

Epidemiological study on childhood cancer in the vicinity of nuclear power plants - KiKK study

Concluding statement of the Federal Office for Radiation Protection (September 2009)

The epidemiological study on childhood cancer in the vicinity of nuclear power plants, called KiKK study (Kinderkrebs in der Umgebung von Kernkraftwerken) was carried out by the German Childhood Cancer Registry in Mainz on behalf of the Federal Office for Radiation Protection and published in December 2007. The Federal Minister for the Environment, Nature Conservation and Reactor Safety has commissioned an evaluation of the study by the Radiation Protection Commission (SSK) after its publication. The Radiation Protection Commission has given a statement on the subject in September 2008 and provided a rationale for its statement to an expert public in February 2009.

The Federal Office for Radiation Protection concludes the following after an examination of the statement by the Radiation Protection Commission and taken into account the statement of the panel of experts, accompanying the study and the appraisal of the current expert discussion on the Kikk study.

1. The KiKK-Study investigated the following research questions:
 - whether there is an increased occurrence of childhood cancer rates in children below five years of age in the vicinity of nuclear power plants
 - whether the risk increases, the closer the location of the nearest nuclear power plant, and
 - whether, if applicable, there are influencing factors, which explain the findings
2. Research question, implementation of the study and type of analysis had been largely defined before study begin between the BfS, the German Childhood Cancer Registry and the panel of experts accompanying the study.
3. The KiKK-study concludes that increased cancer rates in children below 5 years of age have occurred in Germany in the vicinity of 16 locations with a total of 22 nuclear power plants between 1980 and 2003. This increased risk has mainly manifested itself in the form of leukaemia.
4. In the vicinity of nuclear power plants, an increased risk of 60% was observed for all types of cancer taken together and for leukaemia, the risk doubled, equalling a risk increase of approximately 100%.
5. This increase in risk is statistically significant for all types of cancer and in particular leukaemia. Looking at the risk increase in absolute numbers shows only a small increase, as cancer incidents amongst children are relatively rare. This means one additional disease incident per year within a radius of 5 km from the investigated nuclear power plant locations. However, comparing incident rates to be expected with the actual observed incident rates, it becomes apparent that from 77 observed cancer incidents within the 5 km radius area from a nuclear power plant, 29 incidents can be attributed to the vicinity of power plants. The incident rates for leukaemia are: from 37 observed disease incidents, 20 can be attributed to the vicinity of nuclear power plants.
6. The KiKK-study concludes further that the closer a five-year old child lives to the nearest nuclear power plant location, the higher is the additional risk to contract cancer under the form of leukaemia. This correlation of the disease

risk with the location was observed for all forms of cancer as well as specifically for leukaemia. The location dependency is for both disease groups statistically significant.

7. The study was conducted as thoroughly as possible. The findings can be deemed as being sound; independent findings of different groups have confirmed these findings. It can therefore be assumed for the risk for a child younger than 5 years to contract cancer increases the closer it lives to a nuclear power plant to be a fact that has been proven in Germany through the KiKK study as well as an assessment of the findings by panels of experts.
8. The radioactive discharges from power reactors is at least 1000 times too small, if the discharges from nuclear power plants is to be the sole cause of those findings.
9. There are also no other risk factors that could plausibly explain these findings. The KiKK study also investigated a number of possible other causes (such as social class, use of pesticide, employment of one parent in the nuclear power plant, x-raying the child). As less people living close to nuclear power plants wanted to participate in this part of the study, it has to be treated carefully. However, this part of the study gave no indication that any one of the other investigated factors had any significant impact on the KiKK study findings.
10. The BfS believes that there is an urgent need for action to further investigate the causes of leukaemia in childhood and, in doing so, to come closer to an explanation of the findings of the KiKK study.
11. Furthermore, it is an ongoing duty to question our knowledge about the effects and the risk of radiation, to increase our knowledge and to transfer our expertise into legal regulations.
12. So far, the Federal Office for Radiation Protection cannot recommend parents living in the vicinity of nuclear power plants to move away to another neighbourhood as there is no scientific proof that discharges from a reactor are the sole cause for the diseases.
13. Due to a lack of comprehensible explanations and the improbability through one single trigger, there is no sound scientific basis to lower any threshold values.

The rationale for the statement follows below:

Background of the KiKK study

The discussion about the negative impact of nuclear energy on the health of people living in the vicinity of such facilities has been going on since the beginning of its use. For instance, a discussion took place in the US in the end of the 1980s about possible increased rates of infant death. In 1984, there were reports about an increased number of leukaemia incidents in children, adolescents and young adults in the vicinity of the British reprocessing plant in Sellafield. Further British studies followed including all larger nuclear facilities in England and Wales. They reported a statistically significant increase of leukaemia incidents in children and adolescents within a radius of 10 miles around nuclear facilities⁽¹⁾. In 1992, a study, methodologically analogue to the British one (KKW study I), was conducted in Germany by the German Childhood Cancer Registry (GCCR) for the period from 1980 to 1990⁽²⁾. It found a statistically significant increased incidence rate for leukaemia among children below five years of age within the 5-km-zone around the sites. Since these results were discussed very controversially and since a statistically

significant increase in leukaemia occurred in the vicinity of the Krümmel nuclear power plant at around the same time, a second study was published in 1997 (KKW study II). This study contained data for the period following the first study, i.e. from 1991 to 1995 and included data from the first study. Therefore the period between 1980 and 1995 was investigated⁽³⁾. The same findings as those from the first study for children below the age of five occurred again, though it was not statistically significant this time. The second study, unlike the first one, did however also include nuclear facilities with low power levels as well as shorter operating times.

The studies mentioned so far are so called ecological studies. In these, the incidence rate in certain areas is compared to other areas, i.e. the incidence rate in an area 5 km from a reactor with an incidence rate of a comparable region with no reactor. These studies cannot make any statements about the factors that are the reasons for such findings. Even more so, there is a danger of a so called ecological false conclusion, as the regions are chosen through averaged data from a number of attributes and not only considering the existence of a nuclear reactor. It is unknown whether these attributes apply for every sufferer in the region. This means that factors significant in the evaluation of the disease risk can be covered up through the exclusive investigation of averaged data and therefore come to possible false conclusions in those studies. Comparisons between incidence rates in different regions can therefore be first indicators for a connection but they need to be verified through further and methodologically more advanced studies.

As a result of the continuing discussion and taken into account the problems when interpreting the findings of ecological studies, the BfS invited to a "Round table" of various groups in 2001. The BfS afterwards decided to commission a methodologically more ambitious study in order to gain more reliable results - a so-called case-control-study, where information known about the individuals partaking in the study are also taken into account. This so-called KiKK-study (Kinderkrebs in der Umgebung von Kernkraftwerken – Epidemiological studies on Childhood Cancer in the Vicinity of Nuclear Power Plants) began in 2003. The research question and study design was proposed by a multidisciplinary panel of experts consisting of 12 members. The BfS acted on their suggestion and, following an invitation to tender, commissioned the German Childhood Cancer Registry (GCCR) in Mainz with the implementation of this study. The real significant improvement in the study was that for the first time, incidence rates in different regions were not compared with each other, but children suffering from the disease were compared on an individual basis with randomly selected control children (matched only by age and gender) from the same region. Based on these findings, exact information on the distance between the place of residence and the reactor could be taken into account.

Research question

The study had three objectives:

- Does cancer occur more frequently in children under five years of age living in the vicinity of nuclear power plant sites?
- Is there a negative trend, i. e. does the risk increase with decreasing distance to the nuclear power plant site?
- Are there confounding factors that could explain the gained result?

To answer the questions the study was divided into two parts:

- Part 1: Case-control-study without interview
- Part 2: For a sub-group of Part 1, a case-control study with interview in order to be able to take into account possible confounders which might explain the findings from part 1.

The research question was formulated in such a way that only statements could be made on a link between the place of residence in the vicinity of nuclear reactor site and the risk to contract cancer. To use the distance of the place of residence as a measure as opposed to the individual radiation exposure of children had the following background:

When formulating the study design, both the BfS as the contracting body and the panel of experts, which at the time included the later contractor the German Childhood Cancer Registry, agreed that for the more than 6000 children in the places of residence in question neither measured results for their radiation exposure was available nor was it possible or feasible to obtain an estimate of the exposure through model calculations.

Basically, radiation exposure through nuclear power plants in normal operating mode can only be estimated with the help of exposure models, but not directly measured. These estimate models include various assumptions on residence time, nutritional behaviour, etc., which to some extent are extremely uncertain. This applies in particular to retrospective exposure estimates which should have taken place back in 1980, when the period relevant for the KiKK study began. As replacement, the distance between the respective child's home and the closest nuclear power plant site at the time of the cancer being diagnosed was used in accordance with the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), as it is practically hardly possible to estimate exposure for all children and reference children included in the KiKK study.

How was the study conducted?

The region studied, for which data from the Children Cancer Registry was available, contains 41 rural districts (Landkreise) in the vicinity of the 16 (west) German nuclear power plant sites with a total of 22 nuclear reactors. The following rural districts were investigated: the rural district where the reactor is located, its closest neighbouring rural district and, due to west winds being predominant in Germany, the closest rural district to the east. The KiKK-study looks at the period between 1980 and 2003 and is divided into two parts: the first eleven years during the operation of a power reactor and the remaining years thereafter. The rationale behind it was that, according to the two previous studies, the risk for the first period was found to be higher than for the second period. Accordingly, one question in the KiKK study was, whether there was a difference in the distance trend possibly to be found between the early and late period of operation.

In the two previous ecological studies undertaken, incidence rates in different areas i.e. 5, 10 and 15 km distance to a nuclear power plant site, were compared with the incidence rates in selected German control areas. Through the case-control study approach, it was possible to take individual places of residence for diseased children as well as for reference children (unaffected healthy children) into account, which

were obtained randomly from the Residents Registration Offices.

Which findings were obtained?

Findings for the KiKK study in accordance with the analysis plan

The study looked at all of the 1592 children who were reported to the German Childhood Cancer registry between 1980 and 2003 and diagnosed with childhood cancer and who at the time of diagnosis lived in one of the defined regions surrounding the 16 German nuclear power plant sites and were younger than five years of age⁽⁴⁾. For each case, three random reference subjects were selected, matched in age and gender to the case and living in the same area. 4,735 reference subjects were found this way. The vicinity of the home to the respective nuclear power plant site could be exactly determined for all 6,327 children up to 25 metres on average. It was then possible to check whether children with cancer lived on average closer to the nuclear power plant site in their area than their respective reference subjects.

A negative distance trend was found for all types of cancer as well as for leukaemia, this means that the incidence rate rises with the increasing vicinity to the reactor site. The findings for all tumours can be essentially attributed to the findings for leukaemia. A negative correlation was found for CNS (tumours affecting the central nervous system) and no correlation at all was found for embryonic tumours. An analysis of the radii showed that incidence rates of tumours and leukaemia taken together occur significantly more often in the areas closer to nuclear power plant sites, i.e. within the 5 km radius as well as within the 10 km radius, than in areas outside this perimeter. The group of all types of leukaemia also showed a negative distance trend. Using a categorical approach here also lead to statistically significant findings for the 5 km and the 10 km radius.

To verify the findings with regards to all diagnoses, a sensitivity analysis was carried out, which excluded one reactor site from the analysis. The same findings were obtained for the remaining 15 sites. This means that the findings cannot be attributed to a single reactor site, but are valid for all 16 nuclear power plant sites in total. The previously alleged so-called "Krümmel" effect (the average increased incidence rate of leukaemia cases around the Krümmel site) has therefore been eliminated. As the willingness of communities in close vicinity of reactors to divulge address data for possible reference children was less than in regions further away, all cases from communities who did not provide any controls or not enough controls were excluded from further investigations. Nevertheless, the findings stating that incidence rates rise the closer the vicinity to reactor sites were confirmed, i.e. a possible confounding caused through this problem is minor. When comparing the two study periods it becomes apparent that there is a more manifest distance trend for the first period than for the second. However, the difference between the two study periods is not statistically significant.

Findings from further analysis of the KiKK study's original data

In December 2007, Sigmar Gabriel, Minister for the Environment commissioned the Radiation Protection Commission (SSK) to verify and assess the findings of the study. The SSK in turn commissioned the British epidemiologists Darby and Read to

verify the core findings of the original KiKK study using the original data. They confirmed the above stated findings from the Mainzer study group analysis. Darby and Read also conducted further-reaching explorative analysis. These further-reaching explorative analyses can provide indications as to which factors contained in the data could have led to the findings and how sound the findings are. It was hence verified whether the observed risk increase for leukaemia only occurs in the 5 km radius or whether this phenomena can also be found further out. The verification concluded among others that the increased risk for contracting acute leukaemia within the 5 km radius from the reactor site can be confirmed, whereas the region of 5 to 10 km distance from the reactor site only showed a small, statistically insignificant increase. It is further important to note that Darby and Read discovered that the risk increase could not be explained through the predominantly rural area in which the nuclear power plant sites are located⁽⁵⁾.

The SSK confirms the BfS' position. "The KiKK study was carried out following the basics of good epidemiological practise. The authors adhered strictly to the requirements of the analysis plan" ⁽⁶⁾. Only in the calculation of the attributive risk did they go beyond the requirements of the plan. Neither the SSK nor the revision through Darby and Read found any mistakes in the implementation.

With regards to the assessment however, the SSK does come to the conclusion that the increase in risk in the vicinity of nuclear power plants is acausally linked to the radioactivity emitted from nuclear power plants. The SSK accounts for this assessment with the little radiation exposure caused through discharges from nuclear power plants compared with the exposure rate from natural sources. The BfS holds the opinion, as the KiKK study is a case-control-study, that when assessing the findings, it is of primary importance to recognize which factors and possible confounders distinguish case subjects from reference subjects. The comparison between exposure rates from natural sources with the level of exposure from discharges cannot, however, be answered in a case-control study.

In October 2008, the German Childhood Cancer registry published findings from analyses which go beyond the analyses defined in the KiKK study. This showed, analogue to the analysis carried out by Darby and Read, a doubling of the risk within the 5 km radius. No increased risk was found in other distances (5-10, 10-30 and 30-50 km).

On the basis of previously conducted ecological studies, the incidence rate in the vicinity of reactors was compared with the average incidence rate for Germany. This showed that the incidence rate within the 5 km radius is 40% higher than for the rest of the country. For all other stated distance categories, the incidence rates are close to the average rates for Germany⁽⁷⁾.

Evaluation of the findings from the KiKK studies final report by three epidemiologists from the panel of experts

In March 2008, three epidemiologists from the panel of experts subjected the KiKK studies final report and further available documentation to a quality test. They came to the conclusion that the study was carried out with the best possible study design. They further pointed out that, using epidemiological causality criteria, radioactive discharge from reactors cannot be excluded as the cause of the observed effect.

These causality criteria define under which circumstances an epidemiological study can make statements not only about the increase in risk, but also the possible causes of it.

The three epidemiologists make the following proposals for further investigations:

1. It appears sensible to follow up the question whether individual nuclear power plants contribute in particular to the overall observed increase in risk and which temporal patterns can be observed;
2. It seems sensible and necessary to develop a number of scenarios which help to assess how much radiation contributes towards the observed increase in risk, possibly in interaction with other causes;
3. Besides a closer inspection of exposure rates, they also recommend to revise current assumptions about radiation impact.

They do not believe that further studies following the design of the KiKK study are useful in Germany, as all available data was utilised in the KiKK study and one would have to wait about 25 years to be able to carry out a further study with the same quality and to the same extent.

BfS activities after the conclusion of the KiKK study

In May 2008 the BfS undertook an international workshop in Berlin together with the World Health Organisation (WHO) and the International Commission on Non-Ionizing Radiation Protection (ICNIRP) on the causes of childhood leukaemia. All causes of leukaemia discussed in scientific literature were presented. These include, among others, environmental factors such ionizing radiation, non-ionizing radiation, the use of chemicals in agriculture, a possible virus genesis as well as genetic factors. The workshop provided good foundations for the development of further research question and approaches. The conference transcript was published in *Radiation Protection Dosimetry* (vol. 132, no 2, 2008). The workshop has made it again very clear that leukaemia is caused by a number of factors, which are not yet fully understood in their complexity. It is important to find the causes of the disease through specific future research, as the genesis of leukaemia is largely not yet understood, despite a number of efforts in different scientific areas. A comprehensive, coordinated research program, which would include all aspects of the disease genesis, is deemed to be necessary. Such a program would require to be built on a wide expert base and be set up for long-term research.

In order to answer the question as to whether emissions from nuclear power plants during normal operation can explain the observed incidence rate of childhood leukaemia, the BfS has revised the current monitoring programmes and regulations to assess the exposure of the public in the vicinity of nuclear power plants. In Germany, the discharge of radioactive material from nuclear facilities are specified and balanced in terms of type and level of activity by the licensee in an internal audit and in accordance with legal regulations on the basis of "discharge air" through the exhaust stack and "discharge water" through receiving water. Moreover, the licensee is required to conduct measurements in the vicinity of his nuclear facility (air pollution surveillance).

The licensee compiles the results of the emission and immission measures in quarterly and annual reports. These are technically assessed by the responsible

regulatory authority and checked for plausibility through the BfS coordinating offices “exhaust air” and “waste water”.

In addition to measurements by the licensee, the activity concentration of radioactive material in the exhaust stack air is continuously monitored and documented by measuring equipment from the regulatory authorities’ Nuclear Facilities Remote Monitoring (KFÜ) within the respective Federal State (Bundesland). Continuous operation of monitoring equipment for air pollution measurements in the close vicinity of nuclear facilities are also part of the remote monitoring systems. Activity discharges calculated from the emission monitoring the “exhaust air” of all nuclear power plants in Germany result in using a conservative assumption, i.e. an assumption overrating the exposure, an exposure rate of less than 10 µSv/a for infants. This is presented in annual reports entitled Environmental Radioactivity and Exposure rate. Exposure rates at this level are around a 1000 times too small to explain the observed increased childhood cancer and childhood leukaemia risk, if these radiation resulting from nuclear power plant discharges is the sole cause of this increased risk.

Assessment of findings through Federal Office for Radiation Protection

In order to be able to explain the observed doubling of the risk for children younger than 5 years to contract leukaemia within a 5 km radius from a nuclear power plant, an exposure rate of around 10 mSv would be necessary, according to the current state of radiobiological and epidemiological knowledge. This dose would be around 1000 times higher than the estimates resulting from the General Administrative Provision (Allgemeine Verwaltungsvorschrift AVV). This only applies if radiations occurring through nuclear power plant discharges are the sole cause of the increased risk. During the current discussion on the KiKK study’s findings, a number of possible causes were examined. None of the other factors mentioned shows a plausible link to the distance from the nearest nuclear power plant. The genesis of childhood cancer and leukaemia shows itself as a multi-factored disease. A sole or predominantly responsible factor, not even the exposure rate resulting from nuclear power plant discharges, was found. This means in reverse that so far, no possible risk factor could be explicitly excluded, in particular not the one where a distance dependency according to the findings of the study appears to be possible.

The Federal Office for Radiation Protection concludes that there is currently no satisfying answer to the questions arising from the KiKK study findings. Due to the significant relationship between the risk and the distance to the nuclear power plant sites, the study provides indications for possible causes, but no proof.

So far, the Federal Office for Radiation Protection cannot recommend parents living in the vicinity of nuclear power plants to move away from their neighbourhood. There is no scientific proof for such a recommendation, there is no proof that the discharges from a reactor are the sole cause of the diseases. Due to a lack of comprehensible explanations and the impossibility of proving a single trigger to be the cause, there is no sound scientific basis to lower the threshold values.

The Federal Office for Radiation Protection concludes that the findings from the world’s methodologically most elaborate study give reason to further investigate the causes for childhood leukaemia. In this, it is particularly important to take into

account the concurrence of various factors such as genetics and the environment. The understanding surrounding the causes of leukaemia is currently insufficient at best. It is possible that there are several factors which together contribute to an increased cancer risk. To understand this presents a scientific challenge. The Federal Office for Radiation Protection advocates that further steps be taken on a national as well as an EU level.

It is additionally an ongoing duty to question our knowledge about the effects and the risk of radiation, to increase our knowledge and to transfer our expertise into legal regulations. The Federal Office for Radiation Protection has among others presented its ideas with its foundations on the further development of radiation protection.

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