups receiving the least exposure, is 254 person-rads per fatal radiation-induced cancer (Go87). This confirmation of my 1981 estimate, with the confirmation based on a de novo analysis of new and separate data, is a good reason for assuring you that the correct Whole-Body Cancer Dose for low-dose exposures is less than 300 person-rads per extra fatal cancer.

Our seminars are called "advances in internal medicine." Adoption

of correct risk-estimates for radiation-induced cancer will be an important advance, but seldom are advances made without tumult. In view of the new evidence reported by Preston, you should expect tumult on this issue before we meet again.

6. • CURRENT ISSUE: SOME HARMLESS DOSE-LEVEL?

For decades, it has been suggested that maybe low radiation doses are harmless with respect to inducing malignancies. We must take such an attractive notion seriously, and I have done so. The purported human evidence for some safe threshold-dose consists basically of comparisons of human cancer-rates in areas with high and low doses from natural radiation sources. I have carefully examined such comparisons (including Fr76), and have explained the nature of their serious flaws (Go81). The existing human evidence simply provides no support for any safe threshold-dose with respect to malignancies.

Instead, valid evidence against any harmless dose is already at hand. Analysis of five separate human studies (My69, Mo77, Bo77, St70, and Ba81 and 83) reveals that even the lowest possible dose-rate is producing radiation-induced cancers (Go86). Even at the minimum dose-rate --- which is the challenge by one primary ionization track to repair-mechanisms in the cell's nucleus --- repair fails to work perfectly. If repair worked perfectly, there would be no excess cancer observed from exposures at the minimum dose-rate per eight hours. But excess malignancies are observed in the five studies.

As this recent disproof of any safe dose enters circulation, there will be tumult, of course, since the hope for a safe threshold is sustained in prominent places (Ev86; Un86). Resistance may be fierce among those who propose "hormesis," the idea that maybe low doses of ionizing radiation help protect humans against malignancies (Lu80). But I expect that evidence will prevail over non-evidence and even over wishful thinking, in the end.

Lastly, I must mention the widely promoted notions that (A) cancer-risk from radiation is less if a given dose is delivered in small increments instead of all at one time, and (B) the risk per rad is less in the low-dose range than in the high-dose range (Beir80; Ev86, Nih85;

Un86). Regarding (A), the human evidence from breast-cancer studies indicates that risk is not reduced by dividing a big dose into smaller doses (My69; Bo77; Bo79; Ba81 and 83). Regarding (B), the evidence from Hiroshima-Nagasaki shows just the opposite; the cancer-risk per rad is actually higher in the low-dose range than in the high-dose range (Go81; Go87).

Denials of radiation's true hazard come in great variety, yet the evidence which refutes all of them is scientifically harmonious. For instance, when the evidence is that risk per rad is growing more severe as dose falls, it would be surprising if a further dose-decline suddenly met a safe threshold. Thus there is harmony in the actual evidence that even the minimum dose-rate of ionizing radiation does cause excess cancer.

As a physician, I could wish for a safe dose, but as a physician I know that patients are better off when we are realistic about the rate of deadly side-effects from anything we order, whether it is a surgery, a pharmaceutical, or an exposure to ionizing radiation.

TABLE 1

Whole-Body Cancer Doses, Percent Increases Per Rad (Lifetime), and Loss of Life Expectancy (For Those Dying Of Rad'n-Induced Cancer)

(1) Age (yrs) When Exposed	(2) Whole-Body Cancer Doses (person-rads per fatal cancer)	(3) Percent Increase In Cancer Fatality-Rate Per Rad	(4) Average Loss of Life Expectancy (years) For Those Dying Of Radiation-Induced Cancer
. . . . . Males			
0	64	8.45	22.3
5	71	7.61	20.1
10	88	6.14	17.9
15	178	3.04	15.9
20	200	2.70	14.2
25	201	2.69	12.8
30	234	2.31	11.6
35	328	1.65	10.6
40	538	1.00	9.6
45	1233	0.44	8.7
50	13434	0.04	8.0
55 *	19590	0.03	7.1
. . . . . Females			
0	68	9.19	28.9
5	80	7.81	26.3
10	104	6.01	23.6
15	217	2.88	21.0
20	249	2.51	18.6
25	252	2.48	16.6
30	285	2.19	14.8
35	399	1.57	13.0
40	636	0.98	11.5
45	1412	0.44	10.2
50	14615	0.04	9.3
55 *	20960	0.03	8.5

* Above age 55 years, no significant induction of fatal cancers by radiation has been proven within the epidemiologic evidence.

TABLE 2

Risk Per Individual of Fatal Cancer-Induction From One Rad Of Whole-Body Radiation

Age (yrs) When Exposed	Risk Per Individual, For Males	Risk Per Individual, For Females
0	1563 per 100,000; or 1 per 64	1471 per 100,000; or 1 per 68
5	1408 per 100,000; or 1 per 71	1250 per 100,000; or 1 per 80
10	1136 per 100,000; or 1 per 88	962 per 100,000; or 1 per 104
15	562 per 100,000; or 1 per 178	461 per 100,000; or 1 per 217
20	500 per 100,000; or 1 per 200	402 per 100,000; or 1 per 249
25	498 per 100,000; or 1 per 201	397 per 100,000; or 1 per 252
30	427 per 100,000; or 1 per 234	351 per 100,000; or 1 per 285
35	305 per 100,000; or 1 per 328	251 per 100,000; or 1 per 398
40	186 per 100,000; or 1 per 538	157 per 100,000; or 1 per 637
45	81 per 100,000; or 1 per 1234	71 per 100,000; or 1 per 1408
50	7.4 per 100,000; or 1 per 13500	7 per 100,000; or 1 per 14500
55	5 per 100,000; or 1 per 20000	4.8 per 100,000; or 1 per 21000

The individual risk of fatal cancer induction per rad is some 300 times higher for those receiving radiation at age 0 than it is at age 55.

TABLE 3A

CE: Common Exam

AGE 20
LUMBO-SACRAL SPINE

Testes, dose CE: 40 mrads
Ovaries, dose CE: 543 mrads
Embryo, dose CE: 527 mrads

Common Exam (CE): One AP, one LAT, and one OBL-PA (Total: 3 shots)
Rate of future *leukemia* from Common Exam:
Males: 46 per million = 1 in 21,700
Females: 29 per million = 1 in 34,500
Rate of future *cancer* from Common Exam: (Smokers)
Males: 3,402 per million = 1 in 294 (CE × 1.03)
Females: 2,970 per million = 1 in 337 (CE × 1.02)

Per Shot	*Ent Dose*	*Beam HVL*	*Male Cancer Risk*	*Female Cancer Risk*
AP	0.911 R	2.4 mm Al	1,502 per million	1,204 per million
PA	1.952 R	2.4 mm Al	1,485 per million	1,319 per million
LAT	3.480 R	2.6 mm Al	926 per million	928 per million
OBL-PA	1.606 R	2.5 mm Al	974 per million	838 per million

mrad: millirad, 0.001 rad
R: roentgen, entrance dose
AP: beam travels from front to back
PA: beam travels from back to front
LAT: beam travels from side to side

TABLE 3B

Question .: What is a person's lifetime chance of getting cancer as a *result* of having one of the following 10 common X-ray exams under common conditions?

- *Newborn Infant: Chest Exam (2 shots)*
  Male: 1 chance in 3,500 Female: 1 chance in 1,800
- *Age 5: Lower Arm Exam (2 shots)*
  Male: 1 chance in 300,000 Female: 1 chance in 350,000
- *Age 5: Angiocardiography (40 films plus 30 minutes fluoroscopy)*
  Male: 1 chance in 120 Female: 1 chance in 80
- *Age 10: Full-Mouth Dental Exam (16 films)*
  Male: 1 chance in 600 Female: 1 chance in 1,400
- *Age 15: Full-Mouth Dental Exam (16 films)*
  Male: 1 chance in 900 Female: 1 chance in 2,400
- *Age 20: Full-Mouth Dental Exam (22 films)*
  Male: 1 chance in 650 Female: 1 chance in 1,750
- *Age 20: Thoracic Spine Exam (2 films, wide)*
  Male: 1 chance in 1,300 Female: 1 chance in 600
- *Age 35: Mammography (2 shots of each breast) by Xeroradiographic method*
  Male: Not Applicable Female: 1 chance in 900 (breast cancer)
- *Age 40: Angiocardiography (40 films plus 30 minutes fluoroscopy)*
  Male: 1 chance in 800 Female: 1 chance in 500
- *Age 55: Hip Exam (2 shots)*
  Male: 1 chance in 210,000 Female: 1 chance in 190,000

* Table 3A is from page 135, and Table 3B is from page 4, of the book X-Rays: Health Effects of Common Exams, 1985 (Go85).

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