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KemaNord



Plastics
Division

Ett företag i KemaNobel
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The Dow Chemical Company
Bennett Building
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Your ref.

Our ref.

CSj/kb

Stockvikmarken, Sweden

1978-04-25

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Dear Mr. Torkelson:

Enclosed you will find the pilot study concerning the Mortality in Njurunda Community that you were interested in. I also enclose a statement by the National Swedish Nature Conservancy Board, Environmental Department, which is made in connection with a claim for a "health examination" of the people in the vicinity of the KemaNord plant outside Sundsvall, Sweden.

Both reports have been translated by KemaNord.

I hope this information will be of some value to you, and if you have any further questions I will be happy to answer you.

Sincerely,

KemaNord
Plastics Division
PVC Operations

Christer Sjölin
Christer Sjölin

Encls.

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The National Swedish Nature Conservancy Board
Environmental Department
Dr. Rune Cederlöf

Dnr 194/75. SNV nr 70-6615-75

Regarding a Possible, Epidemiologic Examination of the Population Living in the Vicinity of the KemaNord Plants in Stockvik.

1. Background and Problem

In the decision of the concession committee to grant KemaNord the permit for production at the plants in Stockviksverken the following conditions, among others, are given for production of polyvinyl chloride (PVC).

For the final conditions as to the emission into air a probationary period was granted till the end of 1978. During this period the company shall supplement the present study material with an investigation of the health of those living in the vicinity with respect to a possible influence of the emission of vinyl chloride.

Therefore, KemaNord asked the Environmental Department of the National Swedish Nature Conservancy Board to give their views as to the need for an epidemiologic investigation of the population living around the KemaNord plants in Stockvik. If it is considered that such a need exists, KemaNord also wishes to receive suggestions how to plan and to carry through such an epidemiologic investigation.

The production of PVC in Stockvik was started during 1945, and in 1973 it amounted to about 60 000 t. Vinyl chloride (VCM) was used in the production. In a number of investigations this material has been linked to the occurrence of angiosarcoma of the liver of workers who have been exposed because of their work. VCM is also suspected of inducing other types of cancer. So far four certain cases of angiosarcoma have been reported among the appr. 750 workers who have been engaged in the PVC production at Stockviksverken. The company has carried out a series of investigations of the employees and because of these, to a limited extent, found certain symptoms of disease which might be linked to the exposure to VCM. However, no investigation of the people living around the plants has taken place. The VCM values of the air have been measured recently and are to-day very low. In only 1.7% of the actual time of measuring, the values within a radius of 1 km exceeded the detection limits of the measuring methods, 10 ppb. Values of 50-90 ppb were only obtained twice (0.04% of the time). This means that at present a maximal mean value does not exceed 10 ppb. However, without doubt at the beginning of the production period the contents were higher and probably much higher than to-day.

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There are no figures that show without a doubt that VCM has had effects on the people living in the vicinity of the VCM-emitting industries. An evaluation of the risks has been done by A.M. Kuzmac and R.E. McGaughey at the U.S. Environmental Protection Agency. The risk of the people living in the neighbourhood has been estimated on the basis of experiences from both professional exposure of workers and from experiments with animals. In the USA 4.5 million people are supposed to live within a radius of 5 miles (about 9 km) from a number of PVC-plants. The average exposure within this radius has been estimated at 17 ppb vinyl chloride, a figure that will be difficult to verify. As to the effect of the carcinogen materials it is now generally believed that the effect is proportional to the dose, even at extremely low levels of dose, i.e. that the so-called zero effect only exists when the dose is 0. Using such a linear form of evaluation one arrived at the fact that between < 1 and up to 10 cases of liver-angiosarcoma should occur annually in the population investigated as a consequence of the exposure to vinyl chloride, this corresponds to a maximum of 2 cases per one million people per year. It is further emphasized that the frequency of malignant tumours of other types than angiosarcoma of the liver should occur twice as often, and also that serious liver injuries among occupationally exposed persons should be 30 times as frequent as angiosarcoma. One is cautious in drawing conclusions and mentions a number of error possibilities that may influence the evaluations.

If the information concerning the frequency of angiosarcoma is correct it means that at an average content of vinyl chloride of no more than 10 ppb in the air and in an area with the number of people as in Njurunda no more than one case of angiosarcoma and no more than two cases of other malignant tumours per 100 year should be expected as a consequence of the exposure. This maximum estimate is based on the highest American figure of risks supposing the unlikely high exposure of 10 ppb around KemaNord. In spite of this it is evident that this low frequency cannot be proved within a reasonable time of observation.

The number of liver injuries of other types of cancer should, according to the American investigation, show a 30 times higher annual incidence. It does not seem appropriate to use a linear extrapolation model here, but in case such a model is used, the exposure at a very high estimate means a case of liver injury every three years, or without regard to latent periods and higher mortality among the cases of liver injury which have already occurred, a total prevalence of no more than 10 cases in the now living population. If the liver injury was specific for the exposure to vinyl chloride it should necessitate a spot check of about 1 200 individuals in order to prove with 95% probability

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that liver injury does exist in the population. If a still higher probability is desired, e.g. 99%, a spot check of almost 2 000 individuals is necessary. But if the liver injury is not specific an essentially larger number of spot checks must be taken, the number depending on the "background frequency" of liver injuries measured by the test in question.

Above calculations are very approximative but in the first place they lead to the fact that observation of mortality from cancer, and then specifically angiosarcoma of the liver, has to be extended over a long period, and in the second place that proof of a possible liver injury needs spot checks from as many as 5 000 - 10 000 individuals from whom specimens have to be taken, i.e. an almost total examination.

In this connection we want to point out that this concerns a prospective investigation to watch out for the risks that may arise as a consequence of the present exposure - such as has been maximally estimated. With regard to the fact that the exposure may have considerably exceeded the present values previously, a larger number of deaths or liver injuries could be principally expected in future among people who have lived within the area during such periods with higher exposure.

In connection with discussion the possibilities to carry through direct examinations of the now living population has to be mentioned, either through inquiries in order to screen the suspected positive cases according to the inquiry for medical examination, or a complete medical examination of a selection of the population. However, there does not seem to be enough specific subjective problems to ask for in an inquiry to serve the purpose of being an effective means of screening. Whether a medical examination of the population should be motivated or not also depends on how specific the objective methods of investigation in question are. This is a medical, clinical question and a decision will have to wait until the final results from the occupational-medical examination are available.

With regard to above the following planned examinations aim only at a registration examination of the population.

2. Planned Investigation

2.1. The Position Taken as a Matter of Principle

Epidemiologic studies of the population can be done in several ways, in this connection two of them may be of interest.

One type (A) means study during a certain period of the mortality within the geographical area which has been supposedly exposed. The mortality figures are related to the average population in the same area during the period. The relation between exposure and mortality is difficult to evaluate in such a material as the mortality also refers to persons who have recently moved into the area. Besides persons who have lived for a long time in the exposed area may have moved away and died in an area that is not being observed. This type of investigation is, however, relatively easy to carry through based on the existing population statistics.

Another type (B) is to define the target population as the number of people having lived within the exposed area during a certain time a number of years back, and then observe the mortality of these individuals, no matter if it has happened in the area or in another place (cohort studies). In the latter case the number of people is clearly defined, and the time for living in and outside the exposed area can be given for each individual. However, the latter type of investigation is much more time-consuming, mostly because of the necessity of checking persons who have moved away from the area.

In both types of investigations it is usual to compare results from selected reference populations which have been examined in the same way. In a suitable way it is also possible to compare the mortality investigation of type A with age- and sex-standardized incidence figures for all the nation. However, it has to be pointed out that especially certain industrial areas may have a population which in other relevant aspects than age and sex may differ from the average of the nation. E.g. it may be the case for a number of behaviour variables like smoking and consumption of alcohol. Therefore, it is important that together with comparisons of incidence figures for all the nation also to study the difference between the target population and a comparison population which has been selected from an area with broadly speaking the same population structure.

The above concerns mainly mortality studies, but the same principles should be applied even when it concerns checking of sickness when registering cancer, deformities, etc.

2.2. Preliminary Mortality Investigation, Type A

In a preliminary study (C-G. Elinder and G. Pershagen) the mortality during the years 1961 to 1974 in Njurunda community has been compared partly to the mortality in the nation as a

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whole and partly to the mortality in a reference area during this period. As reference area the Själevad community outside Ömsköldsvik was chosen because after going through a great number of communities and counties along the coast of Norrland this community turned out to be the best alternative to the reference area. Själevad has a similar population distribution and pattern of employment as the population of Njurunda and is also geographically similar: a coastal district close to a larger industrial town. Information of mortality has been obtained through using the so-called register of cause of death (Central Bureau of Statistics) where every death since 1961 is available on computer.

When it had been proved that VCM might cause cancer of the liver this diagnosis attracted the most attention, of course. However, during this period only 7 such cases had occurred, which have to be considered as low, indicating that the previous, high exposure at any case has not yet been reflected in increased mortality from angiosarcoma within the population in general. On the other hand the investigation showed a relatively increased incidence of cancer of the pancreas for men, where the SMR¹⁾ within Njurunda amounted to 148, i.e. an increase of about 50%. Similar calculations from Själevad showed no noteworthy proportion.

When technically, statistically evaluating this increase of cancer of the pancreas - which is significant - reservations have to be made to the fact that the result has emerged in connection with an explorative procedure where a great number of diagnoses have been observed. At a level of significance of 5% 1/20 of all observations are expected to be significant at random. There has been found no reason to put forward any specific hypothesis concerning only cancer of the pancreas. In every explorative procedure of this kind "significant" results shall be followed up and, if possible, be the object of tests of independent material. Thus it is not possible now to comment on the causes of the result.

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Standard Mortality Ratio expresses the relation between the observed number of cases and the expected number of cases based on a specific figure of incidence related to age and sex for all the nation.

When going through the cases it turned out that 5 of the 20 men who died from cancer of the pancreas were found among those who had been employed by the industry. This does not mean a reliable increase among the employees. However, if these are not taken into consideration the SMR does not differ significantly from 100.

2.3. Investigation Plan for a Mortality Study, Type B

As has been pointed out above the mortality study, type A, is not comprehensive. A study, type B, means that the population registered within Njurunda in 1960 has been defined as the target population. This can be done by making lists from the census of 1960, which can even give certain structural and socioeconomic data concerning the individuals. When combining a register based on this and the so-called cause of death computer tapes (see 2.2.), then a list of all deaths in the registered population is obtained in principle. For control "the survivors" are compared to the register of the total population where, except for emigrants, everybody should be found. The same procedure is carried through within a reference area. The statistical analyses were carried through as a comparison between both the regions of figures of sex- and age-standardized incidence.

A similar checking of the individuals listed in the personal registers can also be done of the cancer register founded by the Social Welfare Board. Besides information about cancer mortality this register also contains data concerning cancer sickness.

The analysis must even take into account whether those living within the Njurunda area during 1960 some time or other before or after that time have been employed by KemaNord AB.

An investigation of this type is estimated to take one year. The total costs should be around Sw.Crs 100 000.

3. Summary and Discussion

In spite of the many investigations the knowledge of the health risks for the population because of the discharge of the vinyl chloride from a PVC-industry is still very limited. To judge from the American estimates the risk for angiosarcoma of the liver in a population the size of the one in Njurunda is very small. If the average content of the air is at most 10 ppb vinyl chloride then no more than one case should occur every 100 years. The risk for malignant tumours of other

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types than angiosarcoma of the liver should be approximately twice that number. These values have been given assuming a linear relation of dose response without threshold values. As to other liver injuries these are indicated to be 30 times as frequent as liver angiosarcoma, but it can be assumed that there is a threshold value which is probably higher than the contents which appear in the air. Besides the liver injuries are not specific for the exposure to vinyl chloride, and there does not seem to be any point in showing possible liver injuries in the neighbouring population, even if an almost total examination takes place.

A comparison of causes of death in Njurunda community during the years 1961 to 1974 and in the reference area Sjölevad during the same period has not shown any noticeable results except for an increase of 50% of cancer of the pancreas within Njurunda. However, available data do not indicate if there is a causal connection between the type of tumour and the exposure to vinyl chloride. It turned out that 5 of the 20 cases had been employed by the industry. This proportion does not give any safe reason for a causal connection, but together with the totally higher frequency within the area it is a point to be observed from an occupational-medical point of view as well as from one of public hygiene.

In these circumstances it is now the question to what extent further examinations of the population in the vicinity of the KemaNord plants will be able to clarify the evaluations of risks based on the American estimates. It has to be pointed out that the evaluations of risks are based on a supposed content of vinyl chloride in the air of about 10 ppb, which is to be assumed as the maximum content to-day. The information to be obtained from studies of the mortality during the years 1961 to 1974 must be related to the proportion of exposure during all the period and possibly even to values before 1961. It seems difficult to make an adequate description of exposure prior to this time, and therefore, the epidemiologic investigations should hardly be of any value to evaluate the dose response relation. On the other hand a completely negative result should speak strongly in favour of the fact that no risks can be expected in future as a consequence of the exposure to vinyl chloride.

In support of above it can be summarized that further investigations of mortality of the population living in the vicinity of the KemaNord plants in Stockvik as to angiosarcoma of the liver and other malignant tumours cannot be expected to give results valid for dose response calculations. The circumstances

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concerning cancer of the liver which have appeared in the pilot study that not even the higher doses which have occurred earlier give any effect on the population in general. Of course, we cannot predict what will happen for the future why continued observations can be justified.

If other authorities under these circumstances think further investigations should be made, a cohort study, type B, should be the one to be considered.

The matter has been decided by assistant department manager, Dr. Thomas Lindvall with Dr. Rune Cederlöf as reporter. Professor, Magnus Piscator and medical doctor Carl-Gustaf Elinder have also taken part in the decision.

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Pilot Study concerning the Mortality in Njurunda Community

by Carl-Gustaf Elinder and Göran Pershagen

Introduction

In the decision of the concession committee to grant KemaNord the permit for production at the plants in Stockviksverken the following conditions, among others, are given for production of polyvinyl chloride (PVC):

For the final conditions as to the discharge into air a probationary period was granted till the end of 1978. During this period the company shall supplement the present study material with an investigation of the health of those living in the vicinity with respect to a possible influence of the emission of vinyl chloride.

KemaNord AB asked the Environmental Department of the National Swedish Nature Conservancy Board, the Karolinska Institute, to investigate the conditions for an investigation of the kind to which the concession relates. The committee is expected to suggest some kind of an epidemiologic investigation in order to demonstrate possible health risks to the population in the vicinity because of the emission of vinyl chloride.

American investigations show a connection between angiosarcoma of the liver and exposure to vinyl chloride (VCM) in the industrial environment during a long time and high contents (Lloyd, 1975). It is further suspected that high contents of VCM can induce other malignant tumours (Moore, 1975).

So far four cases of angiosarcoma of the liver have been observed among the appr. 750 workers who have been employed in the vinyl chloride and/or the polyvinyl chloride production since production started 1945 at the plant in question (deaths occurred 1970, 1972, 1976 and 1977).

This pilot study is independent of the investigation regarding epidemiologic investigation around Stockviksverken which has been made by the department, but it should give valuable background information.

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Exposure of the Neighbourhood

The production of polyvinyl chloride in Stockviksverken started during 1945, and during 1973 it amounted to about 60 000 t. The VCM content in the industrial environment was very high during the 50s and the 60s but has been reduced considerably during the 70s, first to 10-20 ppm during 1974 and from January 1, 1976 to below 1 ppm which is the limit in force now. A number of measurements of immission in the housing area close by was made in 1976, and the result showed that the immission of vinyl chloride in question was low, mostly beyond detection by the measuring method, the limit being 0.01 ppm (0.03 mg/m³). However, the emission and the exposure of the environment was considerably higher earlier before vinyl chloride monomer was identified as a carcinogen material.

Besides polyvinyl chloride even calcium carbide, sodium chlorate, formalin, formaldehyde resins of urea, phenol and melamine, as well as special chemicals consisting of, among other things, fatty chemical products and agricultural chemicals are produced at the KemaNord plants in Stockviksverken. The production of most of the chemicals was started in the 40s and the 50s, but some of the special chemicals were not produced until the last decade.

However, it has to be pointed out that other industries have or have had manufacturing within the area in question. Thus Gränges Aluminium, a producer of aluminum, is located 3-4 km north of Stockviksverken, and Svartviks Cellulosafabrik, which was closed down in 1973, 2-3 km south of Stockviksverken. Until the mid-60s there was a production of cellulose in Essvik 2-3 km southeast of Stockviksverken and until the early 40s in Nyhamn about 2 km also southeast of Stockviksverken. Chemical products have been produced in Nyhamn since the production of cellulose was closed down, and for the last years sulphur dioxide has been manufactured in Essvik.

In table 1, which shows the population distribution within Njurunda community in 1974, it can be seen that about 2 500 of the Njurunda population of 12 000 people live close to Stockviksverken, i.e. within a distance of about 2 km.

Program for the Pilot Studies

When studying possible health effects around a certain polluting industry it is necessary to define an exposed population. The exposed population must not be so numerous that possible health effects are "wiped out", but on the other hand not so small that it does not cover the whole area where health effects may occur.

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Of practical and of work resource reasons the exposed population in this study is defined as Njurunda community in Sundsvall county. Information on mortality in this area has been compared to the mortality in the nation as a whole and to a control area.

In this case the methods are very rough as only a limited number of the population of Njurunda community lives close to Stockviksverken (see table 1).

As reference area the Själevad community outside Örnsköldsvik was chosen. Having checked a large number of communities and counties along the coast of Norrland this community appeared to be the best alternative as a reference area. The population distribution and industrial profile of Själevad are similar to the ones of the population in Njurunda, and besides it is geographically alike: a coastal community close to a larger industrial town.

Information about the mortality has been obtained through using the so-called cause of death register (SCB) where all deaths have been computerized since 1961.

The methods used in the study in question are the same as the ones used for a similar study around the Rönnskärsverken, outside Skellefteå. This has recently been published (Pershagen, Elinder and Bolander, 1977).

Result and Discussion

As a first step the mortality in Njurunda community from the years 1961 to 1974 inclusive was compared to the average of the whole nation, as well as to the reference community of Själevad. The so-called crude ratios (SRR) for a number of different causes of death were calculated, see table 2. Besides the total number of causes of death table 2 shows different types of causes of death in Njurunda community between the years 1961 and 1974 inclusive, also the so-called crude rate ratios (CRR). In this case the CRR means that the specified causes of mortality in the population in question during a period of 14 years has been compared to the mortality of the reference populations. In the case in question the mortality for various causes of death in Njurunda community has been compared partly to the community of Själevad, partly to Sweden as a whole. The table shows that the total mortality in Njurunda community gets a CRR of 1.6 which is higher than the expected 1.0, but this can be explained by the fact that the average age within the Njurunda community is higher than within the Själevad community and also compared to the nation as a whole.

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When the total mortality is divided into different groups no marked differences from the CRR of 1.6 appear, except cancer of the pancreas, where the CRR is 2.7 and 2.4 when compared to Sjöleåvad and the nation as a whole resp.

It is to be noticed that we have only been able to find a total number of seven cases of cancer of the liver (4 men and 3 women) during the whole period that VOM has been proved to cause only cancer of the liver, and consequently we had first expected to find an increase of that from possible effects on the population living in the vicinity.

As suggested above the crude rate calculations can be misleading because of the different age distribution within the investigated population and the reference population (as known the frequency of cancer increases steeply with increasing age) therefore, we continued with an age-adjusted comparison and with calculation of standardized mortality ratios (SMR) for cancer of the pancreas.

Tables 3 and 4 show an age-adjusted comparison of the number of cases of cancer of the pancreas in Njurunda and Sjöleåvad to what should be expected based on the statistics for causes of death for all the nation.

The size of the population and the age distribution in the communities investigated have been calculated as the mean value of the census of 1960 and of the ones of 1965 and 1970. The expected number of cases of cancer of the pancreas has been calculated as the mean value of those recorded in the whole nation in the years 1961, 1964, 1971 and 1974 (Official Swedish statistics).

Tables 3 and 4 show that an overmortality of cancer of the pancreas exists among men in Njurunda community (SMR = 148). When the reference area, Sjöleåvad, was compared to the national average the observed number of cases of cancer of the pancreas decreases instead by about 25% more than what was expected (SMR = 74). Even in Njurunda the SMR should be below 100 as the incidence of cancer of the pancreas is higher in big cities.

When going through the register of KemaNord employees it turned out that five of the 20 men who had died from cancer of the pancreas had been employed by the company for more than two months.

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That five of the twenty had been employed by KemaNord does not mean a safe increase of the number of cancer of the pancreas among the employees, as approximately 25% of the male population in question within Njurunda community some time or other during their lives have been employed by the company.

Conclusion

This pilot study is very rough and can with certainty neither prove nor exclude possible effects on the vicinity as a consequence of the emission from Stockviksverken. However, the study shows that only seven cases of cancer of the liver (4 men and 3 women) have occurred in Njurunda community in the years from 1961 to 1974, which is not higher than expected.

However, the study also shows that the mortality from cancer of the pancreas in Njurunda community is higher than what can be expected. Any conclusions as to the aetiology of this cannot be drawn at this stage, however, but as chemical induction of cancer of the pancreas has been described (Finklea, 1976) such should be suspected.

In order to make it possible to trace any possible causes of the increased mortality from cancer of the pancreas a so-called case reference study based on the cases in question is urgent.

Besides occupational exposure at KemaNord factors such as employment by another industry, location of housing, alcohol consumption, smoking habits will have to be thoroughly investigated in such a study.

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TABLE 1

The Population of Njurunda 1974

Stockvik, Bredsand	2,355
Svartvik	1,088
Kvissleby, Nolby	3,702
Dingersjö, Klockarberget	583
Njurundabommen, Mjösund	2,196
Skottsund	842
Essvik	674
Juniskär	311
Skatan	138
Ångon, Öjestränd	100
Västana	70
Total number	<u>12,059</u>

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TABLE 2

The mortality from various causes of death within the Njurunda community 1961 to 1974, as well as Crude Rate Ratios (CRR) for the various causes of death

Cause of Death	♂			♀		
	Total number Njurunda	CRR Njurunda Sjöleivad	CRR Njurunda Sweden	Total number Njurunda	CRR Njurunda Sjöleivad	CRR Njurunda Sweden
Deaths, total number	1082	1.51	1.61	829	1.47	1.53
Tumours, total number	182	1.21	1.35	182	1.30	1.53
Tumours in the digestive duct	81	1.10	1.55	65	1.27	1.60
Tumours in the respiratory organs	25	1.62	1.22	9	1.81	1.72
Tumours in the lymphatic and haemopoietic tissue	5	0.23	0.36	16	1.73	1.52
Tumours in the pancreas	20	2.71	2.36	7	1.09	1.00
Tumours in the liver	4	1.40	1.70	3	1.84	1.82
Tumours in the gall ducts and the gall-bladder	0	-	-	9	1.81	1.85
Nervous system and sense organs	146	1.71	2.19	155	1.48	2.12
Heart and circulatory organs	489	1.65	1.71	328	1.84	1.54
Respiratory organs	62	2.30	1.62	35	1.76	1.14
Malformation	9	1.40	1.70	6	0.84	1.66

CRR = 1, means that there is no difference in mortality, while

CRR = 2 means that the mortality in the investigated area is twice the one in the reference area.

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TABLE 3

The mortality from cancer of the pancreas within Njurunda community from 1960 to 1974 compared to the national average:

NJURUNDA

		Average population 1960, 1965, 1970	Expected number of cancers of the pancreas based on the whole country	Observed numbers of cases in Njurunda
20-29	men	813	0.00	
	women	711	0.01	
30-39	men	744	0.06	
	women	698	0.10	
40-49	men	835	0.43	
	women	796	0.38	
50-59	men	861	2.01	2
	women	849	1.02	1
60-69	men	704	4.06	7
	women	678	2.43	3
70-	men	506	6.97	11
	women	511	5.00	3

$$\text{Men SMR} = \frac{20}{13.54} \times 100 = 148$$

$$\text{Women SMR} = \frac{7}{8.94} \times 100 = 78$$

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TABLE 4

The mortality from cancer of the pancreas within Sjölevad community from 1960 to 1974 compared to the national average:

SJÖLEVAD

		Average population 1060, 1065, 1970	Expected number of cancers of the pancreas based on the whole country	Observed numbers of cases in Sjölevad
20-29	men	1326	0.01	
	women	1216	0.02	
30-39	men	1148	0.05	
	women	1182	0.09	
40-49	men	1282	0.67	1
	women	1233	0.49	
50-59	men	1145	2.67	4
	women	1098	1.32	
60-69	men	772	4.46	3
	women	749	2.82	2
70-	men	395	5.69	2
	women	490	5.04	7

$$\text{Men SMR} = \frac{10}{13.55} = 74$$

$$\text{Women SMR} = \frac{9}{9.78} = 92$$