

SAN LUIS OBISPO COUNTY PUBLIC HEALTH
DEPARTMENT

RESPONSE TO A REPORT ON HEALTH
CONCERNS TO RESIDENTS OF SAN LUIS OBISPO
AND SANTA BARBARA COUNTIES DUE TO
CONTINUED OPERATION OF DIABLO CANYON
NUCLEAR POWER PLANT



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World Business Academy, located in Santa Barbara County, described on its website as “a nonprofit think tank and action incubator”, on March 3, 2014 issued “*Report on Health Status of Residents in San Luis Obispo and Santa Barbara Counties Living near the Diablo Canyon Nuclear Reactors Located in Avila Beach, California*”, by Joseph Mangano, MPH, MBA, Ocean City, New Jersey. The report makes claims regarding health effects on the residents of San Luis Obispo County and northern Santa Barbara County. The San Luis Obispo County Public Health Department, with input from State and Santa Barbara County epidemiologists, undertook a detailed review of the study in order to confirm or refute its conclusions that state “...official public health data presented in this report suggest a *probable link* between the routine, federally-permitted emissions of radioactivity from the Diablo Canyon nuclear power plant and elevated health risks among infants, children and adults living closest to the reactors.” The study further concludes “These findings *strongly suggest* that federally-permitted radiation releases pose a health risk to the public, especially to people living near Diablo Canyon in California.” Given the powerful epidemiologic language of these conclusions and the reported serious health risks, it was deemed very important that local Public Health officials carefully and independently review the findings.

Summary

The study’s major findings are of increased rates of cancer, low birth weight, and infant mortality among San Luis Obispo County residents and, for some findings, in persons living most proximate to the Diablo Canyon nuclear power plant (DCNPP). Throughout the report claims of ill health effects are based upon comparisons of health indicator trends between years prior to or early in the operation of the DCNPP versus more recent time periods. Findings are commonly stated in terms of change of comparative health rates over time between San Luis Obispo County and the State as a whole. Comparisons are also made of trends in health rates of geographic areas considered proximate to the DCNPP versus areas considered more distant, such as zip codes around Santa Barbara City or California as a whole. After thorough review of the study, and the methods used, none of these claims hold up. There are substantial and obvious problems in methodology wherein basic statistical precepts were overlooked. In addition, the study shows selection bias in choosing case and control groups. In the Executive Summary of the report, there are twelve major findings listed which cite health concerns. Each of these findings is erroneous or not substantiated with proper scientific methods. Each will be addressed in turn.

This response specifically focuses on the report of health outcomes from DCNPP emissions. Therefore this response does not include comment on Sections II and III of the report, which deal with potential health hazards of nuclear reactor meltdowns and amounts of radioactive emissions, respectively. This response to the current report also omits comment on the claim by the author regarding Strontium-90 levels in baby teeth from babies in SLO and SB Counties, as a prior Mangano report on this concern has been previously disavowed.

Epidemiological Concepts Defined

To appreciate established epidemiologic practices, several definitions are given to help the reader better comprehend this response to the Mangano report.

Case-Control Study - a widely-used type of observational study design in which two existing groups differing in outcome are identified and compared on the basis of a proposed causal attribute. Case-control studies are often used to identify factors that may contribute to a medical condition by comparing subjects who have that condition/disease (the "cases") with those who do not have the condition/disease but are otherwise similar (the "controls"). This study denotes cases as persons with a health condition (i.e., cancer, low birth weight, or infant death) who were exposed to the suggested causative factor (i.e., radiation from DCNPP), whereas controls would be persons without the health condition yet otherwise similar except for the radiation exposure.

Selection Bias - a bias in which there is an error in choosing the individuals or groups to be included in a scientific study. Improper selection of cases or controls alters the statistical analysis, resulting in inaccurate or biased conclusions.

Rate – a calculation in which two measurements are related to each other such as frequency of an event per population over a unit of time. Examples in epidemiology include:

Birth rate = # childbirths in a population per 1,000 people in that population per year

Mortality rate = # of deaths in a population divided by total population in a given time period

Crude Rate – a rate giving the total number of events (illnesses or deaths) occurring in an entire population over a period of time, without reference to any of the individuals or subgroups within the population.

Adjusted Rate - a summary rate statistically adjusted to remove the effect of a variable, such as age or sex, to permit unbiased comparison between groups having different compositions with respect to these variables. An example is "*age- adjustment*" - a statistical process used to allow valid comparison of groups of people with different age proportions. For example, since cancer is more common in older age groups while bicycle injuries occur at higher rates amongst a younger population, statistical adjustment is needed to produce meaningful results.

Confounding variable - an extraneous variable (i.e., a variable that is not a focus of the study) that correlates with both the dependent variable (e.g., cancer incidence) and the independent variable (e.g., exposure to radiation). In not statistically adjusting for a confounding variable (e.g., age or ethnicity in this study) a relationship between a dependent variable and an independent variable will be misestimated and will result in a false analysis.

Rate Ratio - a measure of association that quantifies the relation between an exposure and a health outcome from an epidemiologic study, calculated as the ratio of incidence rates or mortality rates of two groups. For example, the cancer incidence rate for SLO County divided by the cancer incidence rate of California over the past decade is a rate ratio.

Review of Findings:

The report at issue lists in the Executive Summary twelve “major findings about health patterns”, each of which is reviewed below.

1. *Since the Diablo Canyon nuclear power plant opened in the mid-1980s, San Luis Obispo County has changed from a relatively low-cancer to a high-cancer county.*

This statement is incorrect.

The author used improper methodology to show increases in cancer incidence over time. By not properly adjusting or controlling for confounding variables, such as age or race/ethnicity, the author creates the impression of increased cancer risk when it simply does not exist. Statistically adjusted rates shows that not only were the overall rates of cancer not increasing in San Luis Obispo (SLO) County, the trend has been downward.

The California Cancer Registry is the State agency responsible for tracking cancer in the State, and conducting studies and analysis of cancer to determine the epidemiology of the disease. When contacted regarding this report, Dr. John Morgan, the cancer epidemiologist assigned to our region, reported that “[u]nlike the increasing age-crude incidence rates across time periods for both San Luis Obispo and Statewide claimed by J. Mangano on p. 22 of his report, the age-adjusted incidence rates...are actually declining for SLO and statewide for all but non-Hispanic White residents. The age-adjusted incidence rate for cancer among non-Hispanic Whites in SLO and statewide was constant across the three time periods assessed, with no increase for all race/ethnicities combined or for any of the race/ethnic groups seen in SLO or statewide.”

The author footnotes on several tables of cancer incidence rates (pp. 21-23) that age adjustment was done, but when the data is rerun with age and race/ethnicity adjustments those results are shown to be inaccurate.

Further all of the cancer data compares the entirety of the County with the State, whereas, later in the report, for other health indicators (infant health and all-cause mortality), analysis was done at the zip code level to make a case that only areas within the county that are “proximate” to DCNPP suffer the disparate health consequences compared with more “distant” areas.

2. *Due to increases in the San Luis Obispo County cancer rate during 2001-2010, an additional 738 people were diagnosed with cancer.*

As noted with finding #1, without adjusting for population variables, this statement is speculative and unsound.

- 3. Cancer incidence in San Luis Obispo County rose from 0.4% below to 6.9% above the average for the state of California during the time period of 1988-1990 to 2003-2010. The current rate is the highest of all 20 counties in southern California.*

This finding mimics findings # 1 and #2, and must also be discounted due to the absence of simple adjustment for the confounding variables of age and race/ethnicity. When that standard analysis is performed, this finding proves false.

Of further curiosity is the selection of time periods for comparison. The author notes that cancer incidence rates were not available prior to onset of DCNPP operations (1984) because the California Cancer Registry (CCR) went live in 1988. Yet, there is no explanation for choosing the first three years (1988-1990) of CCR data in comparison to an eight-year period (2003-2010) of CCR data 13 years later. The author states that cancer incidence can often occur years to decades after exposure, but then does not apply that concept in the analysis.

- 4. Significant rapid increases occurred for the incidence of thyroid and female breast cancer in San Luis Obispo County, both highly radiosensitive cancers.*

The absence of routine adjusting for confounding variables creates inaccurate findings.

Dr. Morgan of the State Cancer Registry re-evaluated breast cancer rates in SLO County against the State's rates. The racial and ethnic make-up of SLO County in comparison to the State of California is markedly different, with SLO County having a population over 70% non-Hispanic White compared with California's 40% non-Hispanic White. Breast cancer is known to occur at higher rates in the non-Hispanic White population. When the rate of breast cancer in SLO County among the non-Hispanic White population is compared to the rate of breast cancer in all California in non-Hispanic Whites, there is no statistical difference in rate. Thus, by not controlling for race/ethnicity in the report, an invalid conclusion is reached.

For thyroid cancer, the data was not re-run after adjusting for confounders, but such adjustment might likely eliminate the finding since thyroid cancer is also related to age and race/ethnicity. Further, selection of a short baseline period post-startup of DCNPP for a cancer that averages less than 10 cases per year, results in such small numbers as to greatly reduce the power of the finding ($p < .04$).

Reporting change over time periods that are unevenly chosen leaves questions about the rationale for time period selection.

5. *After Diablo Canyon began operating, infant mortality in San Luis Obispo County rose significantly.*

This statement is incorrect.

The infant mortality rate (IMR) has decreased significantly since the period prior to DCNPP coming on line and remains below the State of California IMR as well as the National Healthy People 2020 goal of 6.0/1000 live births.

The first comparison in the study of infant mortality covers “...the first two years after the Diablo Canyon startup vs. the prior two years...” The author states that the numbers are not statistically significant due to small numbers. Indeed, the unpredictable nature of results when studying a condition with few events, such as infant deaths in SLO County, is a common pitfall. This circumstance would advise selecting a longer study period, which the author does. It is unclear why a 5-year period pre-plant operation was chosen to compare with a 27-year period post-plant opening. Nonetheless, the result shows that infant mortality decreased 25% in SLO County between those two time periods. The argument made, to support the finding of *increased* infant mortality since operations began at DCNPP, is that the IMR did not decrease as fast as in the rest of the State.

An ethnic confounder is present again and needs to be controlled for in the study to yield a valid comparison between SLO County and State rates. The changing demographics of San Luis Obispo shows an increasing Hispanic population. The author notes that Hispanic births have increased in the County, but then goes on to make an unfortunate statement of “if the trend of more white Hispanic births with infant death rates above the state continues, the county’s infant death rate, well below the state for decades, may soon draw even with California.” The point the author is seemingly trying to make is that because the non-Hispanic White IMR is well below (15.4%) the State IMR, while the Hispanic White rate was slightly (0.6%) above the State rate, over time the County’s IMR will move us closer to the state average. The unintentional upshot is that the changing demographics, *not* the presence of a nuclear power plant, will yield less favorable statistics. This may be true, due to widely recognized health inequities across racial and ethnic groups, but it winds up reading that if we could only avoid more Hispanic births in SLO County, our infant mortality rate would be better.

Also of note is that the author uses an unconventional definition for infant mortality. Rather than the textbook definition and the one in conventional use worldwide “the number of deaths of children less than 1 year old per 1,000 live births”, the author shows deaths per 100,000 births (p.19). The result is that a person reading the report sees a higher number (e.g., 761.31) which may heighten the level of concern. The actual infant mortality rate should instead be cited as 7.61 (per 1000 live births per year).

6. *After Diablo Canyon began operating, child/adolescent cancer mortality in the county rose rapidly.*

The report misrepresents the actual change in the County's cancer mortality rate over time by showing (non-statistically significant) narrowing of the gap in cancer mortality rates between the County and the State over the selected time period.

Further anomalies are the non-standard use of dates and ages for this particular finding.

For all-cancer incidence (see finding #1) 1988-1990 was considered the *pre*-operational baseline (deemed acceptable by the author because cancer has a long latency – biologic initiation to symptoms or lab findings). However, those same years (1988-1990) are included in the *post*-operational period for which the author claims an increase in child/adolescent mortality as a result of radiation exposure. If anything, death has a longer latency period than incidence (new onset of cancer), and thus inclusion of the early years of plant operation as a period of exposure is inconsistent and of questionable merit.

The age grouping for this particular finding is also unusual. The National Cancer Institute at the National Institutes of Health considers childhood cancer to include cases in persons below the age of 15 years. Cancers in young people (adolescents and young adults 15-39 years old) are grouped separately based on the commonality of distinct cancer types within these age groups. There is no stated basis for the selection of 0-24 year olds for analysis in this study.

7. *Melanoma incidence in San Luis Obispo County soared from 3.6% above to 130.2% above the state incidence rate during the period from 1988-1990 to 2003-2010, and is now the highest of all California counties.*

Melanoma is another cancer for which the risk is higher in non-Hispanic Whites than in other populations. The American Cancer Society estimates that "the lifetime risk of getting melanoma is about one in 50 for Whites, one in 1,000 for Blacks, and one in 200 for Hispanics". Thus, the ethnic make-up of SLO County once again impacts the comparison of SLO County to the State of California overall. By not controlling for race/ethnicity in the study, a significant distortion of risk and outcome has been reported.

8. *Cancer mortality for people of all ages in San Luis Obispo County rose from 5.1% below to 1.4% above California from 1988-1990 to 2008-2010, making SLO the 25th highest county in the state (up from 43rd highest).*

This finding is again comparing rate ratios between the County and the State over two time periods.

As is true with all of the above findings, without applying the standard epidemiologic practice of adjusting for confounding variables, the data is rendered meaningless.

Also, the selection of comparative time periods is not explained and differs from other time periods used for the other reported cancer findings.

9. *The ratio of babies born at very low weight (below 3 pounds, 4 ounces) rose 45.0% higher in the 9 San Luis Obispo County zip codes closest to Diablo Canyon, versus the other more distant 10 county zip codes.*

The previous eight findings of the report focused primarily on comparing rate ratios of health data over two time periods using the entirety of SLO County vs. the State. For the next three findings (# 9-11) the author uses a more refined geographic analyses to establish a causal effect of radiation-induced health outcomes.

Nonetheless, there are two striking examples in the study of selection bias in assigning “proximate” and “distant” zip codes. The study purports to use closest and downwind to DCNPP zip codes as “proximate” to identify exposed persons (cases) vs. further “distant” zip codes for those not exposed (controls). In reviewing the lists and maps of zip codes chosen as “proximate” and “distant” one finds discrepancies for both SLO and Santa Barbara (SB) counties.

Specifically, the study classifies as “distant” some zip codes (e.g., Arroyo Grande and Nipomo) that are in fact closer to the DCNPP than northern Santa Barbara zip codes which are labelled as “proximate”. In fact, parts of the Arroyo Grande 93420 zip code fall into the 15 mile buffer the author proposes as a basis for “proximate” designation (p.18). In contrast, maps in the appendix of two other downwind zip codes not within the 15 mile buffer are included as “proximate”. The analysis for SLO County was re-run with inclusion of southern SLO County zip code 93420 in the “proximate” area rather than the “distant” area. In so doing, for San Luis Obispo County, the increase drops from 16.9% to 10.97%. In comparing SLO County to California, the purported increase of +7.2% becomes a decrease of -3.14%.

The second anomaly is the omission from the study of the 93454 (So. SLO County/Santa Maria) zip code. The author offers a justification for exclusion of 93454 stating that any zip code crossing SLO County lines would not be used (p. 8). This same rationale is not mentioned in the description of zip code selection in Santa Barbara County where selection is based solely on proximity to DCNPP (p. 28). The justification is weakened further by the author’s own words criticizing a 1990 large-scale federal study for

classifying counties as control (distant from the nuclear plant) “even though the control counties were often those adjacent to the county where a reactor was located. This methodology overlooks the fact that radiation does not abruptly stop at the county line.” (p. 17). By the author’s own logic, including more distant zip codes while excluding the 93454 zip code from analysis, based on its crossing a county line, does not make sense.

This particular zip code exclusion has profound effects on the study’s findings. It should be noted that 93454 is a sizable Santa Maria zip code. The population residing in 93454 represents 27% of the Santa Maria population. In births, it is even higher. During the 1989-1991 baseline period, 93454 had 5,196 births compared to total 6,950 births in all SB zip codes listed as “proximate”. By excluding 93454, 42.8% of “proximate” SB County births in the baseline (not exposed) period and 19.1% of births in the comparison (exposed) period were not analyzed. The omission of 93454 winds up excluding roughly 50% of low weight births in northern SB County. Whereas the study reports an increase of 40.2%, between baseline and exposed periods, in the low birth weight rate ratio of “proximate” to “distant” areas, when the analysis is run including 93454, the ratio actually shows a slight decrease (.007%).* Similarly, the change in low birth weight ratio between the “proximate” SB area and California as a whole becomes a more modest 4.2% rather than the reported 14.2% when the proximate area includes zip code 93454.*

[*It should be noted that there was a small variance (<2%) in the number of low birth weight births and live births stated by the study and obtained from the State of California; the origin of the variance is not known. Tables, with data re-run after inclusion of the above two problematic zip codes classified as proximate, can be found in the Appendix at the end of this paper.]

10. The ratio of all-cause mortality rose 47.9% higher in the 9 San Luis Obispo County zip codes closest to Diablo Canyon, versus the other more distant 10 county zip codes.

This finding reveals selection bias in assigning certain zip codes to comparison groups.

Also, there is no explanation as to why only two years from the same decade is used for this particular comparison. The author reports that age-specific population data was not available prior to 2000, but that is not an accurate statement.

11. In the 10 zip code areas in Santa Barbara County closest to Diablo Canyon, there was a greater rise in the rates of infant mortality (61.7%), low weight births (40.2%) and total mortality (19.1%), than in the 5 zip codes areas in the city of Santa Barbara, located approximately 90 miles from the plant.

This finding also has the selection bias of zip codes.

In addition, the finding is misleading by stating that “there was a greater rise in the rates of infant mortality..., low weight births..., and total mortality...” in “proximate” zip codes compared to “distant” zip codes. In fact, the IMR and total mortality decreased in both geographic groups over the time periods compared, just not as much as in the zip codes labelled as “proximate.”

12. The major findings of this report show increases in various rates of disease and death in San Luis Obispo County, as compared to the state of California, since the 1980s (before plant startup and during its early years of operation). This includes increases in infant mortality, child/adolescent cancer mortality, cancer incidence for all ages (especially thyroid, female breast, and melanoma), and cancer mortality for all ages.

This summary finding has been disproven in review of the other eleven findings above.

General Comments

It is important to restate a few broad points that give indication that the study analyzed and included only that data which would yield desired results.

- The author uses the entire County as the exposed group for some health indicators, e.g., cancer incidence and mortality, but then uses only a portion (downwind) of the County as the exposed group for other health indicators such as low birth weight and all-cause mortality. In so doing, the same residents with the same level of potential radiation exposure are used as cases and controls. This inconsistency is flawed and not in keeping with common peer-review scientific practice.
- The selection of zip codes to include or not include in creating a case group of proximate zip codes and a control group of more distant zip codes is capricious. The effect of these selections on resultant data is noteworthy and opposite to what results would have emerged had more logic and consistency been applied.
- The years of study are erratic throughout the report. Length of time, i.e., the number of years selected to analyze pre-exposure vs. post-exposure is altered repeatedly, as are the specific years selected for different health indicators. In a very few instances explanation is offered that certain data is not available. That circumstance is incongruously applied.
- The author demonstrates knowledge of the effect of differing population demographics, such as age and ethnic distribution, in diseases and conditions, but fails to routinely control for them in his study.

- The author dismisses other obvious causal considerations by the complete absence of other reasonable explanations for changes in health data over time. We cite here just one example of this customary approach to scientific examination. The increasing rate of very low birth weight babies across the County and the entire State over the past >20 years might be explained by increased substance use among pregnant women, or improved medical technology and treatment resulting in more of these babies surviving to be counted as a live birth.

Conclusion

The report claims to be a scientific review on the health status of San Luis Obispo and Santa Barbara County. Yet, it appears to have substantial bias. In the conclusion section, the claim is made that

“This is the first known analysis of local health status patterns and trends near the Diablo Canyon nuclear power plant.”

This is patently untrue. Multiple health status reports have been published by the County Public Health Department and the California Department of Public Health on local San Luis Obispo County health trends, including low birth weight, infant mortality, and cancer rates. The major difference between the Mangano report and reports published by the County and State pertain to methodology. While the State and the County use common accepted epidemiologic measures of morbidity and mortality, and control for confounding variables, the Mangano report cites crude rates, and omits significant data that would not support its conclusions. The author fails to control for confounding variables, including the racial make-up of the County and age distribution in some cases.

The conclusions that the author of the study makes are unsupported by the evidence and health data presented in the report. The author writes that this report supports findings in three other reports, all of which were also written by Mangano. For the one of these prior articles that is readily available, the author also used crude rates, and did not control for age, ethnicity or any other potential confounders. Using one flawed study to support another does not strengthen the conclusion.

The San Luis Obispo County Public Health Department takes very seriously the potential impact of radiation exposure to residents from any emissions from the Diablo Canyon Nuclear Power Plant (DCNPP), and most especially any possibility of a melt-down at the DCNPP in San Luis Obispo County, which would have devastating health consequences to nearby residents. It is true that there is no lower limit of radiation exposure which eliminates health risk. Yet it is also true that there is no means by which individuals can completely evade exposure to ionizing

radiation in their daily lives, given the background levels that emanate from earth and air. There may be as yet unknown additive health consequences of very low levels (known as permissible exposure limits) of radiation emission in and around nuclear power plants. However, this study does nothing to advance that theory and is in fact irresponsible in its treatment of the subject, raising a specter of invalid concern by reporting unsubstantiated findings. We look forward to a forthcoming robust national analysis from the National Academy of Sciences, slated to begin in 2015, on the rates of cancer in the vicinity of nuclear power plants.

For health trend analysis, it is recommended that both State of California and San Luis Obispo County health status reports be accessed.

State of CA:

<http://www.cdph.ca.gov/programs/OHIR/Pages/CHSP.aspx>

San Luis Obispo County:

http://www.slocounty.ca.gov/health/publichealth/famhealth/epi/epidemiology_data_and_publications.htm

APPENDIX

Table 1: Low Birth Weight (LBW) Babies Born in SLO County 1989-2011

SLO County Zip Codes in Analysis Control Zip Codes	Baseline period			Comparison Period		
	1989-1991			2004-2011		
	Births	LBW	% LBW	Births	LBW	% LBW
	4032	198	4.91%	8555	529	6.18%
	5062	283	5.59%	13312	792	5.95%

Table 2: Low Birth Weight Babies Born in Santa Barbara County 1989-2011

	SB % LBW 1989-91	SB % LBW 2004-11
W/O 93454	4.59%	6.04%
Control Zip Codes	4.85%	4.59%
93454 only	5.68%	6.69%
W/ 93454	5.06%	6.16%
California Births	5.86%	6.81%

Table 3: Ratio Changes in SB Proximate/Distant Ratio Due to Excluding 93454

	Proximate/Distant SB ratio		% change
	1989-1991	2004-11	
W/O 93454	0.947	1.316	39.04%
W/ 93454	0.908	0.902	-0.68%

Table 4: Ratio Changes in SB/California Ratio Due to Excluding 93454

	Proximate / California ratio		% change
	1989-91	2004-2011	
W/O 93454	0.783	0.886	13.18%
W/ 93454	0.862	0.904	4.90%

Table 5: Births, LBW births with 93420 Moved from Case to Control

	Baseline period			Comparison Period		
	1989-1991			2004-2011		
	Births	LBW	%LBW	Births	LBW	%LBW
SLO Case zip codes	4850	244	5.03%	10531	642	5.66%
Control zip codes	4014	237	5.90%	11336	679	5.99%
All Control zip codes	4037	238	5.90%	11336	679	5.99%

Table 6: Low Birth Weight Percentages for SLO County and California with 93420 in Case Counts

	SLO % LBW 1989-91	SLO % LBW 2004-11
Total Cases	5.03%	5.66%
Total Control Zips	5.90%	5.99%
California Births	5.86%	6.81%

Table 7: Ratio Changes in SLO Proximate/Distant Ratio due to Reclassification of 93420

	Proximate/Distant SB ratio		% change
	1989-1991	2004-11	
93420 in proximate	0.852	0.946	+10.97%
93420 in distant	0.878	1.026	+16.9%

Table 8: Ratio Changes and Proximate/California Ratios due to Reclassification of 93420

	Proximate/Distant SLO ratio		% change
	1989-1991	2004-11	
93420 in proximate	0.858	0.831	-3.14%
93420 in distant	0.837	0.897	+7.2%