Tomoya Yamauchi Graduate School of Maritime Sciences, Kobe Univreisty 21st April 2019 Shin-Osaka Maru-biru Bekkan, 5-3

UNSCEAR United Nations Scientific Committee on the Effects of Atomic Radiation

DEVELOPMENTS SINCE THE 2013 UNSCEAR REPORT ON THE LEVELS AND EFFECTS OF RADIATION EXPOSURE DUE TO THE NUCLEAR ACCIDENT FOLLOWING THE GREAT EAST-JAPAN EARTHQUAKE AND TSUNAMI

A 2016 white paper to guide the Scientific Committee's future programme of work



Focusing on two paragraphs of 111 & 112 in UNSEAR 2016 White Paper, we examine by what way they deny the analytical result of the excess of childhood thyroid cancer in Fukushima Prefecture based on the conventional epidemiology.

As the report style, these paragraph is completely out of usual scientific manner.

They have never adequate knowledge about epidemiology, especially on the role of regional classification as an operation variable, an importance of external comparison based on ordinal incidence, and time interval after the exposure.

The main paper in the present discussion is that published by Tsuda et al. in *Epidemiology* in 2016.



Toshihide Tsuda, ^a Akiko Tokinobu, ^b Eiji Yamamoto, ^c and Etsuji Suzuki^b

(Epidemiology 2016;27: 316–322)

OPEN

TABLE 2. Prevalence, Prevalence Odds Ratios (POR), and Incidence Rate Ratios (IRR) in Each District up to December 31, 2014

	Dravalance of Thuroid Concer	Internal Comparison	External Comparison IRR ^a (95% CI)	
Areas and Districts (1) to (9)	Cases per 10 ⁶ (95% CI)	POR (95% CI)		
Nearest area (1) (2011 fiscal year)	359 (201, 592)	1.5 (0.63, 4.0)	30 (17, 49)	
Middle area (2012 fiscal year)	402 (304, 522)	1.7 (0.81, 4.1)	33 (25, 43)	
North middle district (2)	237 (123, 414)	1.0 (0.40, 2.7)	20 (10, 35)	
Central middle district (3)	605 (302, 1,082)	2.6 (0.99, 7.0)	50 (25, 90)	
Koriyama City district (4)	462 (299, 683)	2.0 (0.87, 4.9)	39 (25, 57)	
South middle district (5)	486 (210, 957)	2.1 (0.7, 6.0)	40 (17, 80)	
Least contaminated area (2013 fiscal year)	332 (236, 454)	_	28 (20, 38)	
Iwaki City district (6)	451 (282, 682)	1.9 (0.84, 4.8)	38 (24, 57)	
Southeastern least contaminated district (7)	236 (95, 486)	1 (reference)	20 (7.9, 41)	
Western least contaminated district (8)	305 (146, 561)	1.3 (0.49, 3.6)	25 (12, 47)	
Northeastern least contaminated district (9)	0 (0, 595)	0.00 (0.0, 2.6)	0.00 (0.0, 50)	

^aThe IRRs were based on diagnosis by cytology. When based on histologically confirmed cases that were operated on, the IRRs for external comparisons using a latent duration of 4 years were 28 (95% CI = 15, 47) in the nearest area (excluding one benign case), 30 (95% CI = 22, 39) in the middle area, and 16 (95% CI = 10, 24) in the least contaminated area for which the secondary examination of cytology positive cases is incomplete.

Iwaki City district (6)

South middle district (5)

Southeastern least contaminated district (7)



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Francine Laden, Sc.D., President Verónica Vieira, D.Sc., Secretary-Treasurer Manolis Kogevinas, M.D., Ph.D., President-elect

The following correspondence was sent on January 22, 2016, to authorities in Japan including

Ms Tomoko Kitajima, Director General, Environmental Health Department, Ministry of the Environment Government of Japan

Mr. Hiroyuki Kobayashi, Chief, Department of Health and Welfare, Section for Fukushima Health Management Survey

Ms Tamayo Marukawa, Minister of the Environment (ascertained), Ministry of the Environment Government of Japan

On behalf of environmental epidemiologist, we at the International Society for Environmental Epidemiology (ISEE), the largest international professional organization for such scientists, are concerned about the recent scientific evidence suggesting an increase in the risk of thyroid cancer among residents of Fukushima that is much higher than previously anticipated.

The recently published study¹ demonstrates a 12-fold higher risk of developing thyroid cancer among residents of Fukushima compared to the rest of the Japanese population. This is an exceptionally high risk, as pointed out in the commentary to the published paper. This study builds on previous concerns about the lack of appropriate data and studies to monitor the long-term impact of the Fukushima nuclear disaster on local residents. Preliminary results of the study were presented at a special Symposium, organized at the ISEE Annual Meeting in Sao Paolo in September 2015. The discussion at the Symposium demonstrated great scientific interest of the Society members in follow up of health consequences of Fukushima accident.

The study illustrates the need of the on-going, systematic screening of the population affected by the accident, enabling early detection and treatment of the cases of thyroid cancer. Besides direct benefits to the affected population, such prospective study has great value for building up global knowledge about risks of ionizing radiation.

We appeal to the government as the stakeholder serving the interest of the people, to develop a series of measures to scientifically document and follow up the health of residents of Fukushima and to better understand and estimate the risks from the accident that happened in 2011. We believe that detailed monitoring of population exposure to radiation possibly remaining in the environment after the accident remains necessary both for scientific and preventive reasons. Such studies would provide invaluable contribution to the global body of knowledge on health consequences of nuclear accidents and ways for reduction such risks in affected populations.

ISEE would be available to assist and support activities where needed by utilizing the expertise of its members. We would be interested to know if, and how, you would envision the involvement of ISEE as an independent international professional organization.

We would appreciate hearing back about your perspective regarding our letter and your future plans regarding this important matter.

Sincerely

francine to

Francine Laden PhD President of ISEE

cc. World Health Organization

Following the publication of Tsudas' study, the president of International Society for Environmental Epidemiology (ISEE) has send a letter to the Director of the Ministry of the Environment Government of Japan, and Fukushima Prefecture.

It said "The recently published study demonstrates a 12-fold higher risk of developing thyroid cancer among residents of Fukushima compared to the rest of the Japanese population. This is an exceptionally high risk, as pointed out in the commentary to the published paper".

It also said "ISEE would be available to assist and support activities where needed by utilizing the expertise of its members".

Japanese Government and Fukushima Prefecture have made no response to this.

¹ Tsuda T et al, Thyroid Cancer Detection by Ultrasound Among Residents Ages 18 Years and Younger in Fukushima, Japan: 2011 to 2014. Epidemiology 2015 DOI: 10.1097/EDE.000000000000385

111. One paper [T17] (and a subsequently published response to criticisms [T16]) claimed to demonstrate that there had been a radiation-induced increase in thyroid cancer incidence: the authors reported a 50-fold (95% CI: 25, 90) excess in Fukushima Prefecture. However, the study design and methods were too susceptible to bias [J2] to warrant this interpretation. Tsuda et al. [T17] did not adequately account for the impact of the sensitive ultrasound screening of the thyroid upon the observed rate of thyroid cancer. Their conclusions were based on a comparison of the rate of thyroid cancer among those people screened by FHMS with the rates found elsewhere in Japan where few children had undergone thyroid screening.

FHMS: Fukushima Health Management Survey

[T17], [T16] [J2], [H3], [T6], [A2], [T5]

111. •••• Studies of other populations screened in childhood, particularly those who underwent ultrasound screening in three unexposed Japanese prefectures [H3], as well as other screening studies of young people in Japan [T6], found baseline rates of thyroid cancer in the absence of radiation exposure that were similar to the FHMS rates. Similarly, the Republic of Korea experienced an apparent large increase in thyroid cancer rates once they instituted universal screening [A2]. It is also likely that some of the cancers detected by screening may have existed before the radiation exposure [T5].

[T17], [T16] [J2], [H3], [T6], [A2], [T5]

112. Wakeford et al. [W2] carried out an analysis of the data in the Tsuda et al. paper by comparing the thyroid cancer prevalence among children studied by FHMS who were residing in localities with relatively low, medium, and high exposures as a result of the accident, as defined by Tsuda et al. The analysis by Wakeford et al. did not show any dose-response trend. In fact, the ratio of thyroid cancer prevalence between the localities with the highest and lowest exposures was only 1.08 (95% CI: 0.60, 1.96) [W2]. Other inconsistencies between Tsuda et al. and the substantial body of data on radiation-induced thyroid cancer in childhood include: (a) the Tsuda et al. paper reported excesses within 1–2 years after radiation exposure, whereas studies after the Chernobyl accident and other studies with much larger doses to the thyroid did not show excesses within 3–4 years;



112. ••• (b) all the thyroid cancers in the FHMS occurred among those 6–18 years old at radiation exposure, while other studies show the greatest incidence of thyroid cancer induction was among those with early childhood exposure (before age 5); and (c) the measured doses to the thyroid were much too low to be consistent with the high prevalence they reported [T6, W2]. Because of these weaknesses and inconsistencies, the Committee does not consider that the study by Tsuda et al. presents a serious challenge to the findings of the 2013 report.

[W2], [T6]

The occurrence of a large number of radiation induced thyroid cancers in Fukushima Prefecture—such as occurred after the Chernobyl accident—can be discounted, because absorbed doses to the thyroid after the FDNPS accident were substantially lower than those after the Chernobyl accident. UNSCEAR 2013 222

[T17], [T16] [J2], [H3], [T6], [A2], [T5].[W2] [T17] Tsuda, T., A. Tokinobu, E. Yamamoto et al. Thyroid cancer detection by ultrasound among residents ages 18 years and younger in Fukushima, Japan: 2011 to 2014. Epidemiology 27(3): 316-322 (2016).

[T16] Tsuda, T., A. Tokinobu, E. Yamamoto et al. Response to the Commentary by Professor Davis and the Seven Letters. - a well-known fact should be disseminated to remedy the problems. Epidemiology 27(3): e21-23 (2016).

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[H3] Hayashida, N., M. Imaizumi, H. Shimura et al. Thyroid ultrasound findings in children from three Japanese prefectures: Aomori, Yamanashi and Nagasaki. PLoS One 8(12): e83220 (2013). Survey of childhood thyroid cancer in Aomori, Yamanashi and Nagasaki prefectures

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Screening and over-diagnosis in Korea for adults

[T5] Takahashi, H., T. Ohira, S. Yasumura et al. Re: Thyroid cancer among young people in Fukushima. Epidemiology 27(3): e21 (2016).

[W2] Wakeford, R., A. Auvinen, R.N. Gent et al. Re: Thyroid cancer among young people in Fukushima. Epidemiology 27(3): e20-21 (2016).

The situation in areas of the for-

Fukushima accident) and there is a clear

and large excess of thyroid cancer in this

group. The thyroids of 13,127 Ukraini-

ans, 17 years old or younger at the time

of the accident, were screened between

1998 and 2000.5 Based on this study, 105

(95% CI: 30, 258) background cases of

thyroid cancer would be expected from

the first screening in Fukushima prefec-

ture.⁶ The good agreement between this

point estimate and the number of 112

cases that has been detected up to the

end of March 2015 in Fukushima Prefec-

ture¹ does not permit the inference that

an effect of radiation exposure has been

demonstrated. A more plausible con-

clusion is that the screening program is

finding an anticipated increase in thyroid

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cancer detection across the prefecture.

Epidemiology has opportunity for open discussions prior to the final publication, using *letters* to editor.

Re: Thyroid Cancer Among Young People [J2] in Fukushima

To the Editor:

read with interest the article by Tsuda et al.1 Nevertheless, I was very disappointed that it failed to identify itself as a classic ecologic study and acknowledge that its findings were, therefore, vulnerable to the ecologic fallacy. Likewise, the accompanying commentary, by Scott Davis, failed to point out the ecologic study design.2

The flawed inferential logic, known as ecologic fallacy, threatens all studies that draw risk inferences based on community incidence rates without individual dose data, yet that is but one of problems with ecologic studies.3 Despite the well-known limitations of this study design, a bibliometric review of ecological studies published in major epidemiologic journals found that only 69% of articles clearly specified their study's design by mentioning the word "ecological" or "ecologic," and 49% failed to acknowledge susceptibility to ecologic fallacy as a major weakness.4

The reluctance of authors to label their studies as ecologic is understandable given the negative reception such studies often receive. But the Tsuda article goes beyond failing to acknowledge that it is ecologic. It actually hides its design by using "the residential address of the subjects in March 2011...as a surrogate for individual [dose]," and then reports measures

The author reports no conflicts of interest.

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vidual dose data and therefore, not prone to be influenced by factors that vary between communities.

The thyroid cancer rates in the Tsuda study are not consistent with the risks found in earlier cohort and case-control studies and therefore. do not seem to be credible based on our prior experience with radioactive iodine. This should be bluntly stated because the media do not appreciate that all study designs are not equally valid, and the public needlessly panics over studies of limited scientific value

I must, therefore, concur with Dr. Davis that "these findings do not add anything new regarding radiationinduced thyroid cancer." But I would further add that publishing studies that use ecologic study designs without acknowledging the issue of ecologic fallacy is a disservice to the people of Fukushima. who have already suffered greatly and do not need the added burden of groundless worry about their risk of thyroid cancer-a risk level that most epidemiologists would consider very small, notwithstanding the Tsuda study.

> **Timothy J. Jorgensen** Health Physics and Radiation Protection Program Department of Radiation Medicine Georgetown University Medical Center Washington, DC

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Disease Control and Prevention" therein. This source is for policy making, not for scientific research. The author states "However, the National Academy of Sciences has reported that childhood cancers have a period of 1 to 10 years. Therefore, based on the best available scientific evidence and the following methodology presented in this revised White Paper on Minimum Latency and Types or Categories of Cancer, the administrator selected a minimum latency of 1 year for use in the evaluation of cases of childhood cancer for certification in the WTC Health Program "

Letters

I would be happy if the present letter might help readers correctly understand the results presented in the last column of Table 2.

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To the Editor:

suda et al.1 reported the current findings of a large-scale thyroid disease screening program in Fukushima Prefecture, Japan, following the release of radionuclides, in particular iodine-131, from the accident at Fukushima Dai-ichi nuclear power station in March 2011. They suggest that these findings indicate an increase in cases of thyroid cancer that is attributable to the accident. We

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were members of an International Expert elevate cancer rates as much as Tsuda et Working Group established by the World Health Organization to perform an initial assessment of the health consequences of the Fukushima Dai-ichi accident.2 and we have serious concerns over this interpretation of Tsuda et al.1

on the detection of thyroid nodules. a relatively small part of the prefecture.

ible difference in thyroid cancer prevalence between the low, intermediate, and high contamination areas of Fukushima Prefecture. The prevalence ratio for the highest to lowest contamination areas was 1.08 (95% confidence interval [CI]: 0.60, 1.96), and the highest prevalence was seen in the area with an intermediate level of contamination (prevalence ratio = 1.21 [95% CI: 0.80, 1.82]). Furthermore, the measured levels of radioactivity in thyroids in Fukushima Prefecture

Drs. Wakeford and Kesminiene have received research funding from the European Commission. Dr. Wakeford has received a grant from Children with Cancer UK (current) and is a Member of Technical Working Party of UK Compensation Scheme for Radiation-linked Diseases (current). He has served as consultant to US Electric Power Research Institute (past), Horizon Nuclear Power Ltd (past), and the UK

ISSN: 1044-3983/16/2703-0e20 DOI: 10.1097/EDE.000000000000466

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al ¹ claim mer USSR heavily contaminated following the Chernobyl accident in 1986 is of relevance here: in these areas, many children received high thyroid doses Thyroid disease screening with (much higher than those following the

ultrasound can have a dramatic effect A 15-fold increase in the incidence of thyroid cancer occurred in South Korea after the introduction of a national cancer screening program in 1999, with the incidence rate in regions increasing in direct proportion to the percentage of screened people.³ Consequently, it is inappropriate to compare the data from the Fukushima screening program with cancer registry data from the rest of Japan where there is, in general, no such large-scale screening. The proper comparison is between different screened areas within Fukushima Prefecture. since significant radioactive contamination from the accident was confined to

There is no statistically discernwere far lower⁴ than would be needed to

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Fukushima. Epidemiology 27(3): e20-21 (2016) critical Letter

References of 111 & 112 in the order of publication



UNSCEAR wrote 2016 White Paper based on the Letters, completely ignoring the Response by the authors. UNSCEAR completely failed to describe the discussions in *Epidemiology* as an academic and expert journal. UNSCEAR insulted the academic activity in *Epidemiology*. 111. One paper [T17] (and a subsequently published response to criticisms [T16]) claimed to demonstrate that there had been a radiation-induced increase in thyroid cancer incidence: the authors reported a 50-fold (95% CI: 25, 90) excess in Fukushima Prefecture. However, the study design and methods were too susceptible to bias [J2] to warrant this interpretation.

The study design and method was constructed by Fukushima Medical University, FMU, not by the authors of paper [17].

The Letter [J2] insisted the study is an "ecological study" but FMU has started this as a "Cohort study".

The Letter [J2] claimed that individual dose have never measured, but this can not be attributable to the authors of paper [17].

Since the paper [17] is utilizing the regional classification as an operation variable to express exposure level, it is adequate analysis from the view point of Epidemiology.

One example of 2x2 table, without miss classification. It is assumed that we know real exposure level for individual.

	exposed	non-exposed	Totals
Cases	40	10	50
Noncases	60	90	150
Totals	100	100	200

Odds for exposed : 40/60 = 0.667 Odds for non-exposed : 10/90 = 0.111

Odds ratio : (40/60)/(10/90) = 6.6

We recognize the causal relationship between the exposure and the cases.

The regional classification is never match with the real classification. Let's consider the case when 20% of exposed to be treated as nonexposure. (40 -> 32, 60 ->48, 100 -> 80)

	exposed	non-exposed	Totals
Cases	32	18	50
Noncases	48	102	150
Totals	80	120	200

Odds for exposed : 32/48 = 0.667 Odds for non-exposed : 18/102 = 0.176

Odds ratio : (32/48)/(18/102) = 3.78

The regional classification has a bias to close the odds ratio to one (no effect). When one find an effect using regional classification, it is enough. The paper [T17] found the effect, applying the regional classification. UNSCEAR do not have enough knowledge on Epidemiology. 111. Studies of other populations screened in childhood, particularly those who underwent ultrasound screening in three unexposed Japanese prefectures [H3], as well as other screening studies of young people in Japan [T6], found baseline rates of thyroid cancer in the absence of radiation exposure that were similar to the FHMS rates.

In [H3] one case of childhood thyroid cancer was found from 4,365 persons. The simple ratio par 1,000,000 persons is 229. UNSCEAR insists this ratio is comparable to that in FHMS. But this kind of discussion lacks statistical consideration. In Poisson distribution, lower and upper limits of 95% confidence interval of count 1 are 0.025318 and 5.57163, respectively. The observation in [H3] is concordant with the ordinal incidence between 5.8 and 127.6 persons par 1,000,000 persons. Age group in [H3] was between 3 and 18 years old. The lower group was not involved, different from FHMS. It is difficult to make any scientifically meaningful discussions.

An importance of external comparison based on ordinal incidence

111. •••• Studies of other populations screened in childhood, particularly those who underwent ultrasound screening in three unexposed Japanese prefectures [H3], as well as other screening studies of young people in Japan [T6], found baseline rates of thyroid cancer in the absence of radiation exposure that were similar to the FHMS rates.

Letter [T6] said three cases of thyroid cancer were found from 2,307 new comers to Okayama University in 2013. Since they were university students, the age group is different from that in FHMS. Response [T16] indicated the fact that no additional cases were found between 2012 and 2015 from 36,927 persons, including elder students.

UNSCEAR ignored this response when they prepare the White Paper in 2016.

An importance of time interval after the exposure

112. Wakeford et al. [W2] carried out an analysis of the data in the Tsuda et al. paper by comparing the thyroid cancer prevalence among children studied by FHMS who were residing in localities with relatively low, medium, and high exposures as a result of the accident, as defined by Tsuda et al. The analysis by Wakeford et al. did not show any dose-response trend. In fact, the ratio of thyroid cancer prevalence between the localities with the highest and lowest exposures was only 1.08 (95% CI: 0.60, 1.96) [W2].



Letter [W2] paid no attention on the time interval after the exposure, nevertheless they spoken about the dose-response relation.

Alfred Korblein. Re: Thyroid cancer among young people in Fukushima. Epidemiology 27(3): e18-e19 (2016).

FIGURE. Prevalence of thyroid cancer in areas of Fukushima Prefecture with different radiation contamination.

L

Between the Accident and Timing of Screening was Considered				
	1st Examinees	Cancer Cases	POR (95% CI) ^a	
Nearest area (1) (2011 fiscal year)	41,810	15	4.6 (2.2, 11)	1 year
Middle area (2012 fiscal year)	139,338	56	2.6 (1.2, 6.0)	2 years
North middle district (2)	50,618	12	1.5 (0.65, 3.9)	
Central middle district (3)	18,194	11	3.9 (1.6, 10)	
Koriyama City district (4)	54,063	25	3.0 (1.4, 7.2)	
South middle district (5)	16,463	8	3.1 (1.2, 8.4)	
Least contaminated area (2013 fiscal year)	119,328	42	-	3 vears
Iwaki City district (6)	49,429	24	2.1 (0.92, 5.2)	- ,
Southeastern least contaminated district (7)	29,820	7	1 (reference)	
Western least contaminated district (8)	33,720	11	1.4 (0.54, 3.8)	
Northeastern least contaminated district (9)	6.359	0	0(0, 2.5)	

TABLE. Results of Internal Comparison from the First Round of Screening in Each Area or District up to June 30, 2015, When the Effect of the Length of Time Elapsed and Timing of Carooning Was Considered

^aWe obtained these results by correcting the observed cancer cases. With regard to central middle district (3) and Koriyama city district (4), we show the means of corrected PORs and 95% CIs because we cannot use numbers with a decimal point in EpiInfo 7.

CI indicates confidence interval; POR, prevalence odds ratio.

Prevalence Odds Ratios are highest in Nearest area and lower in the least contaminated districts. Higher POR is found in Iwaki City, where radio iodine plume had passed away. Iwaki city is not so contaminated by radio cesium.

Conclusion

Description about childhood thyroid cancer in UNSCEAR 2016 white paper (111&112) was examined.

The description by UNSCEAR has failed to correctly reconstructed the scientific discussions which were made in the academic and expert journal of "Epidemiology".

UNSCEAR have never enough knowledge about epidemiology, especially on the role of regional classification as an operation variable, an importance of external comparison based on ordinal incidence, and time interval after the exposure for dose-resopnse relation.

We can not accept the description in 111 & 112 of UNSCEAR2016 white paper, from the view points of sciences.

For Japanese reading persons 本発表に関連する論考が『科学9月号』(岩波書店)に掲載されています。 以下のサイトから無料でダウンロードできます。 <u>http://www.lib.kobe-u.ac.jp/handle_kernel/90005240</u> 神戸大学学術成果リポジトリ