Childhood Leukemia and Cancers Near German Nuclear Reactors:

Significance, Context, and Ramifications of Recent Studies

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A government-sponsored study of childhood cancer in the proximity of German nuclear power plants (German acronym KiKK) found that children < 5 years living < 5 km from plant exhaust stacks had twice the risk for contracting leukemia as those residing > 5 km. The researchers concluded that since "this result was not to be expected under current radiation-epidemiological knowledge" and confounders could not be identified, the observed association of leukemia incidence with residential proximity to nuclear plants "remains unexplained." This unjustified conclusion illustrates the dissonance between evidence and assumptions. There exist serious flaws and gaps in the knowledge on which accepted models for population exposure and radiation risk are based. Studies with results contradictory to those of KiKK lack statistical power to invalidate its findings. The KiKK study's ramifications add to the urgency for a public policy debate regarding the health impact of nuclear power generation. *Key words*: cancer; childhood cancer; childhood leukemia; nuclear power; nuclear reactors; radiation health; radiogenic risks; radiation safety; low-dose radiation effects

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Since the late 1980s, when a childhood leukemia cluster was first reported in the vicinity of the nuclear plant Krümmel near Hamburg, Germany, public anxieties have remained high.[1,2] The affected population suspected that radioactive emissions from the nuclear reactor were the causal agent. Ionizing radiation is a generally accepted risk factor for leukemia although there is still some controversy about the existence of a threshold dose below which there is supposedly no effect.[3–8] In response to citizens' pressure, the German government contracted the German Childhood Cancer Registry at the University of Mainz (GCCR) to conduct an ecological health study of all German nuclear plants over an 11-year study period (1980-1990). Comparing the incidence rates of all cancers in children < 15 years in communities within 15 km of these plants with those in reference communities with similar populations, no statistically significant increased risk was found (relative risk [RR] 0.97; 95% confidence interval [CI], 0.87–1.08).* Nevertheless, exploratory analyses of a subset of children < 5 years diagnosed with acute leukemia and living < 5 km from the plants, did show a statistically significant increased risk (RR, 3.01; 95%CI, 1.25–10.31).[9] This finding motivated a second study by the GCCR scientists to investigate the following 5-year period, 1991–1995. The researchers found a non-significant increased risk (RR, 1.05; 95%CI, 0.92–1.20) for all cancers among children < 15 years living < 15 km from the plants, and a non-significant increased risk (RR, 1.39; 95%CI, 0.69–2.57) for acute leukemia among children < 5 years living within a 5 km zone. From this, the researchers concluded *that their initial 1992 finding for acute leukemia*[9] *was a chance result* and that "no further investigations of this kind are necessary," implying that the hitherto contentious issue had finally been resolved.[10]

This scientifically unsupportable pronouncement re-kindled the controversy, and in 1998 the GCCR data for 1980-1995 were re-analyzed by two independent German scientists, who restricted their analysis to 15 sites with 16 operating commercial nuclear power plants (one of which has two reactors), excluding 2 small research reactors and 3 sites of decommissioned reactors. These 5 sites contained or released much smaller amounts of radioactivity by several orders of magnitude compared to power reactors.[11] Hence, excluding them increased the sensitivity for detecting a health effect. The independent study found that the all-cancer risk for young children (< 5 years) living within 5 km of the operating power plants was significantly increased (RR, 1.54; p=0.0034), while their leukemia risks were even higher (RR, 1.76; p=0.012).[11] The fact that the association of cancer incidence with proximity to the plants becomes statistically significant

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*Conventionally, *statistical significance* for increased RR > 1.00 is expressed *either* by a p < 0.05 for RR or a *lower limit* > 1.00 in a 95% confidence interval. Both statistical measures indicate that there is more than a 95% probability that the RR for an exposed population is significantly elevated or the equivalent statement, that there is less than a 5% probability that a RR > 1.00 is a chance result. Instead of RR, in case control studies odds ratios (OR) are used to express relative risk with comparable meaning.

by limiting the study areas to those with high radioactive inventories indicates that radioactivity and cancer incidence are associated.

With these new results for the 16 commercial reactors, citizen groups supported by independent scientists, including members of International Physicians for the Prevention of Nuclear War (IPPNW), persisted in their challenges to continued government assurances that there was no association of health detriment with radioactivity released by nuclear plants. In response and guided by the advice of GCCR scientists, the German government initiated a more comprehensive and authoritative study.

THE KIKK STUDY

KiKK Study Team and Design

In 2002 the German government contracted with the GCCR to conduct a state-of-the-art case-control study of childhood cancers and leukemia in the areas around the country's 16 commercial nuclear power plants. This Epidemiological Study on Childhood Cancer in the Vicinity of Nuclear Power Plants (Epidemiologische Studie zu Kinderkrebs in der Umgebung von Kernkraftwerken) is known by the acronym KiKK. In contrast to ecological studies that compare geographic averages of disease rates at area mid-point distances from the suspected source, a case-control study compares characteristics of *individual* children who suffer from disease (cases) with those of the same age and sex who live in the same area and do not suffer from this disease (controls). In the KiKK study, researchers Kaatsch et al. determined the distances of the places of residence of cases (at the time of diagnosis) and of controls with an accuracy of within 25 m. Thus a possible distance dependency of cancer risk could be determined with much greater reliability than in ecological studies. Based on radioactive emission data, as provided by the operators of the nuclear power plants, and using internationally adopted low-dose radiation risk factors as tabulated by committees of the United Nations (UNSCEAR),[6] the US National Academy of Sciences Committee on the Biological Effects of Ionizing Radiation (BEIR),[7] and the International Commission on Radiological Protection (ICRP),[8] the researchers predicted that radioactive emissions from nuclear power plants would not cause an increased risk for childhood malignancies.

Due to the superior study design and an extended study period (1980-2003), the KiKK study was expected to test once and for all whether there existed an association between residential proximity to a nuclear reactor and elevated incidence rates of childhood malignancies. In order to lend maximum credibility to the new investigation, the German Federal Office for Radiation Protection (Bundesamt für Strahlenschutz, BfS) appointed an independent external review committee of 12 scientists (5 epidemiologists, 2 pediatricians, 2 statisticians, and 3 physicists) to assist in the study's design and evaluation.

The study area included 41 counties in the vicinity of all 16 German nuclear power plants. Since individual radioactive exposure data for cases and controls were not available, residential distance from the likely point of radioactive emissions (the exhaust stack) served as a surrogate variable. Addresses of all children with leukemia or other malignancies < 5 years at the time of diagnosis (1592 cases) were compared to those of 3 times as many randomly selected children of the same age and sex, residing in the same region who did not have either of these diseases (4735 controls). Residential distance to the 16 power plants was the only variable for cases and controls.[12,13] The investigators' choice of the < 5 year age group of children was based upon the known high radiation sensitivity from conception through embryonic and fetal development to infancy.[3-5,14-16] To my knowledge, no other health study comparable in scope and power has ever been conducted anywhere in the world among populations potentially exposed to environmental radioactive contamination.

Therefore, the KiKK study's power and scientific significance is unique in radiation epidemiology.

KiKK Findings

On the basis of their 1998 categorical conclusions,[10] the authors of the KiKK study stated that "no effect would be expected on the basis of the usual models for the effects of low levels of radiation."[13] Yet a logistic regression analysis of the ratio of KiKK cases to controls as a function of proximity (= 1/r with r the residential distance in meters, chosen as the independent variable) showed a strongly increasing risk for all cancers, and especially for leukemia, the closer the children had lived to nuclear plants at the time of diagnosis, with the sharpest rise within 5 km. During the study period 1980–2003, children < 5 years living within 5 km of a nuclear power plant were more than twice as likely to develop leukemia compared to children living > 5 km distant (OR, 2.19; lower limit 95%CI, 1.51). The increase in leukemia remained significant in children < 5 years living in the < 10 km zone compared to the > 10 km zone (RR, 1.33; lower 95%CI, 1.06), as reported in Kaatsch et al., Table V.[12]

Kaatsch et al. checked for plausible confounding factors, but they found none within the limits of uncertainty. However, because of variable response rates to questionnaires, this second part of the KiKK study lacked statistical power. Therefore, confounding factors could not definitively be excluded. The KiKK team also tested whether the findings were primarily influenced by any single plant, such as the well-known Krümmel leukemia cluster, by excluding that site from the analysis. Even when Krümmel (or any other single plant) was excluded from the study, the distance trend remained significant. Also, the trend is considerably stronger in the KiKK study with *individual* proximity of residential addresses as surrogate exposure variable, compared with the trends found in previous ecological studies, confirming the greater statistical power of the case-control design with individual characteristics.

Communication of KiKK Findings

In the *European Journal of Cancer* Spix et al. concluded in their abstract that:

> The [KiKK] results are compatible with the corresponding subgroups in the previous German ecological studies, with which this study shares most of the cases. They contrast with the lack of an effect observed or expected from other studies due to low doses from routine power plant operation.[13]

Apart from the fact that these studies only shared less than half of cases and controls, Spix et al.'s contention that the KiKK study results were "compatible" with previous findings contradicts earlier conclusions by the same authors. In the abstract of their 1998 ecological study, they state:

> No exploratory results could be reproduced. This is also true for children with acute leukemia younger than 5 years who were living within a 5 km radius of an installation [. . .]. Results did not show significantly increased incidence rates for any subgroup with previously significant exploratory results. . . . We conclude that at present in Germany no further investigations of this kind are necessary.[10]

In light of the 2008 KiKK results, the GCCR scientists should have withdrawn or revoked the quasi-definitive conclusion they drew from their 1998 study. Instead, in the last paragraph of the KiKK report in *International Journal of Cancer*,[12] Kaatsch et al. state that "The recent study confirmed previous German findings regarding leukemia in the 5 km zone of nuclear power plants," apparently in reference to the 1992 study,[9] which these same scientists claimed to have invalidated in 1998.[10] However, they neglect to explicitly note that the 2008 findings conflict with the 1998 study. This oversight distorts the scientific record, especially given the fact that the authors conclude their 2008 report by stating, "In view of the fact that this result was not expected under current radiation-epidemiological knowledge, and considering that there is no evidence of relevant accidents, and that possible confounders could not be identified, the observed [negative] distance trend remains unexplained."[12]

The GCCR scientists' surprising interpretation of their 2008 data negates the basic design of the KiKK study: it was to test whether or not there exists an association between incidence rates of malignancies and proximity to the suspected source of radioactive emission, the exhaust stack (surrogate for individual levels of exposures). The categorical dismissal of radiation as a possible cause of the observed health effects voids the design of the study as a test of this possibility. Based on unquestioned acceptance of official assumptions about radioactive emissions and related radiation risks, referred to by the GCCR scientists as "the current state of radiobiological knowledge," they claimed that radioactive emission from these nuclear plants would have to be several orders of magnitude higher to explain the observed health effects.[12]

RESPONSES TO THE KIKK FINDINGS

In 2008, the BfS contracted three epidemiologist members of the external scientific review panel for the KiKK study to produce a critical review of the study. In their report,[17] the epidemiologists challenge Kaatsch et al.'s conclusion that elevated childhood cancer leukemia rates near nuclear reactors were unexplainable.[12] They criticized the investigators for ignoring relevant and statistically robust studies consistent with an association of residential proximity to nuclear installations with childhood malignancies. They point to a sophisticated meta-analysis of incidence and mortality rates of childhood leukemia near 136 nuclear facilities in the UK, Canada, US, Germany, Japan, and Spain which shows statistically significant increases between 14% and 21% of leukemia incidence in children < 9 years near many of these sites, although its authors, Baker et al., do not suggest an explanation for the excess.[18]

In summary, the BfS-sponsored external epidemiological review panel concluded that according to the widely accepted causality criteria for environmental health studies, as formulated by the eminent epidemiologist Sir Austin Bradford Hill,[19] the KiKK study did suggest a causal relationship between radioactive emissions from nuclear power plants and the undisputable positive trend of childhood malignancy incidence with decreasing residential distance from these plants within a radius of 10 km. The external panel concluded: "There exists no plausible alternative hypothesis."[17]

An editorial in the same journal in which the KiKK study was published[20] challenged Kaatsch et al.'s interpretation of their own data as "unexplainable" and suggested possible explanations, including: (1) chance, (2) unexpected high exposure of some individuals, and (3) the so-called Kinlen hypothesis. To explain a leukemia cluster that was observed in the vicinity of a British nuclear installation, Kinlen had proposed in 1988 that leukemia might be induced by a viral infection related to population mixing near that plant.[21] However, such a leukemia-causing virus has yet to be identified and significant population mixing does not apply to the KiKK study population. There is no supporting evidence in the KiKK data for any of the editorial's suggestions. Thus, the editors were forced to conclude "that these findings [of the KiKK study] cannot be dismissed."[20]

CONSISTENCY WITH OTHER STUDIES

A review of leukemia studies in children and young adults around 198 nuclear sites in 10 countries[22] is compatible, within its wide uncertainty range, with Baker et al.'s statistically more robust meta-analysis of studies mentioned above.[18]

Other studies have also found an association between environmental radiation exposure and leukemia incidence. A 1997 case-control study of leukemia among young people < 25 years of age with 27 cases and 192 controls near the La Hague (France) reprocessing plant concluded there existed "some convincing evidence in childhood leukaemia of a causal role for environmental radiation exposure from recreational activities on beaches."[23] A 2001 ecological study also found "an increased incidence of leukaemia in the area situated at less than 10 km from the [La Hague] plant."[24]

On the other hand, a 2008 ecological study of leukemia incidence among children < 5 years near 19 French sites by Laurier et al., designed in response to the KiKK study, did "not indicate an excess risk of leukemia in young children living near French nuclear power plants."[25] Yet, Laurier's data, if combined differently, do in fact show a 19% increased leukemia incidence in the 0–10 km zone compared to the 10–20 km zone. However, with only 25 observed cases, this increase is not statistically significant (p=0.248).[26] In contrast, with 95 cases, the KiKK study found a significant 33% increase in the 0–10 km zone (lower limit 95%CI, 1.06) compared to the > 10 km zone.[12] In 2006, Evrard et al. used "geographic zoning" to study leukemia in children < 15 years of age around 23 French nuclear facilities and found "no evidence of an increased incidence of childhood leukaemia."[27] Several features of this ecological study make it less powerful than the KiKK study: Evrard et al.'s study period of 12 years is half as short as the KiKK study period; it looked at children < 15 years, despite the fact that earlier ecological studies had shown the highest risks for childhood leukemia appears in children < 5 years; and instead of residential distance, the independent exposure variable was an estimated bone marrow dose, which involves large uncertainties.[28]

A 2008 British study by Bithell et al. was also designed in response to the KiKK study.[29] Comparable to the earlier German ecological studies,[9,10] it found "no evidence that acute leukaemia in children < 5 years has a higher incidence close to nuclear power stations in Britain." However, the authors conceded that the 95% confidence intervals in their study are so wide that the difference with the data reported in the KiKK study "is only marginally statistically significant."[29]

The words "no evidence" in the conclusions of the papers by Evrard et al.[27] and Bithell et al.,[29] as well as Laurier et al.'s statement that their data "do not indicate an excess risk," are often misleadingly interpreted as *negative* rather than as *inconclusive* findings. These interpretations ignore a fundamental rule in epidemiology: *Absence of evidence of an effect does not constitute evidence of absence of that effect.*[30] Clearly, studies that are inconclusive due to low statistical power or flawed design cannot invalidate positive findings in studies with a high statistical power, such as the KiKK study.

DISSONANCE BETWEEN ASSUMPTIONS AND EVIDENCE

The various contradictory statements made by the GCCR scientists before and after the publication of the KiKK study illustrate the dissonance between evidence and existing assumptions about emissions and radiation risks. It is this set of assumptions that the KiKK team refers to as "the current state of radiobiological knowledge." The investigators dismissed without questioning the conclusion that radioactivity would most plausibly be responsible for the observed distance trend purely because such a finding would contradict widely adopted presuppositions about radiation health effects.

The same dissonance has also been evident in reactions to observed increases in health problems throughout Europe following the Chernobyl reactor disaster of 1986. Observations of excess cancers, neonatal mortalities, spontaneous abortions, and other diseases have continued to clash with claims by the International Atomic Energy Agency (IAEA), speaking for the United Nations World Health Organization (WHO), that exposures from Chernobyl fallout were orders of magnitude too low to be causally associated with these reported health effects.[16,31–34] This contention is based on population dose estimates by UNSCEAR,[6] combined with radiation risk factors for low-dose external exposures adopted by that organization and the ICRP.[8] However, numerous "authoritative" reports on the health legacy of the Chernobyl catastrophe have ignored evidence of serious flaws and gaps in knowledge on which the currently accepted models for population exposure and radiation risk estimates are based.[35] A number of radiobiological and dosimetric effects are ignored in the most widely-accepted version of the "current state of radiobiological knowledge:" It does not take into account:

1. The fact that *radiation risk models* adopted by the majority of radiation health studies are mainly based on a life span study among a Japanese survivor population. This study started in 1950, by which time that population had lost its most vulnerable members, the very young and the very old, during the first 5 years after the nuclear bombing of Hiroshima

and Nagasaki. Thus the A-bomb survivors are a *selected population,* hardly an appropriate cohort to use as a standard for determining radiation risks in normal populations.[35]

2. *Internal exposures* that are not adequately modeled in current low-dose risk estimates. The A-bomb survivors had been exposed to a single flash of high energy gamma rays from the atomic bombs (*external* exposure). A fraction of the "low dose" survivors were also exposed to radioactive fallout resulting in external and internal exposure.[36] The additional dose due to fallout was never included in the survivor study.[35,36] Contrary to official assumptions, health effects from reactor emissions, like those in the KiKK study, are likely the result of *internal* exposures, inducing radiobiological mechanisms quite different from those induced by external exposures.
3. The evidence that *sensitivity to radiation is much higher during early embryonic and fetal stages.*[3–6,14-16]
4. The incompleteness of the *inventory of biologically effective fission products* in reactor exhaust that has been used to estimate the radiation risk for residents nearby. Ingestion and inhalation of several radioisotopes, such as tritium or carbon-14, has been ignored.[16,37,38]
5. The fact that individual exposures are decisively determined by *highly variable local conditions,* such as wind, precipitation, and topography—conditions which affect environmental distribution of radioisotopes into the biosphere and eventual human intake. The resulting effects on health have not been adequately considered in the predicted radiogenic detriment around nuclear power plants. The suggested causal association of leukemia incidence rates with fission product emissions could more sensitively be tested by comparing these incidence rates in areas directly downwind with those found upwind of plant exhaust stacks, instead of in circular zones.
6. The *diversity in human uptake* of particular radioisotopes emitted by reactors (such as tritium, carbon-14, cesium, and radioiodine, including the long-lived iodine-129), *and in their accumulation* in specific organs or tissue.[16,36–38]
7. The *enhanced biological effects of very low energy electrons* (a major component of the primary and secondary radiation emitted by certain fission products).[39,40] In addition, the diversity in molecular *bond-breaking properties of alpha, beta, and gamma emissions,* and their strong dependence on energy, has not been adequately integrated into current dosimetric models.
8. That the assumed negligible exposures could in some cases be verified by studying *radiation-specific-chromosome aberrations* in blood of the populations near nuclear reactors.[1,16]
9. A likely *non-linear dose-effect relation* for low dose exposures, which introduces large uncertainties into risk estimates which are currently based on a linear model.[34,41,42]

SCIENTIFIC AND PUBLIC HEALTH RAMIFICATIONS OF THE KIKK STUDY

Historically, in the evolution of scientific ideas, major contradictions between established beliefs and incontrovertible findings would spawn critical reviews of long accepted assumptions, often resulting in revolutionary changes of basic axioms. At least from the time of Galileo, powerful interest groups have strenuously opposed these paradigm shifts. The claim that the unassailable KiKK findings are unexplainable and the attempts to invalidate them have their historical antecedents.

The KiKK study points out the need for a critical re-examination of uncertainties, flaws, and inappropriate generalizations in fundamental assumptions and models on which current radiation safety standards and regulations are based. A US government-sponsored case-control study, similar in design to the German KiKK study, would provide invaluable additional data for a sound scientific basis for such a re-examination since there are only minor design variations between US and German nuclear reactors. The KiKK study's ramifications add to the urgency of a policy debate regarding the high toll exacted in public health for nuclear power production.

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