

A Progress Report of the Marshall Islands Nationwide Thyroid Study: An International Cooperative Scientific Study

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Department of Preventive Medicine and Health Promotion, Nagasaki University School of Medicine, Nagasaki 852-8523, ¹Board on Radiation Effects Research, National Academy of Science, Washington, D.C., USA, ²Department of Radiation Biology, St. Bartholomew's and the Royal London School of Medicine and Dentistry, London, UK, ³Second Department of Surgery, Tohoku University School of Medicine, Sendai 980-8574, and ⁴Cancer and Public Health Unit, London School of Hygiene and Tropical Medicine, London, UK

TAKAHASHI, T., SIMON, S.L., TROTT, K.R., FUJIMORI, K., NAKASHIMA, N., ARISAWA, K. and SCHOEMAKER, M.J. *A Progress Report of the Marshall Islands Nationwide Thyroid Study: An International Cooperative Scientific Study.* Tohoku J. Exp. Med., 1999, 187(4), 363-375 — The objective of this report is to present a summary of progress of the Marshall Islands Nationwide Thyroid Study. As well known, the US atomic weapons testing program in the Pacific was conducted primarily between 1946 and 1958 in the Marshall Islands. The nuclear tests resulted in radioactive contamination of a number of atolls and resulted in exposure of Marshallese to undefined levels before our study. Little information has been paid to health consequences among residents of the nearly twenty inhabited atolls except for some information about nodular thyroid disease which was reported on by an US group. In a cooperative agreement with the Government of the Marshall Islands, between 1993 and 1997 we studied the prevalence of both thyroid nodules and thyroid cancer among 4766 Marshallese potentially exposed to radioiodines from bomb test fallout. That group represents more than 65% of the population at risk. We diagnosed 45 thyroid cancers and 1398 benign thyroid nodules. In addition, 23 study participants had been operated on prior to our study for thyroid cancer. Presently, we are developing a database of information

Received December 28, 1998; revision accepted for publication March 5, 1999.

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to estimate radiation doses and planning a statistical analysis to determine if a dose-response relationship exists. These data will be important for the health promotion of exposed people all over the world including Hiroshima, Nagasaki, Semipalatinsk, Chernobyl and other locations. A timely completion is important for purpose of assisting Marshallese as well as to add the global understanding of radiation induced thyroid cancer. ——— thyroid cancer; radioactive fallout; atomic bomb; Marshall Islands; radiation © 1999 Tohoku University Medical Press

The objective of this report is to present a summary of progress of the Marshall Islands Nationwide Thyroid Study. For this purpose, details of analyses of the data collected to date would not be provided here.

This report pertains exclusively to that study began in 1993 as a component of the Marshall Islands Nationwide Radiological Study—a study whose primary goal was to investigate the radiological contamination of the entire Marshall Islands nation. The primary investigation team of the thyroid disease study discussed here includes Steven L. Simon (National Academy of Sciences, Washington, D.C., USA—formerly Marshall Islands Nationwide Radiological Study), Keisei Fujimori (Tohoku University, Sendai), Klaus R. Trott (St. Bartholomew's School of Medicine, University of London, London, UK), Minouk J. Schoemaker (London School of Hygiene and Tropical Medicine, London, UK) and Tatsuya Takahashi (Nagasaki University, Nagasaki).

This report underscores the need for timely completion of our study as well as our present need for funding to complete the analysis. There are three primary reasons that we feel the completion of this study is important: (1) A commitment was made to the Marshall Islands Government and the Marshallese people to provide data on the frequency of thyroid disease in their country and to assess whether the prevalence was related to past radiation exposure from nuclear weapons testing, (2) Only by acquiring sound data and conducting the proper analysis can an understanding be obtained of the causes of thyroid disease in the Republic of the Marshall Islands (R.M.I.) and the appropriate health promotion be formulated, and (3) Completion of this study can significantly contribute—at extremely low cost—to the state-of-knowledge concerning the dose-response relationship between thyroid diseases and radioiodines from low- to moderate- intakes and doses. Despite our commitment toward these goals, completion of our study has been delayed for over 2 years because of the absence of any financial support.

ORGANIZATIONAL HISTORY

The Nationwide Radiological Study (NWRS) was the precursor study to the Nationwide Thyroid Study; it was directed by one of our team (SLS). The NWRS was a study of the radioactive contamination of the entire Marshall Islands nation; it was commissioned by the Marshall Islands Government in 1989 and completed in late 1994. The NWRS successfully monitored the entirety of the

R.M.I. for the first time; the present levels of contamination at all atolls are now known in detail and reported elsewhere (Simon and Graham 1994, 1997).

A comprehensive study of the incidence of thyroid disease in the Marshall Islands was considered in 1990 during discussions held between the director of the NWRS (SLS) and an international advisory board appointed by the R.M.I. Government. The original purpose of the envisioned study was to collect new data to reinvestigate the hypothesis put forth by Hamilton et al. (1987) that palpable nodular thyroid disease occurred in the R.M.I. with decreasing prevalence with increasing distance from the Bikini test site. The implication of that hypothesis was that radioactive contamination from the Bikini test was the primary causal agent which was responsible for an excess of thyroid disease in the Marshall Islands and that the affected area was significantly larger than previously believed.

In 1991 and 1992, numerous meetings were held by two of our group (SLS and KRT) with officials in Majuro (capital city and the largest population center in the R.M.I.) from the Ministry of Health and Nuclear Claims Tribunal (NCT that is the R.M.I. organization for claims potentially related to radiation exposure) to discuss how to achieve support for, and how to organize, a nationwide study of thyroid disease.

After considerable discussion, the R.M.I. Government gave the NWRS permission to hire a physician in 1991. However, at that time, hiring new staff was prohibited due to lack of government finances. Since the NWRS had its own funding (through Section 177 of the US-Marshall Islands treaty [the Compact of Free Association]), the R.M.I. Government endorsed and authorized the hiring of the physician. A radiologist was recruited from Japan to Majuro, however, strong opposition by the physicians of the NCT prevented the study from beginning. Drs. Simon and Trott through a persistent effort reorganized the study to begin in Ebeye (the second largest population center in the country), Kwajalein atoll in 1993 after forming collaboration with Dr. Hiroshi Ohtomo (Tohoku University) and others from the Second Department of Surgery, Tohoku University, Sendai (KF and TT). Since the inception of the Nationwide Thyroid Study, they have provided the main medical contribution.

In mid 1993, Dr. Simon received notice that the R.M.I. NWRS might be able to receive funding from the US Centers for Disease Control and Prevention (Radiation Studies Branch) to continue its health surveillance. This was viewed as an important opportunity as the completion of the environmental and health monitoring program left little financial resources for a medical surveillance study. In late 1993, Dr. Simon and the R.M.I. Minister of Health visited the CDC to discuss the possibility of the funding. Subsequently, they made application for a cooperative agreement. An agreement for funding was awarded to the Marshall Islands on August 1, 1994 for support of its thyroid study in the amount of \$350 000 per year for 3 years (to be renewed annually). Following the award, the

CDC stipulated that the money could not be used for clinical investigations—only for the staff and office support—until a protocol had been reviewed and approved by an advisory group in the USA. Thus, the Nationwide Thyroid Study continued to depend on its funding provided by the Compact of Free Association, for its clinical work was already well underway at the time.

Following the end of the collection and analysis of the environmental radiation data by the NWRS (December 1994), Dr. Simon and the R.M.I. Government-appointed advisory panel presented the results of the environmental monitoring program to the R.M.I. President and Cabinet. After 5 years of investigations, the findings of the radiological survey were greeted with concerted skepticism and the data were not accepted by the Marshall Islands Nitijela (Parliament). It was the interpretation of the Scientific Advisory Panel, that the R.M.I. government was not interested in the truth about the radiological conditions (McEwan et al. 1997). Because of this and other events, no further funding was available to our research group through the cooperative agreement with the CDC.

The Nationwide Thyroid Study team has continued its investigations, depending on relatively small grants from the Ministry of Education of Japanese Government and the University of London and our individual commitments to the project at the moment. Milestones have been completed since 1995 include conducting medical examinations on the atolls of Likiep/Ailuk/Mejit in 1997, publishing one paper in an international conference proceedings (Fujimori et al. 1996), making presentations at several international scientific conferences (Fujimori et al. 1997; Takahashi et al. 1997b; Trott et al. 1996, 1998, Tuttle et al. 1997), and preparing and publishing three analyses of the data collected in Ebeye and Majuro in the open literature (Takahashi et al. 1997a, 1999; Trott et al. 1999). The individual members of the study team are continuing to collaborate and have maintained communication over the 3 years.

The intention of our research team at present is to estimate past individual radiation doses to the study participants from radioactive fallout, to complete the analysis of the entire set of clinical data collected during all the investigative phases, and to relate the clinical data to estimated thyroid doses. The Nationwide Thyroid Study, once a study supported by the R.M.I. through the Compact of Free Association, has evolved into an international research effort despite the absence of funding for the past three years.

MEDICAL PHASES OF INVESTIGATION

Prior to the medical phases of the investigations, the first Institutional Review Board (IRB) was assembled in the Health Ministry of the Marshall Islands. That group reviewed and approved the medical procedures to be used in the thyroid study including the informed consent forms.

The medical surveillance program was composed of two components, namely, a personal interview and a clinical examination. The methods have been

described in detail elsewhere (Takahashi et al. 1997a). Generally, each Marshallese study participant was first informed about the purposes of the study and the risks of involved. They were subsequently interviewed to ascertain a variety of basic health information including height, weight, blood pressure, reproductive history, dietary preferences, and residential history. Interviews were conducted verbally in the Marshallese language by locally hired assistants and data was recorded on forms written in the Marshallese language. The medical examinations were conducted by two physicians from Tohoku University, each initially blinded to the others findings. The first physician conducted a traditional physical examination including palpation of the neck. The second physician did an ultrasound examination. Differences in diagnoses when they occurred were resolved collaboratively by the two attending physicians. From palpable nodules or other abnormality, tissue samples were taken by fine needle aspiration biopsies (FNA).

The first medical investigation phase of the study was held in Ebeye (the second largest population center), Kwajalein in 1993 with cooperation and assistance from the Ebeye Hospital. All examinations were conducted at the Ebeye Hospital over a three month period. A temporary clinic including a facility to stain FNA biopsy slides was established in Ebeye Hospital. Biopsy slides were subsequently taken to Japan for pathological examination. In this phase of our study, 1371 residents of Ebeye at the moment were examined. A progress report describing the clinical findings was issued to the R.M.I. Government (Simon et al. 1993).

The second and largest medical examination phase of the study was held in 1994 in Majuro (capital city and the largest population center) in cooperation with the R.M.I. Ministry of Health and the Majuro Hospital. For this work, a large medical storage facility behind the Majuro Hospital was renovated into two examination rooms, a waiting area used mainly for interviewing, a supply storage room, and an office. Local Marshallese residents (about 20 in all) were hired as interviewers and translators, and as clinic assistants. The majority of the study participants examined in this phase of our work were residents of Majuro at the time of examination though some individuals resided in Laura (a village on the far-side of the Majuro atoll). Some participants who were living on the other atolls were examined while visiting Majuro. Those examined in this phase also included most of residents of the Utrik atoll and Mejatto island (Kwajalein Atoll) who were examined during short trips made to those atolls in conjunction with the US Department of Energy (DOE) sponsored medical missions. During a 7-month period, 5263 Marshallese were examined.

The third medical examination phase supported mainly by the Japanese Ministry of Education was carried out in Ebeye in 1996. The purpose of this phase was to reexamine Marshallese identified with nodular disease in 1993 in order to observe the course of their condition. In addition, this phase of work was

useful for re-interviewing 300 subjects to check the reliability of dietary and residence information collected at the time of the first interview three years earlier. During this short phase, 239 additional individuals were examined for the first time.

The fourth medical examination phase of the study took place in early 1997. It was also supported by the Japanese Government grant. The decision for this phase was made during a meeting of the study collaborators in London in 1996. After thorough review of the environmental radiological data collected by NWRS (Simon and Graham 1994, 1997), it was recognized as requisite to collect further medical data from those locations that had received intermediate levels of the fallout. During the first three examination phases, few study participants were from atolls or islands in between the southern atolls, which received lowest fallout contamination and the Utrik atoll, which received much higher levels of radioactive fallout. Since it was important to ascertain the disease prevalence from atolls at all levels of exposure, plans were made to hold temporary examination clinics on Likiep and Ailuk Atolls and Mejit Island. This mission was conducted by Dr. Noriaki Nakashima (Tohoku University) and us (TT, KF and MJS). During this phase, additional 348 R.M.I. citizens were examined.

Follow-up medical care for subjects with diagnosis of thyroid cancer was provided by the surgeons of our group who also participated in the medical surveillance. The medical care was provided mainly by Dr. Kiyoshi Takaya (Tohoku University) and us (KF and TT). Funding for medical care was provided jointly by the R.M.I. Ministry of Health, the Japanese Ministry of Education grants and other donations from the Second Department of Surgery, Tohoku University School of Medicine. Costs for thyroid hormone replacement is supported by an US supported medical care program in the R.M.I. for exposed Marshallese citizens. The majority of the surgeries conducted by participating surgeons ensured the availability of biopsy samples for histopathological confirmation of the disease.

SUMMARY OF MEDICAL EXAMINATIONS

In all four examination phases, 7221 Marshallese were examined. Table 1 shows a summary of study participants by examination phase.

TABLE 1. *Participation by examination phase*

Examination Phase	Number of participants	Percent of total (%)	Cumulative percent (%)
Ebeye 1993	1371	19.0	19.0
Majuro 1994	5263	72.9	91.9
Ebeye 1996	239	2.3	95.2
Ailuk/Likiep/Mejit 1997	348	4.8	100.0
Total	7221		

TABLE 2. *Distribution of study subjects by age cohort*

Cohort	Number of participants	Percent of total (%)	Cumulative percent (%)
BRAVO*	3712	51.4	51.4
EOT*	1054	14.6	66.0
AT	1059	14.7	80.7
Later	1396	19.3	100.0
Total	7221		

*Potentially exposed population.

The age distribution of the subjects is important for understanding the number and proportion of the potentially exposed Marshallese that have been examined. For simplicity in this report, we have defined four cohorts of subjects (see Table 2): (1) BRAVO-those alive at the time of the BRAVO test, i.e., born before March 1, 1954, (2) EOT-those born or in utero after the BRAVO test but before the end of the testing, i.e., born between March 1, 1954 and March 1, 1959 (Note that the last test in the Marshall Islands was conducted on August 18, 1958 though some subjects were in utero. To be included in the cohort, the unborn subject must have been at least 90 days fetal age at the time of test, thus, their birth date would have been as late as March 1, 1959), (3) AT-those born after the nuclear testing stopped but born before January 1, 1965, and (4) Later-those born after January 1, 1965. People born after January 1, 1965 were examined if requested, as no one of any of age was refused. The subject in this group received no exposure from the nuclear tests conducted in the R.M.I. This group was not the prime focus for our study, though the data are reported here for completeness.

The number of Marshallese examined in this study that were alive during the era of nuclear weapons testing in the Marshall Islands was 4766 (BRAVO and EOT cohorts). We believe this group represents, at minimum, 65% of all Marshallese alive today who were alive during the weapons testing era, and thus were possibly at risk to radiation induced thyroid disease. Since some of the potentially exposed Marshallese have migrated to Hawaii and the US mainland, we believe that there are no more than 2000 Marshallese in the Marshall Islands who have not been examined but who are part of the population potentially at risk.

In addition to the thyroid screening as described, other types of data were collected during the course of the investigations including measurements of thyroid stimulating hormone (TSH), thyroid hormones (T_3 and T_4), antithyroid antibodies, histopathological results from operated cases, and iodine concentration of casual urine samples as an estimate of dietary iodine intake. A summary of the types and quantity of information collected is shown in Table 3.

The most common diagnosis was that of benign nodules including adenomatous goiters and follicular neoplasms. As noted in our publications (Fujimori et al.

TABLE 3. *Clinical methods and number of subjects*

Method	Number of participants
Clinical examination of the neck and ultrasound	7221
Fine needle aspiration biopsy	699
Definitive surgery of suspected cancer	
Performed by our team	43
Performed by other surgeons	17
TSH determination	4050
T ₃ /T ₄ and antithyroid antibodies determination	3000
Iodine excretion	433

TABLE 4. *Prevalence of nodules among cohorts*

Birth cohort	Male participants	Number of cases w/nodules	%	Female participants	Number of cases w/nodules	%
BRAVO	1787	384	21.2	1925	730	37.7
End of testing	444	44	9.9	610	145	23.6
After testing	443	33	7.4	616	78	12.0

TABLE 5. *Distribution of medical conditions among study subjects (BRAVO, EOT and AT cohorts)*

Diagnosis	Sex		Total (%)
	Male	Female	
Normal	2190 (81.9)	2155 (69.8)	4345 (74.6)
Benign nodules	456 (17.1)	921 (29.2)	1398 (24.0)
Cancer	23 (0.86)	45 (1.43)	68 (1.17)
Graves disease	2 (0.07)	1 (0.03)	3 (0.05)
Other conditions	3 (0.11)	8 (0.25)	11 (0.19)
Total	2674	3151	5825

1996; Takahashi et al. 1997; Trott et al. 1999), frequency of nodules was relatively high though this is partly a result of screening with high-resolution ultrasound. Nodule prevalence in males of the BRAVO cohort was about 21% and about 38% in females (see Table 4).

The distribution of diagnoses by medical condition (BRAVO, EOT and AT cohorts together) is shown in Table 5. We diagnosed 45 thyroid cancers and 1398 benign thyroid nodules by our screening program. In addition, 23 study participants had been operated on prior to our study for thyroid cancer. Seventy-five percent of all Marshallese were normal, 1.17% (68 cases) had a diagnosis of cancer. A variety of other conditions were noted including benign nodules and Graves'

disease. There were few cases of Hashimoto's thyroiditis in the participants examined.

Among the BRAVO cohort (3712 subjects), the percentage of normal diagnoses, benign nodules, and cancer was 69.7% (2587 cases), 28.9% (1073 cases), and 1.4% (52 cases), respectively. As expected, the number of cancers and nodules among women was higher than that among men. Summary statistics for the other cohorts are also available. In general, the prevalence is lower for the younger cohorts.

PLANS FOR CONTINUED RESEARCH

The continuation of work to be conducted by the Nationwide Thyroid Study falls into four categories: (i) Database management and record keeping, (ii) Medical diagnosis verification, (iii) Radiation dosimetry and (iv) Epidemiological analysis. Each of these activities is briefly described here.

Database management and record keeping

This activity is the continued development and management of the computerized database of the clinical and medical data to assist with future analyses.

Medical diagnosis verification

This activity uses the copy of the medical records and other archives held in Japan and includes the inspection of records for accuracy and comparison with the database (verification).

Radiation dosimetry

This activity will be constructed upon methods of previous studies (Lessard et al. 1985; Simon et al. 1990; Simon and Graham 1997). The goal is to provide a credible estimate of thyroid absorbed dose to each study participant and an estimate of statistical and subjective uncertainty (Hoffman et al. 1996). The dosimetry related work will rely on data from; (1) a number of historical documents identified through several years of document review, (2) the radioactive contamination data collected by NWRS, (3) established models of intake and radiation dose per unit intake and residence histories of each study subject, which were collected at the time of the medical examinations.

Other work contemplated includes measurements of ^{129}I in soil samples (Simon and Graham 1996) acquired from all the atolls of the Marshall Islands nation. Methods for extraction of iodine from soil were developed by the NWRS in conjunction with a laboratory in Canada as a preliminary step for accelerated-based mass spectrometry (AMS) measurement. This analysis, while possibly useful and revealing, is expensive. Thus, there are no current plans for completion though it remains as a possible source of supplementary information.

Epidemiological analysis

This activity will be built further on the analyses presented in Takahashi et al. (1997a) and Trott et al. (1999). The primary goal of this analysis will be to determine if there is evidence to support a hypothesis that the radiation absorbed dose to the thyroids of study participants was a causal agent in inducing an excess of thyroid disease—benign or cancerous. A number of accepted statistical analyses are planned using data provided by all three of the activities described above. This activity will also include modeling the prevalence of thyroid cancer and benign thyroid disease as a function of radiation dose to the thyroid, age at exposure, calendar year of birth, gender, reproductive history and some dietary factors. Our data should enable us to determine a dose-response function if such a relationship exists. Any dose-response function that we might determine will be compared with those published in the literature for other populations. Finally, if there is no evidence to support a dose-response relationship but the prevalence of diseases appears to be higher than expected, alternative factors which might be responsible for the high prevalence should be examined.

Expectations for completion

The various activities noted above will be carried out over the next 1 to 2 years, though the rate of progress is highly dependent on the availability of funding. Presently, the Nationwide Thyroid Study is without funding. Regardless of the rate of progress in the near future, our group is committed to completing our analyses and publishing the findings.

CONCLUDING REMARKS

Part of the impetus for this progress report is to inform interested agencies of our progress and of the clear need for funding to ensure a timely completion of the study. The R.M.I. NCT speculated in their 1996 annual report (NCT 1997) that there had been no overall report of the Nationwide Thyroid Study because of lack of funding. However, it is very important to note that medical reports have been provided to each of all participants diagnosed as abnormal status and to the R.M.I. Ministry of Health. It should be noted that 69% of the total compensational awards were for thyroid abnormalities in the 1996 annual report of the NCT. A high proportion of these individuals was able to file valid claims because of the evidence that provided by the Nationwide Thyroid Study.

The data and findings of this study are important to all exposed population in the world. Support of our study will ensure timely release of the study findings and would allow for a legitimate assessment of the need for additional investigations in the Marshall Islands to be made. Any future investigations contemplated should take advantage of what we have learned from our extensive medical examinations, the detailed environmental radiological data we have

collected, and the radiation doses we are in the course of preparing. Following completion of our analysis, availability of all data will be made to interested groups.

Acknowledgments

We are appreciative of the assistance from numerous Marshallese who participated in the study as research assistants and as volunteer subjects and from the colleagues in Tohoku University School of Medicine. This publication was made possible by contributions of Prof. Hiroshi Saito, Dean of Nagasaki University, School of Medicine. His continued support and understanding of the importance of this study is appreciated.

Authors Note—This manuscript represents the opinions of the authors only and does not represent the opinion of the US National Academy of Sciences, the US National Research Council or the Ministry of Education, Science, Sports and Culture, Japan.

*23 July 1998 in Cambridge, UK (Signatures of authors are available on original.)
Amended November 18, 1998, and December 21, 1998 for Tohoku J. Exp. Med.*

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