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Linear No-Threshold Model and Standards for Protection Against Radiation; Notice of Docketing and Request for Comment

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General Comment

Dear ladies and gentlemen,

for the last more than 20 years I have studied radiation effects on the human embryo and fetus. These efferct are widely ignored by UNSCEAR and other organizations.

Only in the UNSCEAR 2000 report, Annex J: Eposures and effects of the Chernobyl accident, my study on perinatal mortality following the Chernobyl accident [1] is mentioned, but the validity of the results is questioned.

Thus, paragraph 382 states:

"According to a recent paper [K4], perinatal mortality in Germany showed a statistically significant increase in 1987, and it was concluded that this was an effect of the Chernobyl accident fallout. The findings were later questioned, since whole-body doses from incorporated caesium were found to be 0.05 mSv [R19]. No effect of the Chernobyl accident could be found when temporal patterns of perinatal mortality in Bavaria were correlated to different fallout levels and subsequent exposures [G24]."

In two later UNSCEAR reports from 2008 and 2013, this study [1] and three more of my publications are

ignored, one about perinatal mortality in Belarus after Chernobyl [2], another one about perinatal mortality in Germany after the atmospheric nuclear weapons tests [3], and a third one about the association of cancer mortality in Bavaria with background gamma radiation [4].

Recently I analyzed the trends of infant and fetal mortality in the U.S. following atmospheric nuclear weapons testing. A write-up of my results is attached.

I ask you to kindly consider my results which all contradict the concept of a threshold dose for radiation damage.

References

[1] Krblein A, Kchenhoff H. Perinatal mortality in Germany following the Chernobyl accident. *Radiat Environ Biophys.* 1997 Feb;36(1):3-7. PubMed PMID: 9128892.

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Attachments

infant-mortality-US

Infant mortality in the U.S. after atmospheric nuclear weapons testing

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The trend of infant mortality rates in the US, 1936-2005, is investigated for deviations from a monotonously declining trend after the atmospheric nuclear weapons tests in the 1950s and 1960s. The deviations are modeled by one or more bell-shaped excess terms. The peak deviation is found in 1965, two years after the maximum of fallout from atmospheric nuclear weapon tests. The excess mortality is more pronounced for the non-white population than for the white population and is driven by an increase in neonatal mortality. The number of excess infant deaths is estimated at some 680,000. A rise of fetal mortality adds about 340,000 excess fetal deaths.

Background: The fallout from nuclear weapons in the atmosphere was the most significant cause of exposure of the world population to man-made environmental sources of radiation. Sternglass found deviations of infant mortality rates in USA from an exponentially declining trend, beginning in 1951 [1, 2]. He estimated the number of excess infant deaths in the US during 1951-1966 at 375,000 and attributed this effect to strontium in the fallout from atmospheric nuclear weapons testing. Whyte analyzed data of first day neonatal mortality data from England and Wales and from the US. The trends were very similar in these two countries, a rise in the beginning of the 1950s relative to the trend in the preceding years [3] with a broad maximum around 1965 and a decline until about 1980 when the data resumed the trend of the years 1935-50. For the US, Whyte estimated a number of 280,000 excess neonatal deaths in 1951-80 relative to the trend in the remaining years of the study period, 1935-87. In 2004, Körblein investigated the trend of perinatal mortality in West Germany, 1955-93, and found similar deviations from a monotonously falling trend, but with a peak deviation around 1970 [4]. As a possible explanation he suggested that incorporated strontium might impair the immune system of pregnant women. In his analysis he used data of strontium concentration in the fallout from atmospheric nuclear weapons testing (see [5] and Figure 1).

The present study analyzes the trends of infant mortality, neonatal- and fetal mortality in the US for a much longer time span, 1936-2005, with a regression model that makes use of all data in the study period.

Data and Methods

Annual numbers of live births, infant mortality, neonatal mortality, and fetal mortality rates are provided for download from the CDC website <http://wonder.cdc.gov/>. Infant death is defined as infant death of a live born infant within the first year. Neonatal death is the death before 28 days of age of a live born infant. Fetal death is the death of a fetus weighing at least 500 g or after 20 or more weeks of gestation. Infant/neonatal mortality is the number of infant/neonatal deaths per 100 live births, while fetal mortality is the number of fetal deaths per 1000 live births plus fetal deaths (see: <http://medical-dictionary.thefreedictionary.com/>).

The statistical analysis of infant mortality rates used a logistic trend model with a linear or linear-quadratic time dependency, superimposed by bell-shaped excess terms (lognormal density functions). Separate regressions are conducted for infant mortality in whites and non-whites, for neonatal and

post-neonatal mortality, and for fetal deaths. The free software R (<https://www.r-project.org/>) is used for data analysis and plotting.

Results

Infant mortality

The objective of the present study is to extend the study period beyond 2000. Here, mortality data are analyzed until 2005. Contrary to the studies by Sternglass and Whyte, all years of the study period are included. A non-linear regression model is used consisting of a monotonously declining secular trend and one or more superimposed by bell-shaped excess terms. The secular trend is modeled by a logistic function with a linear-quadratic time dependency. Thus, the regression model for mortality rate p as a function of time t has the following analytical form:

$$(1) \quad p \sim 1 / (1 + 1 / \exp(\beta_1 + \beta_2 * t + \beta_3 * t^2 + \beta_4 / t / \exp((\log(t) - \log(\beta_5))^2 / 2 / \beta_6^2)))$$

where t is calendar year minus 1930, β_1 through β_6 are parameters. Mortality rates p are weighted initially with weights = $1/\text{var}$ where var is the binomial variance $p \cdot (1-p)/LB$. The fitted values \hat{p} are used for reweighting the data with variance $\text{var} = \hat{p} \cdot (1-\hat{p})/LB$ for a second regression.

The data show very large overdispersion; the deviance is 2621 with 64 degrees of freedom ($df=64$). But a regression without the bell-shaped excess term yields deviance = 36350 ($df=67$), so the effect of the bell-shaped excess term is highly significant. The regression results, i.e. parameter estimates, standard errors (SE), t values, and P -values, are listed in Table 1.

Table 1: Regression results for infant mortality

Parameter	Estimate	SE	t value	P value
β_0	-2.467	0.020	-122.54	<0.0001
β_1	-0.0589	0.0019	-30.87	<0.0001
β_2	3.3E-04	2.2E-05	15.01	<0.0001
β_4	16.360	0.894	18.3	<0.0001
β_5	39.810	0.434	91.85	<0.0001
β_6	0.264	0.012	22.33	<0.0001

The median of the lognormal function is $\beta_5 + 1930 = 1969.81 \pm 0.43$ and position of the maximum (mode) is $\exp(\log(\beta_5) - \beta_6^2) + 1930 = 1967.1$

The data fit can be considerably improved by adding three additional bell-shaped excess terms to the regression model; then the deviance reduces to 1500 ($df=55$), a highly significant improvement of the model fit ($P=0.0002$, F test with 9 and 55 degrees of freedom). The extended regression model has the following analytical form

$$(2) \quad p \sim 1 / (1 + 1 / \exp(\beta_1 + \beta_2 * t + \beta_3 * t^2 + \beta_4 / t / \exp((\log(t) - \log(\beta_5))^2 / 2 / \beta_6^2) + \beta_7 / t / \exp((\log(t) - \log(\beta_8))^2 / 2 / \beta_9^2) + \beta_{10} / t / \exp((\log(t) - \log(\beta_{11}))^2 / 2 / \beta_{12}^2) + \beta_{13} / t / \exp((\log(t) - \log(\beta_{14}))^2 / 2 / \beta_{15}^2)))$$

where time t is calendar year minus 1930, and β_1 through β_{15} are parameters.

Table 2: Regression results for infant mortality; model with 4 excess terms

Parameter	Estimate	Std.Error	t value	P value
β_1	-2.458	0.017	-148.70	0.0000
β_2	-0.059	0.002	-38.08	0.0000
β_3	3.4E-04	1.8E-05	18.57	0.0000
β_4	1.288	0.502	2.57	0.0131
β_5	28.230	0.328	86.15	0.0000
β_6	0.026	0.012	2.07	0.0436
β_7	16.490	0.725	22.76	0.0000
β_8	39.700	0.388	102.29	0.0000
β_9	0.257	0.011	23.69	0.0000
β_{10}	1.129	0.627	1.80	0.0772
β_{11}	34.950	0.550	63.53	0.0000
β_{12}	0.026	0.017	1.48	0.1457
β_{13}	4.763	0.934	5.10	0.0000
β_{14}	58.620	0.622	94.19	0.0000
β_{15}	0.047	0.012	4.00	0.0002

The peak positions of the excess terms are estimated in calendar years 1958.2 ± 0.3 , 1964.9 ± 0.6 , 1967.2 ± 0.4 , and 1988.5 ± 0.6 . Figure 2 shows the trend of infant mortality rates (upper panel) and the deviations from the secular trend (lower panel). The maximum excess mortality is found in 1965, two years after the maximum of fallout intensity. From the difference between observed and expected rates, 682,141 excess infant deaths are determined.

Separate analyses were conducted for the white and non-white U.S. population (see Figure 3). Table 3 compares the parameter estimates, i.e. intercept, linear (t), quadratic (t^2) and cubic term (t^3) of the time trend, amplitude, median, and standard deviation (σ) of the excess terms, for whites and non-whites. The regression model for non-whites uses an additional cubic term for the time dependency, but only needs 3 bell-shaped excess terms. Most parameter estimates agree within the limits of error.

Table 3: Comparison of parameter estimates for infant mortality in whites and non-whites

parameter	whites		non-whites	
	estimate	SE	estimate	SE
intercept	-2.458	0.017	-1.917	0.036
t	-0.059	0.002	-0.071	0.004
t^2	3.4E-04	1.8E-05	7.1E-04	1.1E-04
t^3			-3.1E-06	8.9E-07
amplitude	1.288	0.502	1.631	0.768
median	28.230	0.328	28.090	0.441
σ	0.026	0.012	0.022	0.012
amplitude	16.490	0.725	16.140	1.143
median	39.700	0.388	36.620	0.550
σ	0.257	0.011	0.247	0.014
amplitude	1.129	0.627		
median	34.950	0.550		

sigma	0.026	0.017		
amplitude	4.763	0.934	6.095	1.474
median	58.620	0.622	59.200	0.712
sigma	0.047	0.012	0.051	0.016

The background rates for the non-white population as well as the excess mortality rates are about double the rates for the white population. The estimated numbers of excess deaths are 444,382 for whites and 187,726 for non-whites.

Neonatal mortality, post-neonatal mortality

Separate regression analyses for neonatal and post-neonatal mortality rates were also conducted. One and the same regression model is used. The secular trend is now modeled by a 4th degree polynomial for the time dependency (variables t , t^2 , t^3 , t^4). Three bell-shaped excess terms are used.

Post-neonatal mortality rates show very large over-dispersion (Deviance= 5181, df=56) essentially caused by the data before 1950. Neonatal mortality rates show a much smaller variance (deviance = 621, df=56). The parameter estimates resulting from the two regressions are compared in Table 4.

Table 4: Comparison of parameter estimates for neonatal and post-neonatal mortality

parameter	neonatal		post-neonatal	
	Estimate	SE	Estimate	SE
intercept	-3.202	0.032	-2.877	0.088
t	-0.037	0.007	-0.144	0.016
t ²	4.1E-04	4.1E-04	3.5E-03	8.9E-04
t ³	-1.3E-05	8.0E-06	-4.2E-05	1.8E-05
t ⁴	1.2E-07	4.9E-08	1.8E-07	1.2E-07
amplitude	4.489	2.117	3.925	1.523
median	30.020	1.789	28.950	0.796
sigma	0.139	0.027	0.046	0.025
amplitude	14.000	1.561	7.819	1.513
median	40.730	1.138	34.580	0.676
sigma	0.168	0.023	0.075	0.025
amplitude	3.833	0.983	5.609	3.372
median	58.170	0.633	58.760	1.717
sigma	0.044	0.014	0.050	0.038

The effect of the excess terms is much greater for neonatal mortality than for post-neonatal mortality (see Figure 4). From the difference between observed and expected mortality rates, 367,106 excess neonatal deaths and 56,779 excess post-neonatal deaths are determined.

Fetal mortality

To analyze the trend of fetal mortality, a logistic function with a 3rd degree polynomial for the time dependency is used for the secular trend of the data. The excess mortality is modeled by 3 bell-shaped excess terms. Figure 5 shows fetal mortality rates and the regression line. The data point in 1944 is an outlier and therefore was omitted from the analysis. From the difference of observed and expected rates, 339,254 excess fetal deaths were determined.

Separate regressions for whites and non-whites were conducted. Three bell-shaped excess terms were applied to fit the data for the white- and two for the non-white population. Except for the intercept, the parameter estimates agree within the limits of error (see Table 5). The effect is much greater for non-whites than for whites (see Figure 6). The excess fetal mortality rates translate to 223,302 excess fetal deaths among whites and 58,807 among non-whites.

Table 5: Comparison of parameter estimates for fetal mortality in white and non-white populations

parameter	whites		non-whites	
	Estimate	SE	Estimate	SE
intercept	-2.874	0.051	-2.224	0.070
t	-0.078	0.005	-0.073	0.007
t ²	9.7E-04	1.3E-04	8.0E-04	1.7E-04
t ³	-4.7E-06	9.9E-07	-3.3E-06	1.3E-06
amplitude	3.195	1.620	4.532	1.948
median	28.240	3.302	30.240	1.858
sigma	0.155	0.062	0.090	0.037
amplitude	13.700	1.187	12.980	1.210
median	39.180	0.950	37.900	0.956
sigma	0.149	0.022	0.104	0.021
amplitude	3.165	1.112		
median	51.490	0.758		
sigma	0.041	0.018		

Discussion

The present study describes the trend of infant mortality, neonatal mortality, and fetal mortality in the U.S. through 2005. The statistical analysis uses a regression model consisting of a monotonously declining secular trend and superimposed bell-shaped excess terms. Excess rates are determined from the difference between observed mortality rates and the expected rates calculated from the secular trend. These excess rates, multiplied by the number of live births, yield the annual number of excess deaths. The total number of excess deaths is obtained by adding up the annual excess deaths over the study period.

The main peak of infant mortality is found in 1965 but the excess continues through 1990. The effect is more pronounced for the non-white population than for whites and is driven by neonatal mortality; the post-neonatal mortality is much less affected.

While the ecological study design does not permit to draw causal conclusions, the method allows estimating the number of excess deaths. The excess mortality rates correspond to some 680,000 excess infant deaths plus 340,000 excess fetal deaths, altogether about a million deaths in the wake of atmospheric nuclear weapons testing.

References

1. Sternglass EJ. Infant Mortality and Nuclear Tests. Bulletin of the Atomic Scientists, 25:26-28, 1969. Available at <https://books.google.com/>

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5. United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) (2000) UNSCEAR 2000 report to the General Assembly, with scientific annexes. Annex C. United Nations, New York.

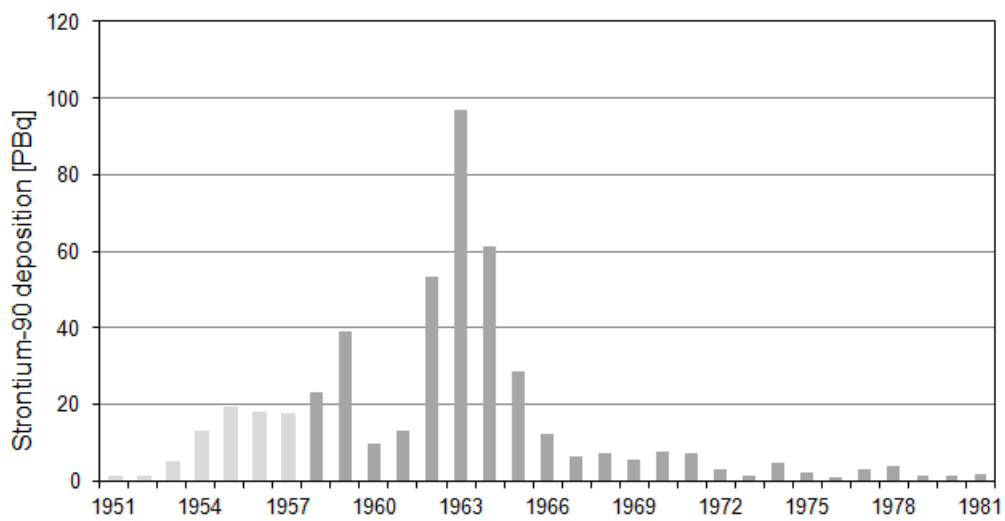


Fig. 1: Strontium activity in the global fallout from atmospheric nuclear weapons tests. Dark columns: measured, light columns: calculated values. Data from UNSCEAR 2000 Annex C, Table 7.

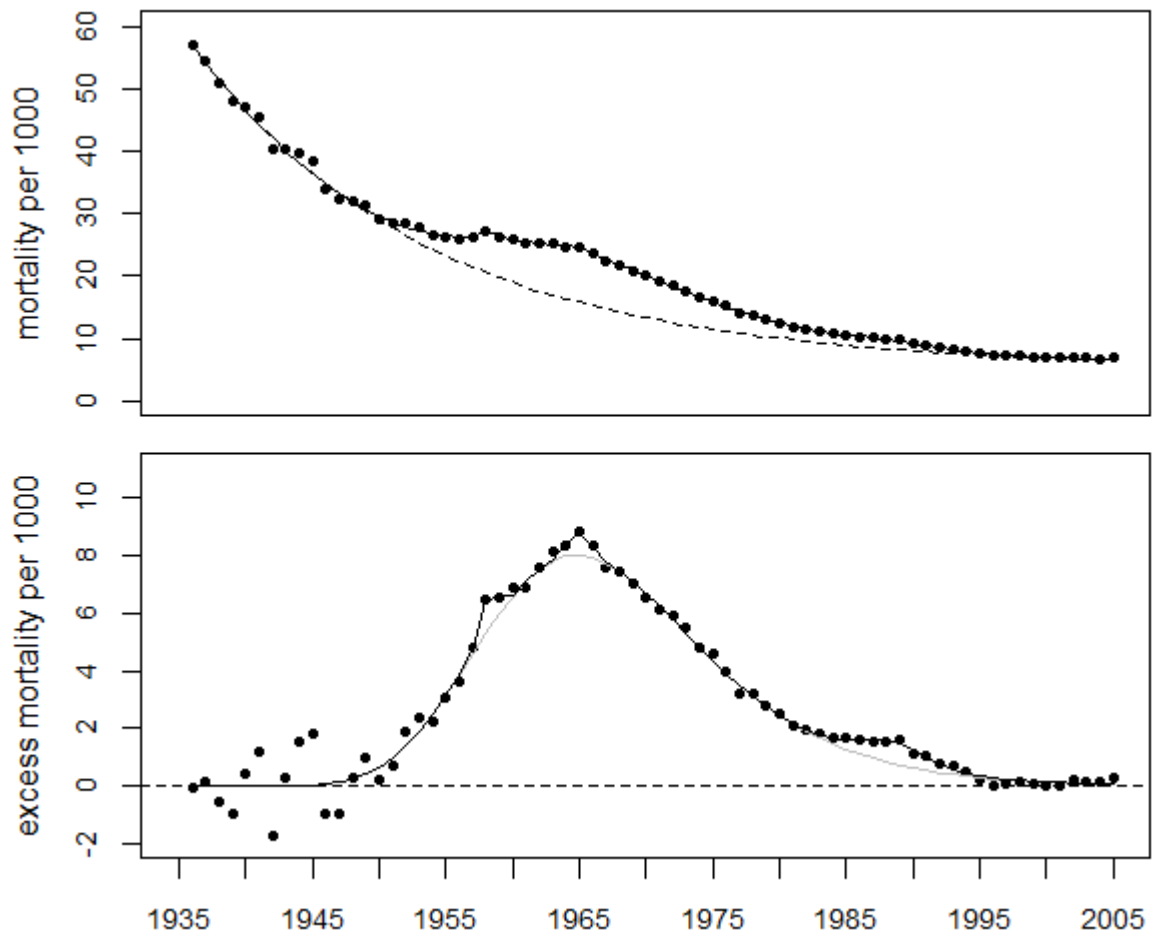


Fig. 2: Infant mortality rates, 1936-2005, and regression line. The lower panel shows the deviations of observed mortality rates from the expected trend (broken line).

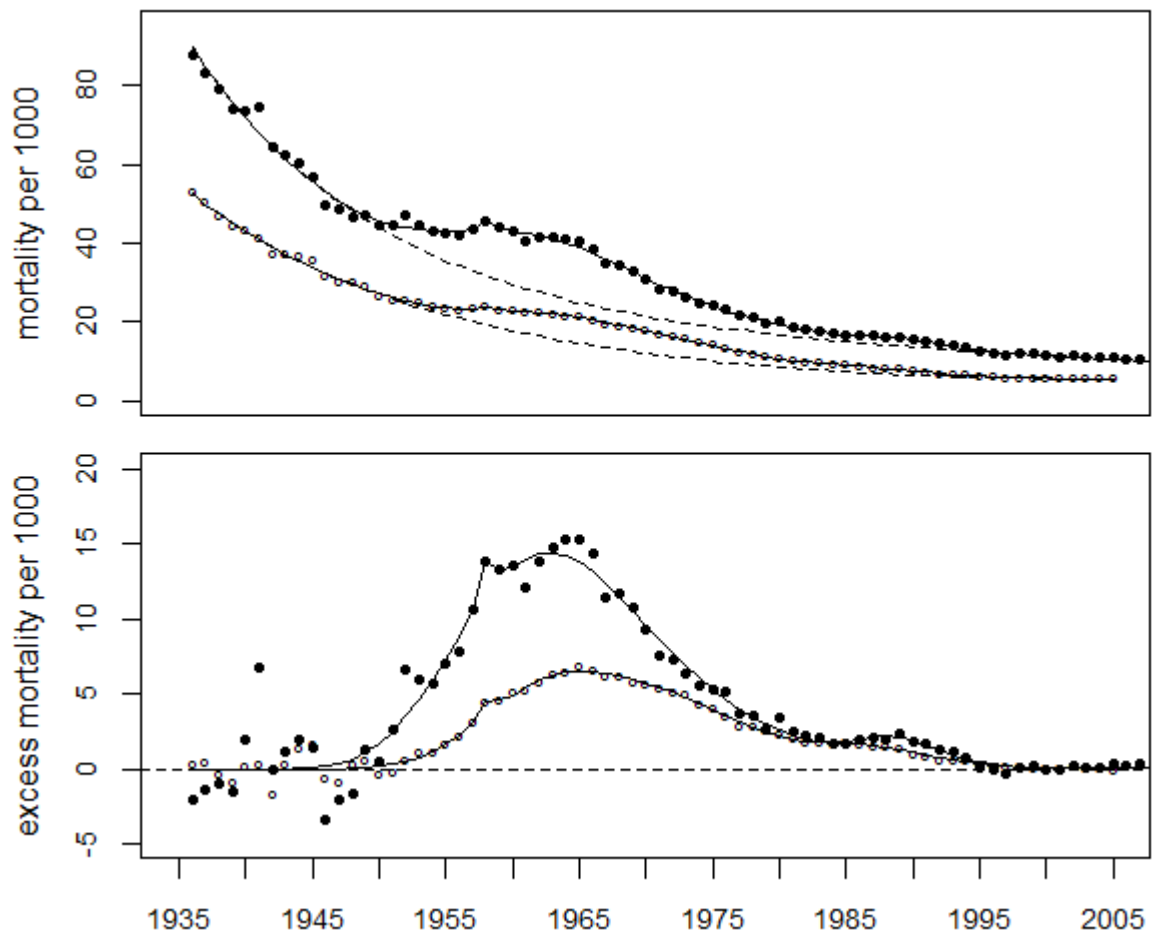


Fig. 3: Trends of infant mortality in USA in whites (○) and nonwhites (●), and regression lines

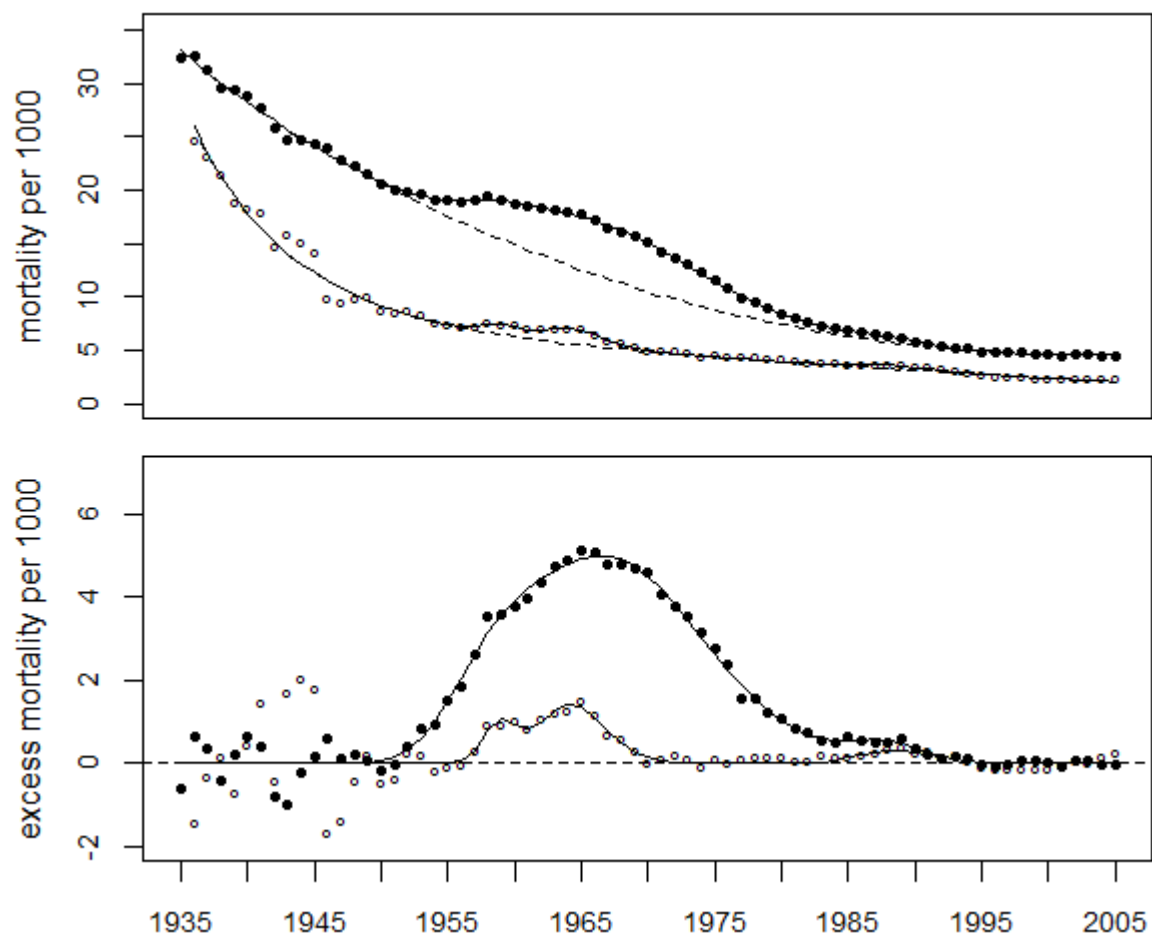


Fig.4: Neonatal (●) and postneonatal mortality (○), and regression lines

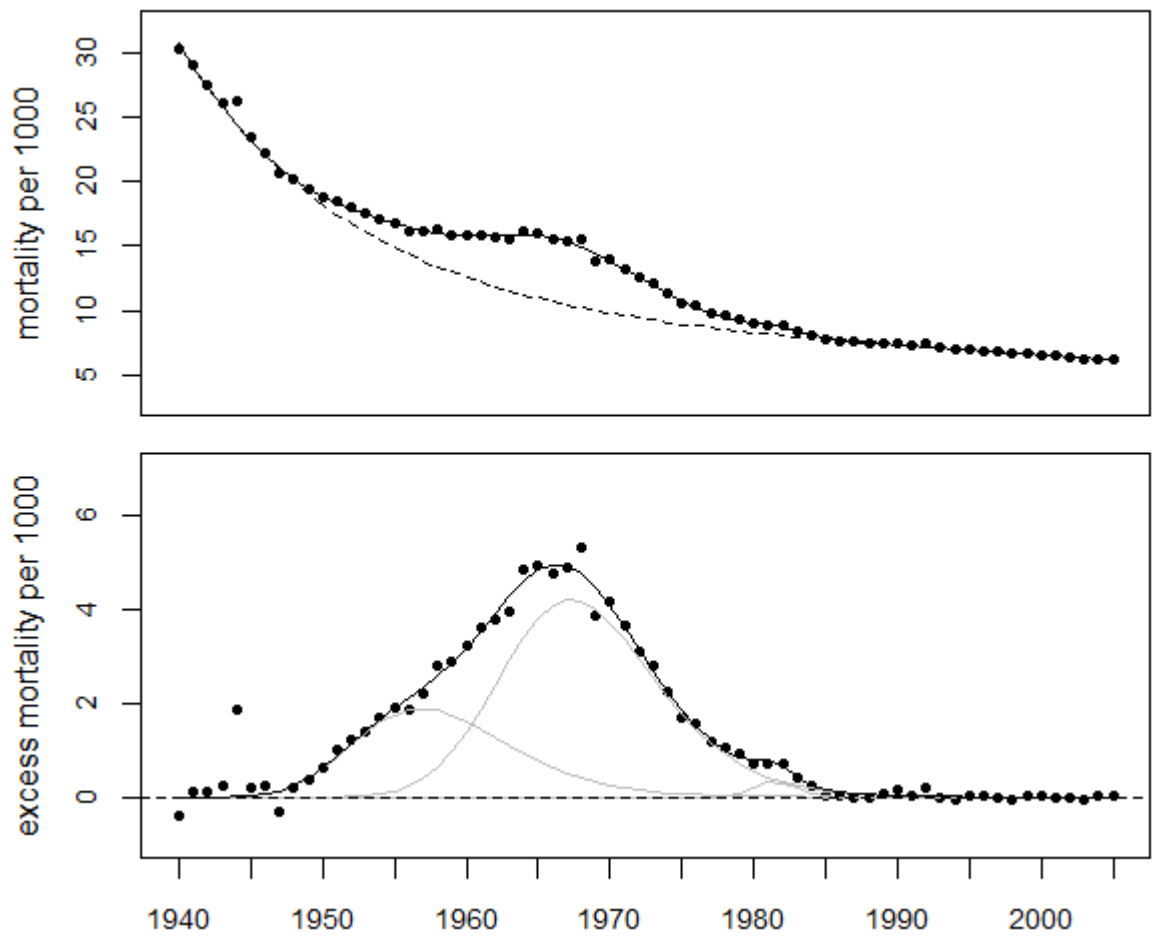


Fig.5: Fetal mortality rates, 1940-2005, and regression lines

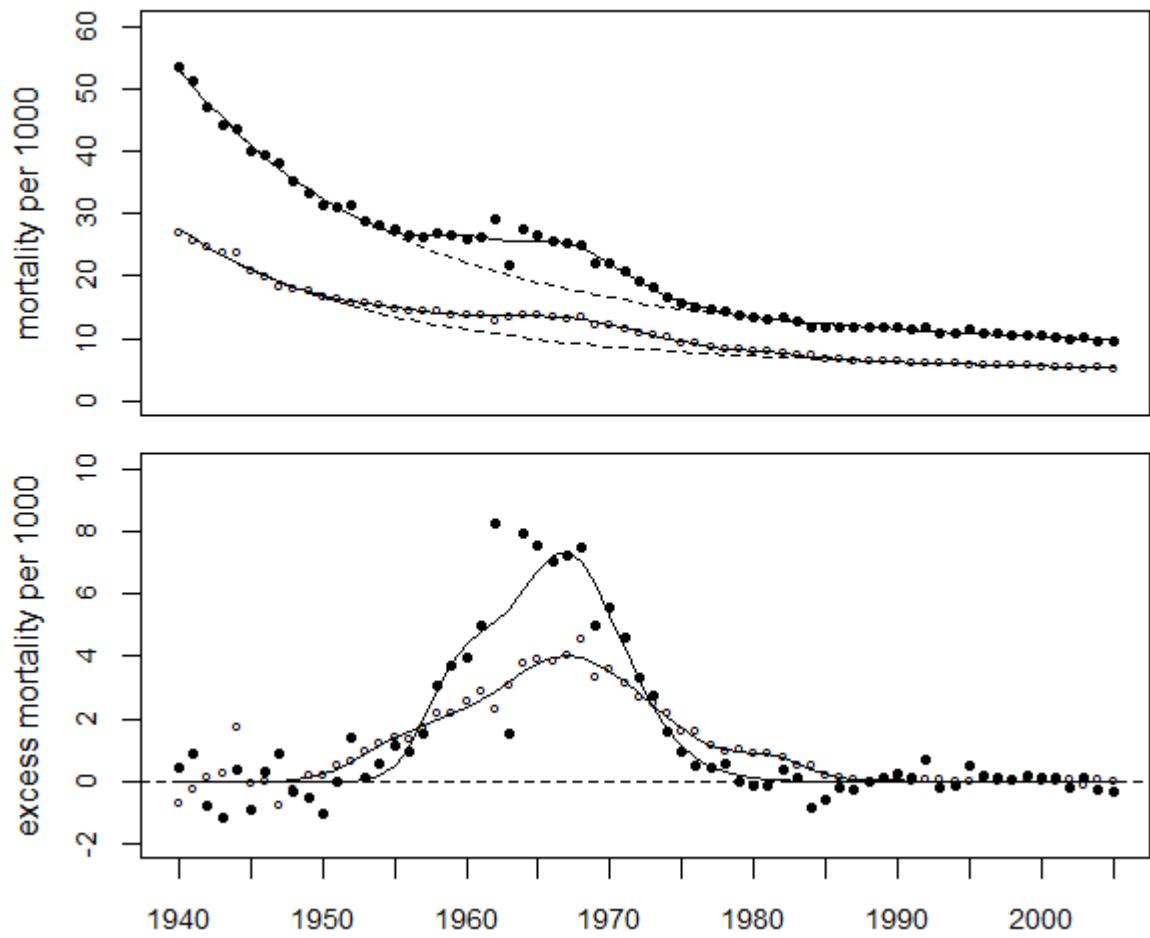


Fig.6: Fetal mortality rates, nonwhite (●) and white (○) population, 1940-2005, and regression lines