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NCRP Claims Six Studies Support LNT But They Show No-Effect to At Least 100 mGy

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Abstract

NCRP Commentary-27 reaffirmed Linear No Threshold (LNT) as the basis for radiation protection and listed six studies with "strong support" for LNT. This paper looks critically at these six studies and shows that they do not support LNT in the dose range of 0-100 mGy. These studies typically admit to no increase in cancer risk at significant dose levels. More importantly this paper shows that these studies assume LNT from the outset, underestimate uncertainty, ignore confounding factors, have biased control groups, and underestimate dose.

Keywords

LNT, NCRP, threshold, radiation, INWORKS, Hiroshima

Introduction

This paper examines the National Council on Radiation Protection and Measurement (NCRP) contention that six studies show strong support for Linear No Threshold (LNT) which the NCRP reaffirms as the basis for radiation protection.[1] This paper examines the data in these six studies to determine if, contrary to LNT, they are consistent with no increase in cancer below 100 milli-gray (mGy).

To quote from NCRP's Commentary 27, herein referred to as NCRP-27: "The specific purpose of this Commentary is to provide a review of recent epidemiological data from studies with low doses or low dose-rates and from the Life Span Study (LSS cohort) of atomic bomb survivors to determine whether these epidemiological studies broadly support the LNT model of carcinogenic risk or, on the contrary, *whether there is sufficient evidence that the LNT model is inappropriate for the purpose of radiation protection*." (underline added).[1] It is not clear what kind of evidence would make LNT inappropriate for radiation protection in the eyes of the NCRP.

The six studies that NCRP-27 claims strongly support LNT include: two Hiroshima/Nagasaki (H/N) studies,[2,3] two medical studies,[4,5] and two nuclear worker studies.[6–8] The H/N studies were based upon the LSS cohort. Subsets of the LSS were included in the two medical studies, which also contained high-dose-rates from medical treatments. The two worker studies included high-doses and high-dose-rates during accidents. In short, these are not studies of low-dose and low-dose-rates as intended by NCRP-27.

Other authors have criticized NCRP-27 and these six studies because of flawed methodology, inappropriate assumptions, and the lack of studies with contrasting viewpoints.[9–14] This paper looks for statistically significant evidence of cancer risk in the 0-100 mGy dose range. Note that although this is often considered to be a low-dose range, it is rarely exceeded.

The six studies are for very specific and unusual cases, typically from before 1970. They include physically and mentally traumatized victims of war; tuberculosis (TB) patients who contracted breast cancer but not lung cancer; thyroid cancer, at least partially in iodine deficient children in a genetically isolated population; and weapon workers during the Cold War. The conditions leading to these high-doses will likely never be repeated even without the radiation protection regulations fostered by NCRP-27. In contrast, studies of the effects of radiation on large populations in high ambient radiation find flat or negative dose response.[15–17]

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This paper shows that the data in these six studies are consistent with no cancer risk below 100 mGy, even if acutely given. This paper will also critique the six studies since: LNT is assumed from the beginning, doses are typically underestimated, binning and graphing of data favors LNT, the control group is problematic, uncertainties are underestimated, and all harm is attributed to radiation.

Comparison of cancer risk in the control group and in a low-dose range can be done directly. However, this was not done in these six studies. Rather, these studies test LNT with Excess Relative Risk (ERR) linear models, which assume LNT, and often produce positive dose responses for three reasons. First, linear models are heavily influenced by high-dose bins (grouping of subjects with similar doses) that are not of great interest since they typically have a small number of subjects and confounding factors. Second, linear models are more influenced by RR = 2 (twice the cancer rate) than by RR = 0.5 (half the cancer rate), and similarly for other RR values. Finally, bins with RR = 0 are averaged with other bins negating the influence of there being no cancer in a dose bin.[18]

This paper is important because the public thinks that LNT means they are at significant risk of radiation from nuclear reactors and waste. In fact, they are not at risk except for exceptional cases like Chernobyl, which we can assume will never be repeated. By contrast, fear of radiation causes many problems, for example, the prudent disposal of nuclear waste is prevented as discussed later.

H/N Studies

Grant Study

NCRP-27 stated that two H/N studies with overlapping cohorts strongly support LNT. These studies are widely believed to be the "gold standard" for radiation epidemiology. The Grant study was of solid cancer incidence in 80 205 survivors of the bombs and 25 239 "Not In City" (NIC) who were not directly affected by the blast.[2] The control group included the NIC group and 35 978 survivors who were between 5 and 10 km from ground zero and received less than 5 mGy. The 44 227 exposed subjects had 5 to ∼4000 mGy. Doses were calculated from neutrons and photons from the blast. Contamination was not included even though it caused acute radiation syndrome in people not exposed to the initial blast.[19] There were almost 46 000 survivors at the end of follow-up in 2009 all of whom were 64 or older, 858 were over 94, and 15 were over 104 years old. The study tried to remove the effect of smoking but had sparse information especially for the NIC group. There were ∼22 500 solid cancer cases in the whole cohort of which the study concluded only 992, 4.4%, were associated with radiation.

The abstract lists the calculated ERR that best fit the data over the whole dose range. The best fit for males was a quadratic model with ERR of 1% at 100 mGy. The abstract also concluded: "At this time, uncertainties in the shape of the dose response preclude definitive conclusions to confidently guide radiation protection policies". Grant lists the Confidence Intervals (CI) for the 5-100 mGy linear models which are consistent with no increased risk of cancer for both males and females.

Figure 1 shows the ERR to 120 mGy for males (blue circles) and females (red triangles) separately in 20 mGy intervals. The red and blue plus signs mark the ends of the 95% CI. The small arrow indicates two CI are out of range. There are 12 ERR, but only the circled CI is statistically significant for ERR>0 and four of the 12 bins, including three with the most subjects, had negative ERR suggesting there is no statistically significant increase in solid cancer below 120 mGy when taken as a whole.

Grant looked for the lowest dose range with a statistically significant dose response using a sex averaged, linear ERR model. There was no positive dose response for the 0-80 mGy range, but there was for 5-100 mGy. However, they did not test the 5-120 mGy range, and since the sex averaged ERR is negative in the 100-120 mGy bin, there is likely no statistical significance to the LNT model for 5-120 mGy. In addition, Grant does not consider uncertainty in the dose estimates. For example, if a small number of cancers had calculated doses of 98 mGy, but actually were 102 mGy, then the ERR values for both bins would change significantly.

In the "Examination of Threshold" section Grant says that for females there was an: "estimated threshold dose of 0.08 Gy (80 mGy)". Grant further said: "For males, the best estimate for a threshold dose was 0.75 Gy (750 mGy)", a huge threshold.

Acronyms and definitions

CML	Chronic Myeloid Leukaemia	mGy	Milli-gray
CI	Confidence interval	NCRP	National council on radiation protection
ERR	Excess relative risk	NCRP-27	NCRP Commentary 27
H/N	Hiroshima/Nagasaki	NIC	Not in city
Gy	gray	PY	Person years
LNT	Linear No threshold	RR	Relative risk
LSS	Life span study	TB	Tuberculosis

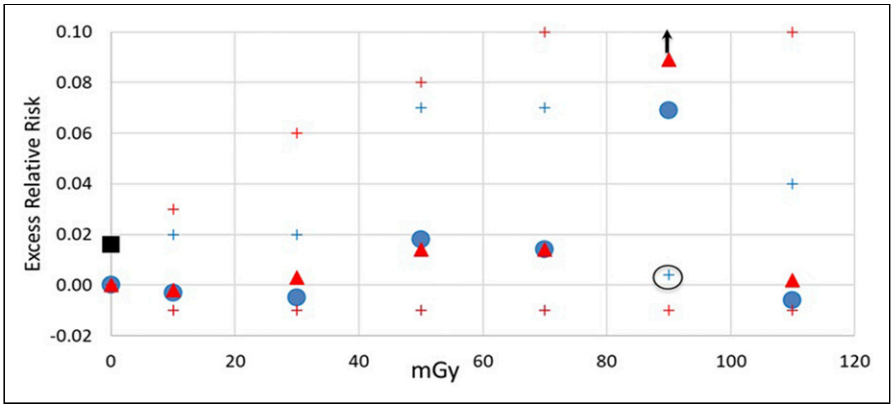

Figure 1. Grant: H/N ERR for Males (Blue Circles) and Females (Red Triangles); Plus Signs are CI, Black Square is the Control Group Without NIC.

The control group is composed of survivors who had less than 5 mGy, and NIC which were added to the control group in recent studies. The NIC group was not directly exposed to the trauma, physical injuries, social isolation, and was not regularly screened for cancer.[20] Regarding trauma, the Fukushima evacuees are known to have suffered pre-diabetes, which is linked to cancer.[21] Fukushima and Chernobyl evacuees have pre-heart disease symptoms and other health issues from stress. Furthermore, over 60% of the NIC's smoking habits are unknown.[2] The group with 0-5 mGy dose is a more representative control group which would mean the control group ERR should be the black square as calculated from the 4% lower cancer rate in the NIC.[2] This would change the results considerably and support a hormetic response for solid cancer for males, females, and both separately to 40 mGy, and no increased cancer risk beyond 125 mGy.

Preston Study

The second H/N study was of 15 388 children under age six and 2452 in-utero at the time of the blast.[3] Follow-up was to the end of 1999. There were 649 cancers incident in the early childhood group and 94 in the in-utero group. Doses from the contamination were not modelled in spite of these being significant.[19] NCRP-27 says: "There was no evidence of excess risk among those exposed to <0.2 Gy (200 mGy)". The statistical uncertainty in the control group is relatively large due to its small number of cancers. It should be applied making the threshold for the in-utero cohort 500 mGy and likely the same for exposed children.

The data plotted by Preston is reproduced in Figure 2. An LNT fit is worse than the polynomial fit. The polynomial fit has a slope of zero up to 200 mGy further supporting a threshold to at least 200 mGy.

The Preston abstract states: "The apparent difference in Excess Absolute Risk ... suggests that lifetime risks following in-utero exposure may be considerably lower than for early childhood exposure". The better outcomes for in-utero exposures could be due to secondary effects that can cause cancer in subjects exposed as children.[20] Those exposed in-utero had a mother, avoided the trauma and injuries from the blast itself, and did not play in soil contaminated with short lived isotopes. Those exposed in early childhood may not have mothers and would have many risk factors from the blast and for weeks after. This substantiates the removal of NIC from the control group of these LSS studies likely supporting larger thresholds.

Discussion of H/N Studies

The data for both H/N studies are consistent with a threshold. Grant states thresholds of 750 mGy for males and 80 mGy for females. NCRP-27 says the Preston data are consistent with a threshold to 200 mGy. Accepting the uncertainties in the control group and dose would make a stronger case for thresholds and over larger ranges. The NIC should not be included in the control group because they did not go through the same traumatic event as the exposed people, the same screening, and did not provide the same amount of information on smoking. Removing the NIC would likely make the thresholds even larger because the cancer rates were lower in the NIC and since the number of subjects would be reduced increasing the statistical uncertainty.

Medical Studies

NCRP-27 stated that two medical studies showed strong support for LNT, both of which included a sub-cohort of the LSS.[4,5] Thyroid cancer from exposure to children was investigated by Lubin et al, and breast cancer in TB patients and the LSS was investigated by Little and Boice. It is important to

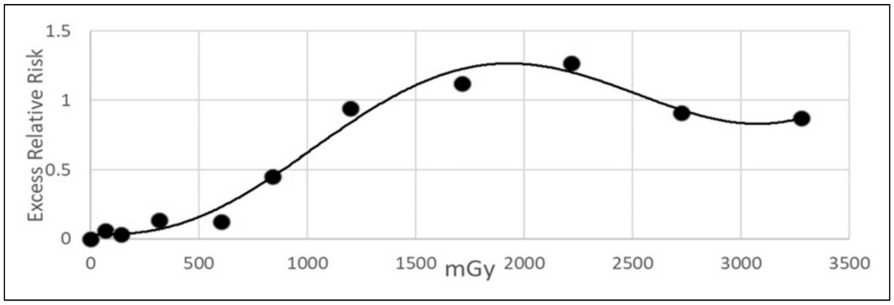

Figure 2. Preston: ERR vs Dose.

note that screening for both thyroid cancer and breast cancer are common and that over-diagnosis is common.[22–24]

Lubin and Thyroid Cancer

The childhood thyroid cancer incidence study combined nine cohorts with thyroid doses up to 200 mGy.[4] The study included the LSS cohort, two medical cohorts for treatment of childhood cancer, and six medical cohorts for treatment of benign conditions. Radiation exposures were as early as 1920 and follow-up was up to 85 years. There were 252 cases of thyroid cancer in 60 000 irradiated subjects (0.4%) with 2.6 million Person Years (PY) and 142 cases in 40 000 unirradiated subjects (0.3%) with 1.9 million PY. This is an incidence study and the number of deaths from thyroid cancer would be very small and possibly there would be no increase with radiation. This study was of a population (children) and organ (thyroid) generally considered to be radiosensitive and yet Lubin estimates just 94 excess cases in 60 000 irradiated subjects.

One of the nine cohorts dominates the results. An Israeli study of ringworm in the scalp (Tinea Capitis) had 58% of the exposed cases and produced the positive dose response. Without it the linear model ERR would drop almost in half and its statistical significance would disappear. The Tinea Capitis subjects had exposures between 1943 and 1960 with follow-up until 2007.[25] Dose to the thyroid is calculated based upon large, more than 1000 mGy, doses to the scalp. A sub-group of this cohort was Jews from a region in Morocco deficient in iodine that had signs of family clustering of thyroid cases.[26] Not uncommon for the time-period, there were also indications that the doses were much larger than those modelled.[26]

In the 0-100 mGy dose range, 129 thyroid cases were expected and 184 observed. There is no statistically significant increase in cancer incidence in the low-dose range when statistical uncertainty in the control group is included. Lubin assumes the small number of extra cases (94) over the entire range are due to radiation, but over-diagnosis is likely to account for many or most of them. Over-diagnosis accounted for over 90% of thyroid diagnoses in South Korea.[23] Children who received radiation are more likely to be screened and so are more likely to be over-diagnosed. Lubin et al stated: "Although medical screening may have increased the ascertainment of thyroid cancer cases, there was little reason to presuppose that increased screening was also related to radiation dose and thus acted to confound our results". However, this is an LNT viewpoint that does not acknowledge that over-diagnosis can eliminate a threshold in the data or evidence of hormesis.

In the top of Figure 3 the black squares are Lubin's RR plotted against average thyroid dose. The red dots are the RR if there was one less case per 25 000 PY. The false call rate in Korea was such that having just one screening per 100 PY would produce one over-diagnosis per 25 000 PY. The black dashed and red solid lines estimate the linear model ERR for Lubin's result and the over-diagnosis result. Removing potential over-diagnosis leads to a hormetic response. Serendipitously, the slope of the red line in the top of the figure is the same as Lubin found with the Tinea Capitis cohort removed. Lubin considers that removing this cohort would still leave data that supports LNT. This example shows that the other eight cohorts in this meta-analysis could have a hormetic response.

The red line in the top of Figure 3 suggests that LNT is plausible, especially if the dose range were larger and the low-dose points obscured. The bottom of Figure 3 redisplays the red points with a vertical scale such that RR = 2 is an equal distance above RR = 1 as RR = 0.5 is below, and so on for other RR. Also, the area of the points is proportional to the PY for each point. This plot makes it clear that there is a threshold or hormesis with this hypothesized over-diagnosis,.

Little/Boice and Breast Cancer

The second medical study is of breast cancer incidence in the LSS cohort and a medical cohort of TB patients who had fluoroscopy before 1950.[5] There were 529 cases in almost 50 000 women with over one million PY follow up in the LSS cohort and 229 cases in almost 5000 women with over 100 000 PY follow-up in the TB cohort. The graph in Little and Boice shows the dose response for the TB cohort had only four dose bins between ~0.35 Gy and ~4 Gy, which is too crude to reach a conclusion about dose response below 1000 mGy. This study used a "parametric model" to calculate

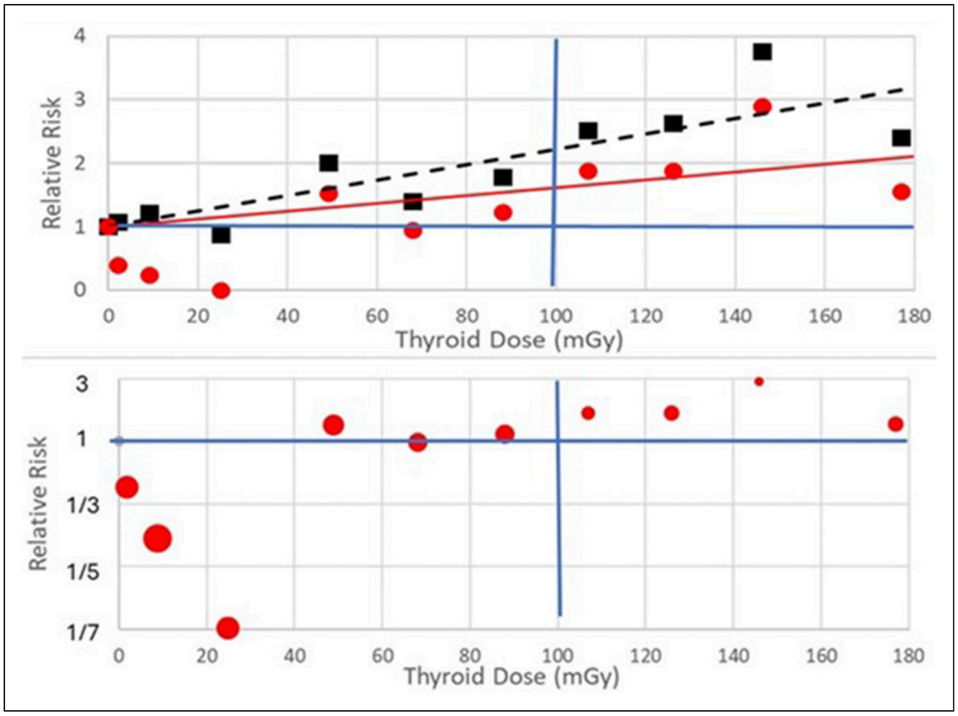

Figure 3. On Top: Lubin RR in Black and RR Modified to Account for Hypothesized Screening in Red. On Bottom, the Same Red Data Points With New Scale and Point Size to Reflect the PY.

the rate of breast cancer at zero dose for the TB cohort, so the study cannot be used to infer LNT in the low-dose range.[27] For the LSS cohort, RR = 0.9 at 40 mGy and RR = 1.15 at 180 mGy, then five more data points out to 4 Gy. The reduction in breast cancer at 40 mGy supports "no effect" or a threshold to at least 150 mGy.

Worker Studies

Two related studies of worker cancer mortality are Leuraud et al for leukemia-lymphoma-myeloma and Richardson et al for solid cancer.[6–8] These studies have the same authors who analyzed the INWORKS cohort of nuclear workers from the US, UK, and France. The author's focus was low-protracted doses instead of the H/N acute doses.

There were just over 308 000 workers, 87% male, that were followed up within the range of 61 years from 1944 to 2005 with just over 8.2 million PY follow-up. A total of 22% died. Average, cumulative, occupational photon dose was 25 mGy, however, this was converted to colon dose of 20.9 mGy for the solid cancer study.[1] Cumulative, occupational, photon, colon dose is referred to herein as dose. Both studies use 90% CI instead of 95%.

Major portions of the cohort were previously studied in a 15-country study providing a preview of the cohort and results.[28] For example: "Less than 20% of deaths from leukaemia were contributed by the other 12 countries".[6] The three countries chosen from the 15-country study were the only three weapon countries and so these studies may not be relevant to nuclear power workers.

A related paper critiques the leukaemia INWORKS study so only the main points are repeated here.[18] Eight disease subtypes including five categories of leukemia, two forms of lymphoma, and multiple myeloma were investigated for their radiation dose response. One of these, Chronic Myeloid Leukemia (CML), had a positive dose response due to eight deaths in the dose range above 200 mGy cumulative, occupational, red-bone-marrow dose. A threshold best describes the data. Furthermore, either five or six of the eight high-dose CML deaths occurred after age 80 and were almost certainly not due to nuclear work. The two or three deaths before age 80 might have been due to nuclear work. However, it was not shown that these two or three deaths were due to low-protracted doses. Rather, they might have been due to chemicals or high-dose-rates.

The abstract of the Richardson study states: "Results suggest a linear increase in the rate of cancer with increasing radiation exposure. The average cumulative colon dose estimated among exposed workers was 20.9 mGy (median 4.1 mGy). The estimated rate of mortality from all cancers excluding leukaemia (leukaemia was dealt with separately)[18] increased with cumulative dose by 48% per Gy (90% confidence interval 20%-79%), lagged by 10 years. Similar associations were seen for mortality from all solid cancers (47% (18%-79%)) per Gy". Later Richardson states that ERR was (0.81 per Gy; 0.01-1.64) for solid cancer excluding leukaemia in the 0-100 mGy dose range. This is statistically significant at 90% but not at the 95% that should be used in these studies.

Richardson's main result, stated in the abstract, is that ERR for solid cancer mortality is 4.7% at 100 mGy (47% per Gy). Richardson claims that its solid cancer mortality ERR are consistent with the H/N LSS mortality results. Table 1 compares Richardson's ERR for solid cancer mortality with Brenner's LSS male mortality ERR.[29] Brenner found a quadratic fit best described the male mortality data. Brenner made four such quadratic fits based upon the H/N data in four different dose ranges, below: 4 Gy, 2 Gy, 1 Gy, and 0.5 Gy. Note that 0 to 0.5 Gy best describes the Richardson data. The two parameter quadratic fits can progressively describe the data better as the dose ranges become smaller. Table 1 lists the five ERR at 100 mGy for Richardson's and Brenner's fits. Brenner's ERR at 100 mGy become progressively smaller as the dose range becomes smaller. The ERR at 100 mGy becomes negative indicating a hormetic response for the 0-0.5 Gy dose range. The next column lists the ratios of the Richardson ERR to three of the Brenner ERR. Richardson's estimate of risk at 100 mGy is 4-24 times larger than the H/N risk estimates for the three larger dose ranges and of course the ratio is negative for the hormetic result. It is surprising that Richardson's worker study had a much stronger dose-response since it did not include children, the males were all healthy, they all had access to good medical care, and dose-rates were much smaller. In fact, the lower bound 90% CI for Richardson was 0.018 at 100 mGy which is up to 9 times larger than the Brenner ERR for the three largest dose ranges. This suggests that the Richardson study significantly overestimates the risk of solid cancer. Moreover, the Brenner study found the quadratic model provided a better fit than a linear model. This is also an important difference between Richardson and H/N results that suggests that Richardson overestimates risk in the range of interest.

It will first be shown that the high-doses were before 1970 when working conditions were quite different leading to high-dose-rates and high missing doses. Second, that the control group does not represent the high-dose workers who are the most important in the analysis. Third, uncertainty in the control group would likely eliminate statistical significance for a ERR>0 linear model for dose ranges up to 0-300 mGy. Fourth, ambient doses should be included in the study. Including the ambient and other doses and changing the control group should help correct the apparent overestimate of risk in the Richardson study.

Confounding Factors: High-Dose Workers and Missing Dose

Military technologies were being hurriedly developed before 1970. Allowable doses were greater, and there were poor worker protection: habits, oversight, dosimetry, and monitors. Dose from photons, neutrons, and internal contamination, were much higher than now. In particular, the 95 percentile dose levels (dose exceeded by only 5% of workers) dropped by a factor of 10 from before 1970 to the year 2000.[8] Cumulative neutron doses were about 1000 mSv/year before 1985 and dropped to 50 mSv in the early 2000's.[8] More importantly, better control after 1970 dropped the maximum doses even more. Occupationally required medical diagnostics gave doses of 20 mGy and more.[12] The poor safety culture also led to high exposure to chemical toxins.[30] Workers from before 1970 also had high recorded doses and PY because they had full careers by the end of follow-up in 2005. By contrast, workers starting between 1970 and 2000 had lower recorded doses and PY both because of increased radiation protection and they were not yet retired by the end of the study in 2005. Consequently, the <0.3% of workers PY in the high-dose range above 300 mGy were predominantly, or possibly entirely, from the early years of the industry.

There was high recorded dose, but very significantly, much more missing dose before 1970. For example, there was a criticality accident in 1950 at Chalk River Laboratories in Canada while researchers were leaning over the ZEEP reactor when it tripped on over-power.[31] This neutron and gamma excursion was measured in a nearby building due to its better instrumentation. They were not wearing dosimeters, which might fall into the reactor, suggesting that not wearing dosimeters happened regularly. These workers might have received more, and unmeasured, dose in seconds than in the rest of their careers.

Dose was also regularly missed because high-dose workers did not wear dosimeters if it meant losing overtime wages by exceeding a dose limit.[32] There are processes in place to prevent this from happening now, but before 1970 high-dose staff increased income by avoiding their dose being measured.

Table 1. Comparison of Richardson[7] and Male Solid Cancer Mortality ERR From Brenner.[29]

	Range of dose in Gy	ERR at 100 mGy	Ratio of Richardson & Brenner	
Richardson 2015	0-0.6	0.047		
Brenner H/N 2022	0-4	0.011	4	Richardson ERR is higher
"	0-2	0.007	7	Richardson ERR is higher
"	0-1	0.002	24	Richardson ERR is much higher
"	0-0.5	−0.006	Hormetic response	Qualitative and quantitative difference

Dose was also missed in people who worked before there were dose registries.

Large doses occur in short time periods during an accident. For example, a non-radiation Chalk River Laboratories worker volunteered for cleanup in 1958, received 190 mGy in about one hour, and survived till at least 1982.[33] It is likely that the 211 INWORKS high-dose workers (above 300 mGy) with cancers: worked between 1944 and 1970, were involved in accidents or their cleanups, and had single shifts with high-doses and dose-rates. In addition, many would be exposed to neutrons. Some of these 211 workers might have had a total dose exceeding 100 mGy in specific months when missing dose and neutrons are included. Doses greater than 100 mGy in a month are confounding factors when investigating low-protracted doses.

Inadequate Control Group

The control group must represent the exposed portion of the cohort to prevent bias. Workers in general tend to be healthier than non-workers.[34] However, it is also true that well educated people are healthier than less educated.[35,36] Officers are also healthier than enlisted men.[37] One study found an ERR of 1 for cancer rates of low vs well educated people. This is much larger than 0.26, which is the highest ERR in the Richardson study.[38] Richardson did find this effect: "adjustment for socioeconomic status reduced the magnitude of dose-response estimates, suggesting positive confounding by socioeconomic status". However, the control group must be modified to properly prevent bias.

Most of the facilities in the study were built in the 1940s to 1960s when workers had the most dose. Nuclear and military facilities were often built in low-income, rural areas. Experienced and educated people were hired from around the country, or even the world, for low-dose scientific, engineering, and administrative jobs. By contrast, high-dose workers were local low-skilled workers. In addition, many of the facilities were military, and low-dose workers were often former officers whereas high-dose workers were former enlisted men. Consequently, this worker study is comparing better educated people and officers, who were born, raised, and with early careers in other regions to less educated people and enlisted personnel often born close to each facility. Genetics, education, background, and behaviours would all be different.

The control group should be expanded to include workers who do not work at the facilities but live near them. In particular, low skill workers from the 1940's to 1970's should be included to better represent the exposed portion of the cohort.

Underestimated Uncertainty

Using standard CI, there is no statistically significant increase in cancer-excluding-leukaemia over the entire dose range, even when statistical uncertainty in the control group is not applied.

The control group has both statistical uncertainty and it does not represent the exposed workers as described above. The statistical uncertainty in the control group can be calculated and the CI are 0.98-1.02 at 90%. Richardson's calculated ERR = $8.1*10^{-4}$/mGy (0.81/Gy). Figure 4 estimates ERR based upon a 2% increase in RR of the control group to test the sensitivity of ERR to inclusion of uncertainty in the control bin and/or upon a modified control group. An increase of just 2% to account for the difference in education levels between the control group and high-dose bins is very small given that ERR = 1 have been found.[36] However, even with this small increase, the estimated ERR for 0-100 mGy is reduced by almost 50% from $8.1*10^{-4}$/mGy to $4.4*10^{-4}$/Gy. This would certainly lead to loss of statistical significance in this dose range even at 90%. The estimated ERR for the 0-300 mGy would be reduced by 30% and the uncertainty in the control group would likely make this ERR not statistically significant.

Ambient Doses

Richardson claims: "The study provides a direct estimate of the association between protracted low-dose exposure to ionising radiation and solid cancer mortality". However, ambient dose is the largest source of low-protracted dose, and it is not included. Some experts believe childhood dose causes cancer and so the low-protracted dose from before employment should be included. A reasonable estimate of average time before employment is 25 years. So total PY of ambient dose would be 25 * 308 297 before employment and 8.2 million PY after employment began. Ambient photon colon dose would approach 2 mGy/year, which increases cumulative dose by at least a factor of five.

Including ambient radiation has three effects. First, the magnitude of the ERR would decrease since the dose range would be larger. Second, the CI for the ERR calculations would be larger since estimates of actual dose of each person would have uncertainties. Third, ambient dose would change the subjects put in each bin, which would affect calculation of all the RR and hence any ERR linear model. A linear ERR model is unlikely to be statistically significant.

The INWORKS studies exclude most of the worker doses, including: occupationally required medical doses, neutron and internal doses, lagged dose, occupational doses from before entry in the dose registry, un-recorded doses, and ambient (background) doses. Furthermore, these excluded doses would be highest for the high-dose workers most of whom started work before 1970.

Discussion of Richardson INWORKS Study

This study should include statistical uncertainty in the control group in calculations of statistical significance of ERR and

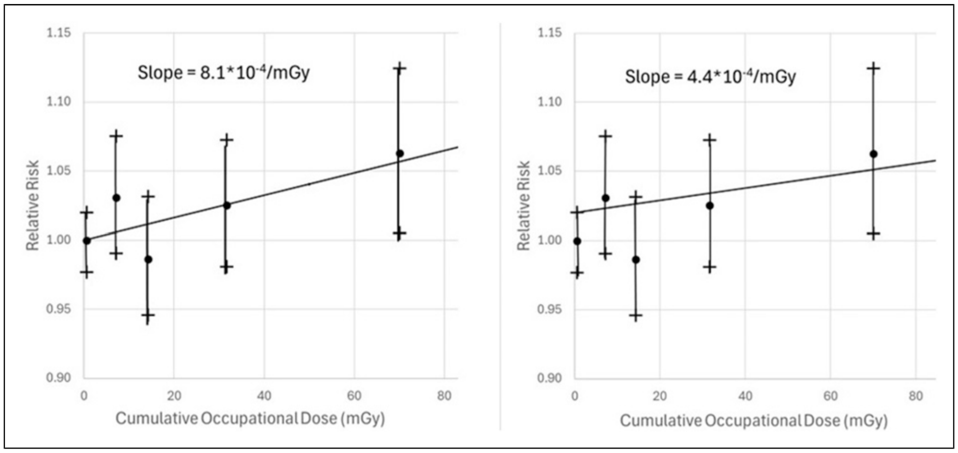

Figure 4. Estimated ERR, as Calculated on Left by Richardson, and With 0.02 Increase in Control Group RR on Right.

other quantities. If the control group uncertainty of 0.02 were applied, then only one of the ten RR data points would be statistically significant above RR = 1. The exposed workers when combined into one bin has no statistically significant increase in cancer excluding leukaemia using standard CI. Furthermore, the linear model ERR would not be statistically significant for the 0-100 mGy range and likely not for the 0-300 mGy range using the studies goodness of fit criteria. The Leuraud and Richardson data when taken together do not show that low-protracted doses cause cancer.

The RR average is 1.05 in the dose range below 300 mGy and 1.2 above 300 mGy. It is the high-dose range that produces the statistically significant linear model ERR of 47%/Gy calculated by Richardson and visually supports the conclusion that low-protracted doses cause cancer. This high range has only 211 cancers, only 36 were considered to be "Fitted Excess".[38] The study mentioned numerous possible confounding factors. For example, neutron exposure was investigated by comparing the ERR for the entire population and the 87% that did not have neutrons. However, it is unlikely to obtain any statistically significant result from such an analysis. A case-control study based upon the 211 high-dose cancers should be more informative. The impact of the confounding factors (specific facilities, chemicals, etc.) can best be determined by examining these 211 cancer deaths. In addition, since this is a study of low-protracted doses, then high-dose-rates are a confounding factor.

Although doses are lagged over a ten-year period, it is not clear how this was done. More importantly, it does not appear that cancer cases in the first 10 years after joining the study are excluded. Since the latency period for solid caner is 10 years, cancers within 10 years of joining the study should be excluded. Excluding just a few cancers in the high dose workers would reduce the apparent effect of radiation substantially since only 36 were considered to be in-excess.

There are several problems with the way this study was done. First, the control group should be extended to include low skill workers, especially from before 1970, from the regions of the facilities studied. Since nuclear facilities were often put into low-income areas, it is expected that the enhanced control group would reduce the RR for the exposed workers. This is supported by the Richardson finding: "adjustment for socioeconomic status reduced the magnitude of dose-response estimates".

Second, since this is a study of low-protracted doses, ambient dose must be included. This would have a major impact since the average dose would increase by at least a factor of five greatly reducing any calculated ERR. Furthermore, individuals would move from one dose bin to another. For example, the control group might be for under 100 mGy and contain people born after 1980 who had low ambient dose but were high dose workers. A middle dose bin of 150-200 mGy would contain people who were born before 1920 and had 80 years of ambient dose before the end of study follow-up but no occupational dose. Also, dose uncertainties would increase greatly since ambient dose must be estimated.

In summary, the INWORKS study resulted in a much stronger dose response than the H/N results. This paper suggests this is because the INWORKS solid cancer study ignores uncertainties and does not account for the bias introduced by the control group. Acknowledging the uncertainties and bias would make many of the results of the study statistically insignificant even at the low acceptance criteria of 90%. Using 95% confidence intervals would likely make all the results insignificant. The visual impression left by the high-dose bins with RR of about 1.2 rests upon 36 cancers, a rather small number given the large number of potential confounding factors. Cancers within 10 years of joining the study should be dealt with. Furthermore, including ambient dose would likely mean there was no statistically significant dose response.

Conclusions

NCRP-27 claims that six studies strongly support LNT, however, these studies all suffer from the same problems: LNT is assumed, dose is underestimated, all harm is assumed to be from radiation, uncertainty is underestimated, and with one exception the dose response is determined by a high-dose range. This paper shows that five of six support the null hypothesis of "no effect" at doses up to and beyond 100 mGy at 95%. The doses were acute or fractionated in four of the six studies.

Authors of all six studies would admit their studies are consistent with "no effect" (thresholds), typically in the 100 mGy range, at 95%. The Grant solid cancer incidence study in H/N survivors states the data is consistent with a threshold for men to 750 mGy and for women or combined men and women to 80 mGy.[2] Grant did not examine up to 125 mGy, but it is likely that Grant would find the data was consistent with a threshold up to 125 mGy for all three groups using Grant's linear models. The Preston solid cancer incidence in H/N children and in-utero were consistent with a threshold up to 200 mGy.[1,3] The INWORKS-leukaemia study is consistent with a threshold up to 200 mGy for CML; the other seven subtypes of blood disease have no dose response.[18] Based upon its own ERR model, the Richardson INWORKS-solid-cancer mortality study is consistent with "no effect" up to 100 mGy at 95%, but not 90%. The entire exposed group does not have a statistically significant increase in cancer. The Little-Boice breast cancer incidence study does not have adequate information to infer a dose response below 1000 mGy for the TB cohort, but "no effect" is supported for the female portion of the LSS cohort.[5] The Lubin data is consistent with a threshold up to 40 mGy.

None of these studies calculated the effects of statistical uncertainty in the control group, which would have made the case for a threshold stronger in the above studies. The Lubin study of thyroid cancer incidence when exposed as children has a high statistical uncertainty in the control group due to the small number of thyroid cases supporting a threshold of 0-140 mGy range using standard CI. Applying statistical uncertainty to the control group in the Richardson data means there is just one of ten RR>1 with statistical significance. In summary, all of the studies produced large thresholds at the 95% level using statistical uncertainty in the control group.

All of the studies have unacknowledged confounding factors. The Lubin study and NCRP-27 only consider confounding factors that are proportional to dose to be in conflict with LNT. Figure 3 shows that the over-diagnosis typical in thyroid and breast cancer, which tends to be proportional to the number of subjects or PY, would reveal a large threshold in the data. The INWORKS study is of low-protracted doses. Therefore, the high-dose-rates present before the 1970's are a confounding factor. Neutrons, chemicals, and high and missing doses should be investigated in a case-control study of the high-dose workers.

The control group must be representative of the exposed population. The H/N control group has a NIC sub-group, and both the Grant and Preston studies showed indications that the NIC artificially increased the apparent effect of radiation. Correcting this would provide strong evidence for a large threshold. The INWORKS studies had a control group that was different from medium and high-dose workers. Correcting that would likely provide evidence for a larger threshold. The TB breast cancer study did not have a control group. The Lubin study relies too heavily on a group of poor people who are genetically isolated and have an iodine deficiency.

Methodological shortcomings affect all of the studies. All studies start by assuming LNT is the null hypothesis instead of "no effect". The INWORKS studies ignore ambient dose which is over 75% of the low-protracted dose. The H/N studies ignore the effect of contamination. Both breast and thyroid cancer are prone to over-diagnosis from screening. It is interesting that the two medical studies found increased cancer in organs susceptible to screening, but no increase in lung cancer was seen in TB patients. In particular, "Despite a wide range of doses to the lung, reaching over 8 Gy, there was no evidence of a dose response".[39]

LNT heavily influences how nuclear projects are viewed by the public and regulator. For example, the Near Surface Disposal Facility, a low-level nuclear waste site proposed for Ontario, is currently on hold due to court challenges. Extensive modelling of this waste site has shown that it is safe now and into the future. Even if heavily damaged thousands of years from now, it will result in lifetime doses less than 10 mGy, mostly from radium, for someone living-on and consuming food and water from the site. This radium dose is thousands of times below the known threshold for radium.[40] In spite of this, LNT led intelligent people to lobby tirelessly for an enormous, deep underground structure to house up to 1-million cubic meters of almost entirely non-radioactive material. NCRP-27 examined photon dose and not alpha dose. Nevertheless, harm from alpha dose is assumed to follow LNT after multiplying the dose in milli-Gy by 20. Universal application of LNT has serious consequences. For example, applying LNT to alpha emitters, even though it is known to not apply and was not addressed by NCRP-27, prevents prudent disposal of waste.

The six studies, that the NCRP-27 claims have strong support for LNT, actually have no evidence for increased cancer below 100 mGy, acutely given or not. These studies confirm a substantial safe level of radiation can be defined as the basis for radiation protection. Despite this, it is not possible to build a low-level waste site due to alpha radiation which is known to not follow LNT.

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