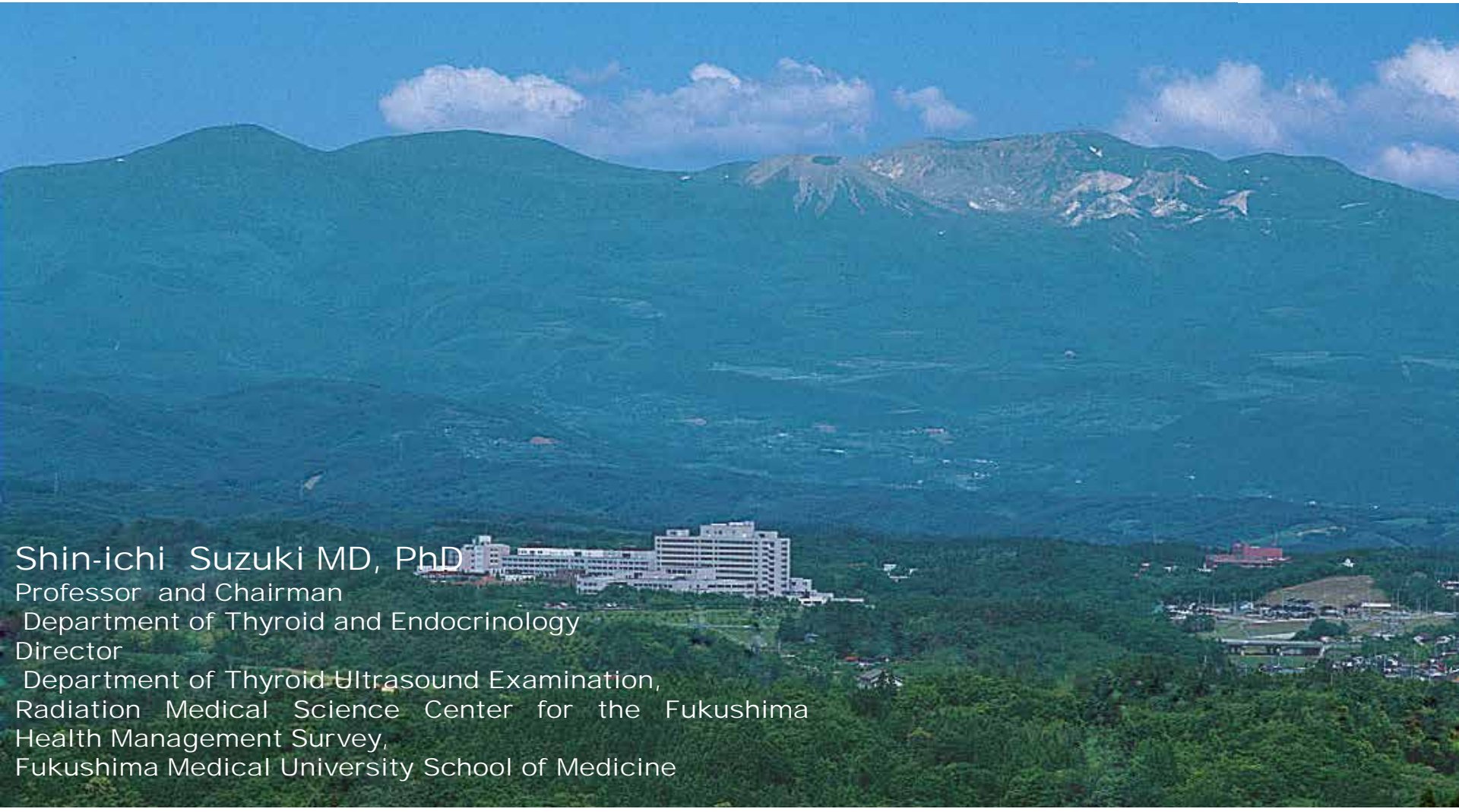


FMU Thyroid Ultrasound Surveys in Fukushima Prefecture



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Introduction 1

- Thyroid cancer is well known good prognosis among all solid neoplasms.
- External (X-ray, γ -) radiation and internal exposure to radioiodine impose increased thyroid cancer risk.
- Risk has strong inverse correlation with age at exposure; highest risk is in youngest children.
- Thyroid cancer in children is usually rare.

Introduction 2

After the Chernobyl nuclear accident in 1986, childhood thyroid carcinoma had a great increase in Belarus and Ukraine, as a consequence of the exposure to iodine radioactive fallout.



After the TEPCO-Fukushima Daiichi Nuclear Power Plant accident on March 11, 2011, the publics in Japan had a particular concern about the increased risk of childhood thyroid cancer in similar to Chernobyl.



Introduction 3

- We decided to perform thyroid ultrasound examinations (TUE) on all children in Fukushima prefecture as one of the detailed surveys of a Fukushima Health Management (FHM) survey.
- The increase in thyroid cancer was reported to start 4 or 5 years after Chernobyl accident.
- Therefore, we started TUE to know the current thyroid status in Fukushima within first 3 years after disaster.

Fukushima Health Management Survey Outline

Basic survey

Subjects: 2.02 million people living in Fukushima
Method: self-administered Questionnaire

Health management file (provisional name)

- ☆ Results of health surveys and examinations recorded and retained by individuals
- ☆ Increase awareness of radiation

Creation of a database

- ◆ Utilized for long-term healthcare and medical treatment of Fukushima prefecture residents
- ◆ Knowledge acquired in providing healthcare will be used for future generations

- Whole-body counter
- Individual dosimeter

Ascertain health conditions

Detailed survey

Thyroid ultrasound examination

Subjects: 360,000 children aged 18 years or younger as of March 11, 2011

Comprehensive medical checkups

Subjects: Residents residing in evacuation areas, etc

Details: General medical checkup items as well as differential white blood count, etc.

Subjects: Residents not residing in evacuation areas

Details: General medical checkup items

Having workplace medical checkups, municipal medical checkups and/or cancer screening helps ensure early detection and early treatment of diseases.

Conducting of medical checkups for Fukushima prefecture

Mental health and lifestyle survey

Survey on pregnant women and nursing mothers

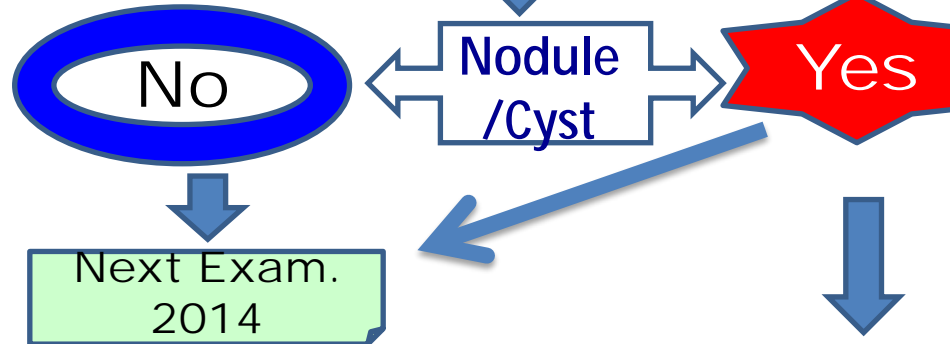
Consultation and support

Follow-up

Treatment

Flow Chart of Thyroid Ultrasound Examination

First screening (primary examination)



Portable US machine

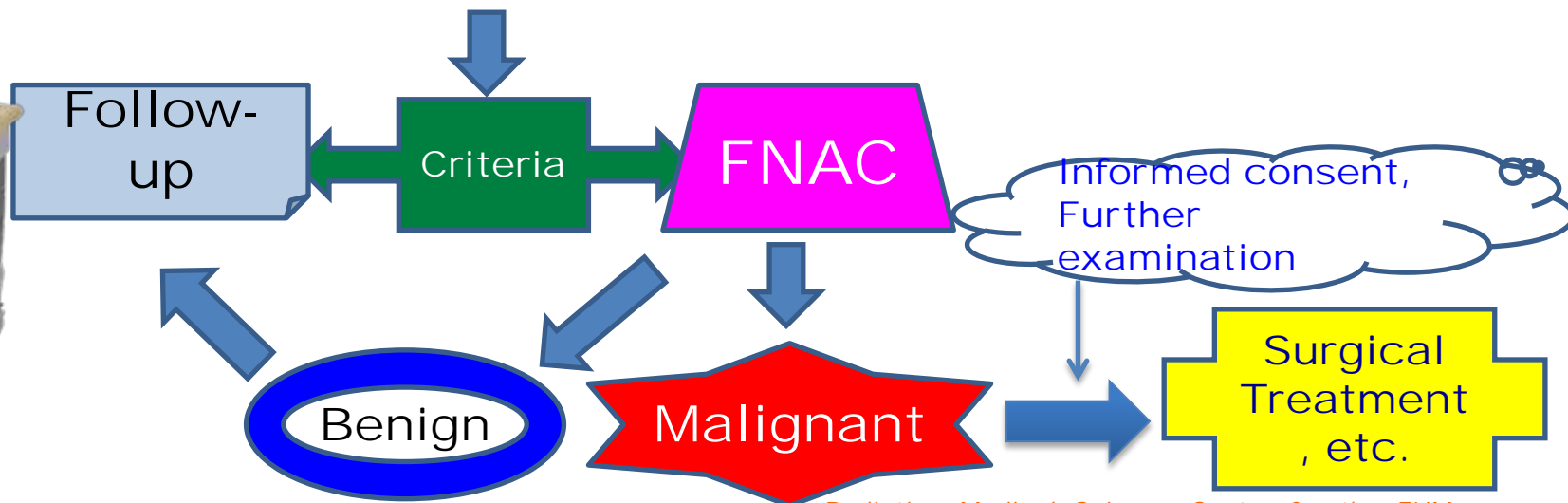


LOGIQ e Expert



Noblus

Secondary screening (Confirmatory examination)
Precise US examination, Blood and Urinary analyses



HIVISION
Ascendus

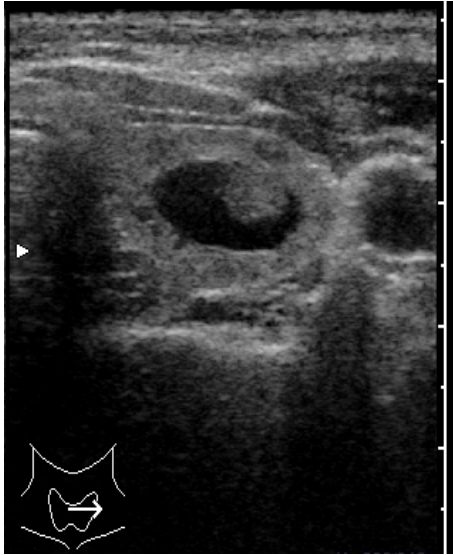
Diagnostic Criteria

Judgment	Interpretation	recommend
A	Within normal	
(A1)	No nodule and/or Cyst*	next primary examination
(A2)	Nodule with $\leq 5.0\text{mm}^{**}$ or/and Cyst with $\leq 20.0\text{mm}$	next primary examination
B	Nodule with $\geq 5.1\text{mm}$ or/and Cyst with $\geq 20.1\text{mm}$	confirmatory examination
C	Required immediately examination	urgent confirmatory examination

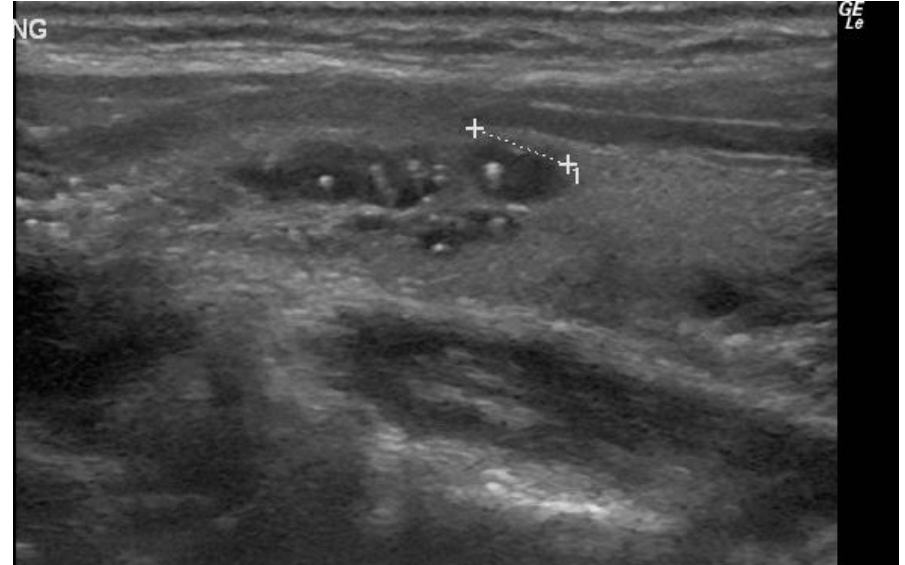
*Mixed cystic-solid nodule is include the category of "nodule".

**Some test results A2 may be classified as B when clinically indicated.

Criteria of Cyst



Mixed cystic-solid nodule is included in the category of "nodule" in this survey. Because mixed type occurs in cancer.

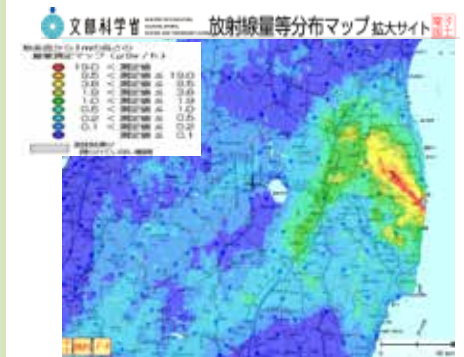


Multiple Cysts with colloid clot (Colloid cysts) which is confirmed by the comet sign, is diagnosed by US examination without FNAC.

In this survey, the category of "cyst" is simple cyst or colloid cyst that means normal.

Schedule of Thyroid Ultrasound Examination (TUE)

- Preliminary survey*: 360,000
from October 2011
to March 2014
1st survey: from October 2011 to March 2012
13 municipalities in the nationally designated evacuation zones
2nd survey: from April 2012 to March 2014 →
- *: This time is considered that radiation-induced thyroid disease do not appear yet .
- Full scale survey: **360,000**
from April 2014
to end of March 2016



The TUE is performed one by one at the time of the Nuclear accident from the residents of the area which was high as for the atmospheric dose of radioactivity.

The full-scale survey will then continue every two years until the age of 20, and every 5 years thereafter for the remainder of the subjects life.

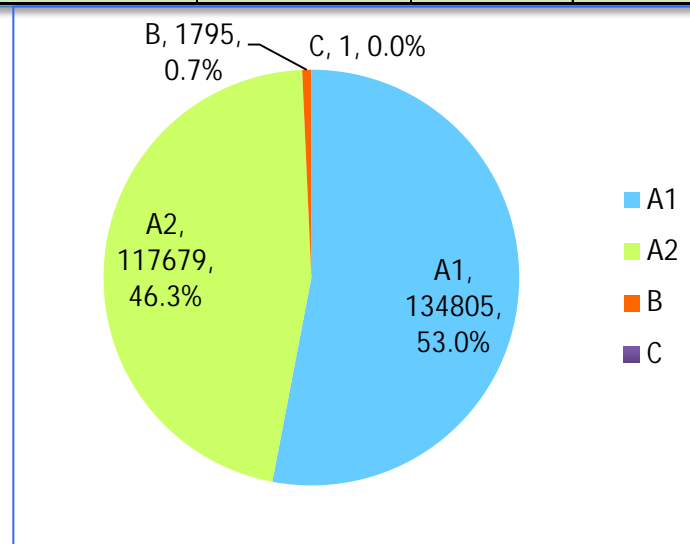
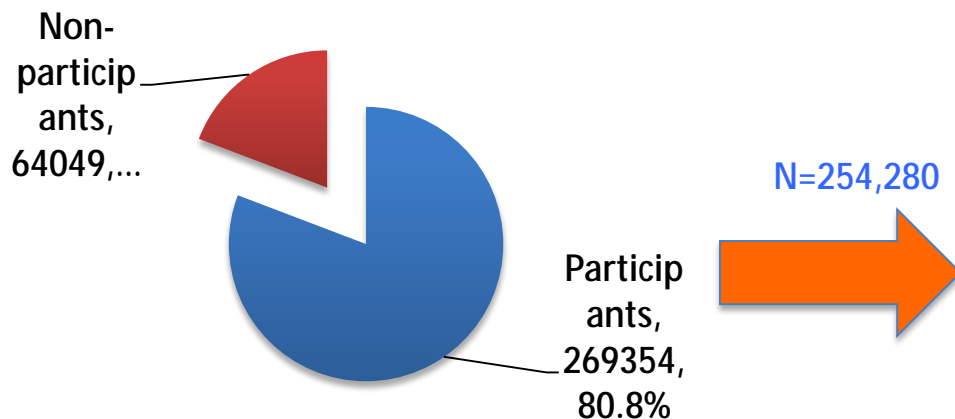
Primary examination of thyroid ultrasound examination (TUE) from Oct 9, 2011 at the Fukushima Medical University Hospital



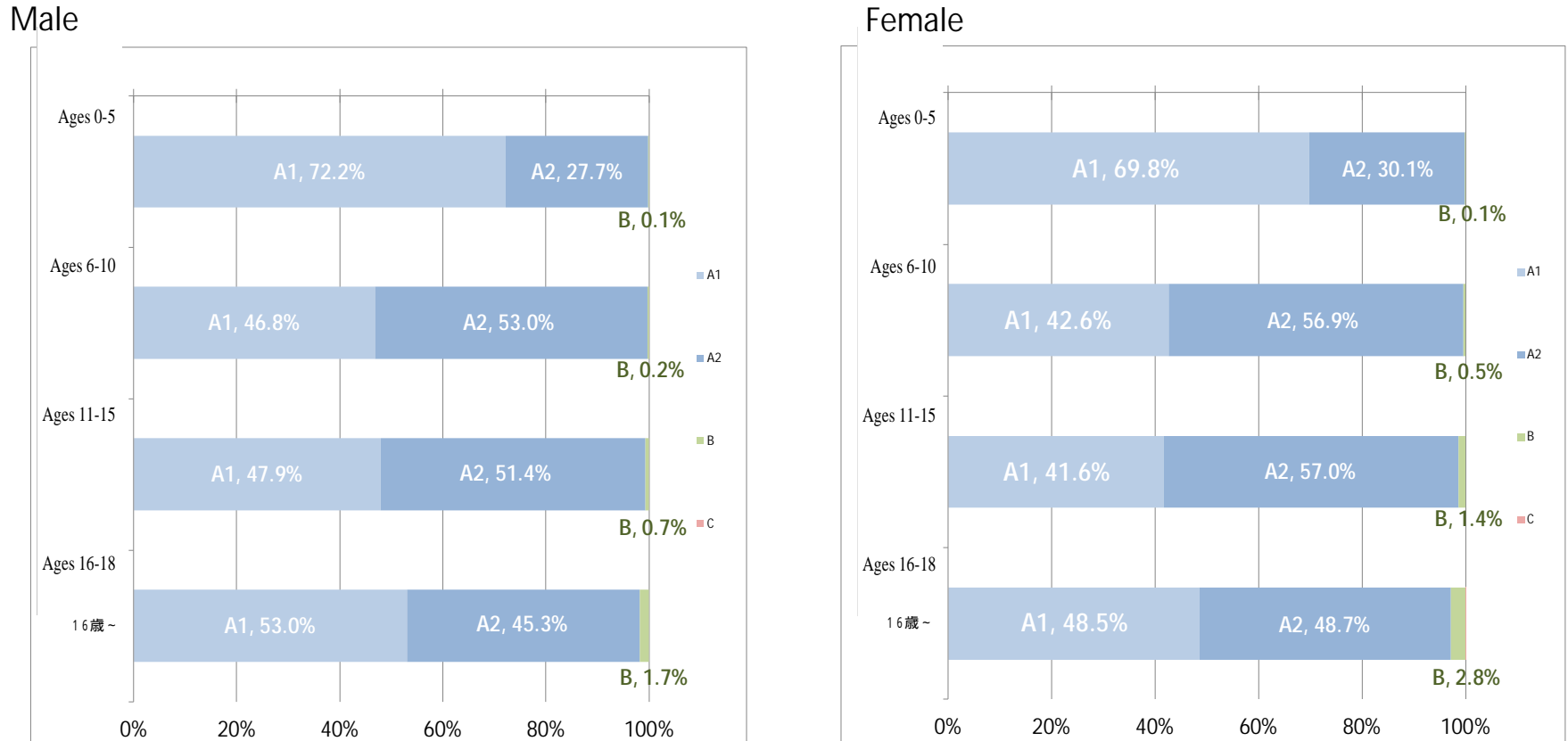
Results of First Screening of Preliminary Survey from October 9, 2011 to the End of December 2013

Screening test coverage as of 31 December 2013 (last screening on 15 November 2013)

	Target Population a	Participants		Test results				
		Proportion (%) b (b/a)	Screened outside Fukushima	Proportion (%) c (c/b)	Class			
					A		Requiring confirmatory test	
					A1 d (d/c)	A2 e (e/c)	B f (f/c)	C g (g/c)
FY 2011	47,766	41,561 (87.0)	1,949	41,522 (99.9)	26,278 (63.3)	15,026 (36.2)	218 (0.5)	0 (0.0)
FY 2012	163,264	139,239 (85.3)	3,905	139,092 (99.9)	76,120 (54.7)	61,985 (44.6)	986 (0.7)	1 (0.0)
FY 2013	122,373	88,554 (72.4)	293	73,666 (83.2)	32,407 (44.0)	40,668 (55.2)	591 (0.8)	0 (0.0)
Total	333,403	269,354 (80.8)	6,147	254,280 (94.4)	134,805 (53.0)	117,679 (46.3)	1,795 (0.7)	1 (0.0)



Result of first screening classified by sex and age



A1 decreases with age and A2 increases with age.

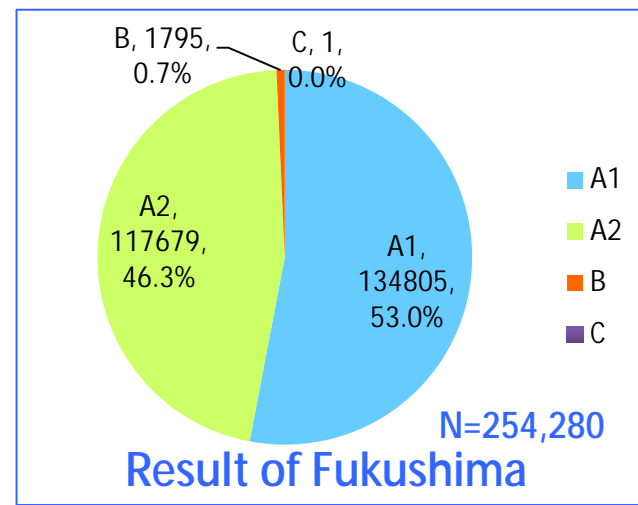
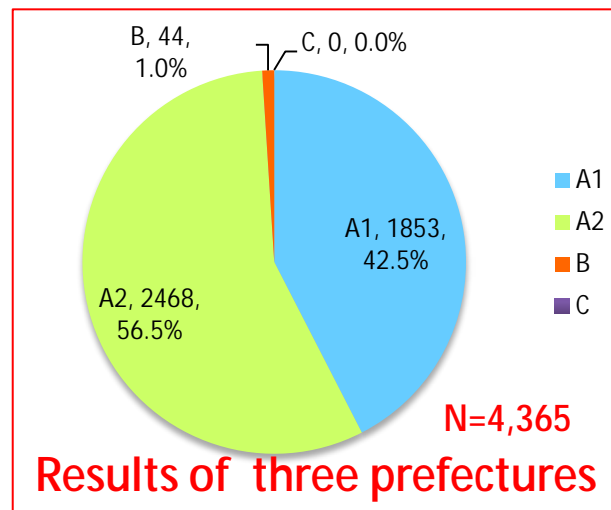
A2 reaches a peak and decreases after that at the age of 13 to 15.

B increases with age after adolescence.

As for sex difference, A2 and B are predominance to the woman after adolescence.

Thyroid ultrasound findings in children from three Japanese prefectures: Aomori, Yamanashi and Nagasaki

To obtain such comparative data, the Japan Association of Breast and Thyroid Sonology (JABTS) was entrusted from the Ministry of Environment using by the same method as Fukushima Thyroid Ultrasound Examination (TUE).



Results of Secondary Examination (Confirmatory Examination) started from March 2012 to December 2013

Confirmatory testing coverage and results as of 31 December 2013

	Number of children requiring confirmatory test a	Participants Proportion (%) b (b/a)	Confirmatory test coverage (%) c (c/b)	Confirmed test results			
				Next screening advised [*]		Follow-up advised ^{**}	
				A1 d (d/c)	A2 e (e/c)	f (f/c)	Cytology g (g/f)
FY 2011	218	192 (88.1)	187 (97.4)	12 (6.4)	41 (21.9)	134 (71.7)	89 (66.4)
FY 2012	987	872 (88.3)	826 (94.7)	50 (6.1)	217 (26.3)	559 (67.7)	243 (43.5)
FY 2013	591	426 (72.1)	329 (77.2)	21 (6.4)	130 (39.5)	178 (54.1)	37 (20.8)
Total	1,796	1,490 (83.0)	1,342 (90.1)	83 (6.2)	388 (28.9)	871 (64.9)	369 (42.4)

*: One-third cases recommended next full scale survey from April 2014 since it was re-judged by A1 and A2 without abnormal findings.

** : The cases are going to shift to the usual medical examination and to re-consult in six months or one year in general.

***: The FNAC in 369 cases revealed that 75 subjects had a malignant tumor or were suspected to have malignancy.

Among 871 cases excluding A1 , A2 re-judged cases, 369 (42%) cases were diagnosed by FNAC after ultrasound examination and 502 (58%) cases were diagnosed by ultrasound examination alone.

Malignant or suspected malignant cases diagnosed by FNAC

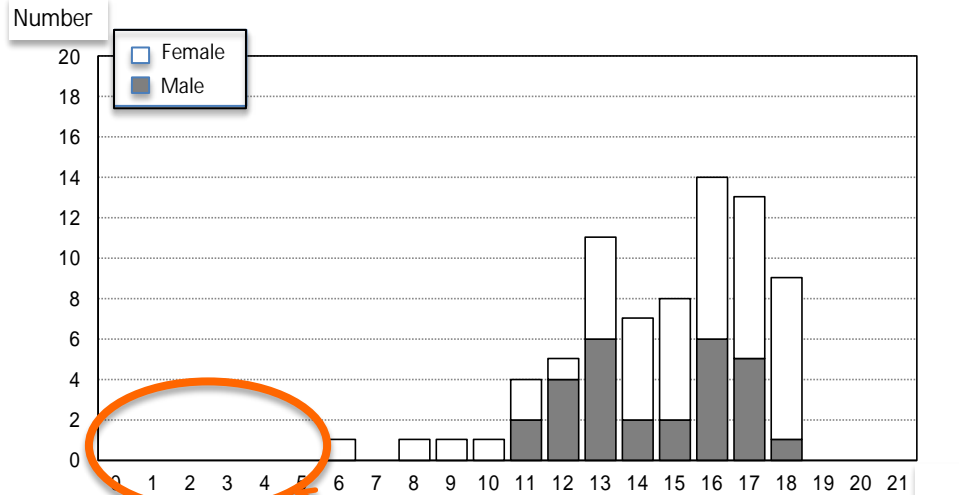
Preliminary surveys from Oct. 2011 to December 2013

Total for cases FY 2011 – FY 2013

Suspicious or malignant	75 (34 surgical cases: 1 of benign thyroid nodule; 32 of papillary thyroid carcinomas; 1 suspicious for poorly differentiated thyroid carcinoma)
Male to female ratio	28:47
Mean age (SD, min-max)	16.9 (2.6, 8-21) 14.7 (2.6, 6-18) at the time of the disaster
Mean tumor size	14.3 mm (7.6 mm, 5.2-40.5 mm)

Proportion of suspicious or malignant cases 0.03%

Age and gender of 75 cases, who were diagnosed with malignant or suspected malignant by FNAC



Suspicious or malignant cases by age as of 11 March 2011

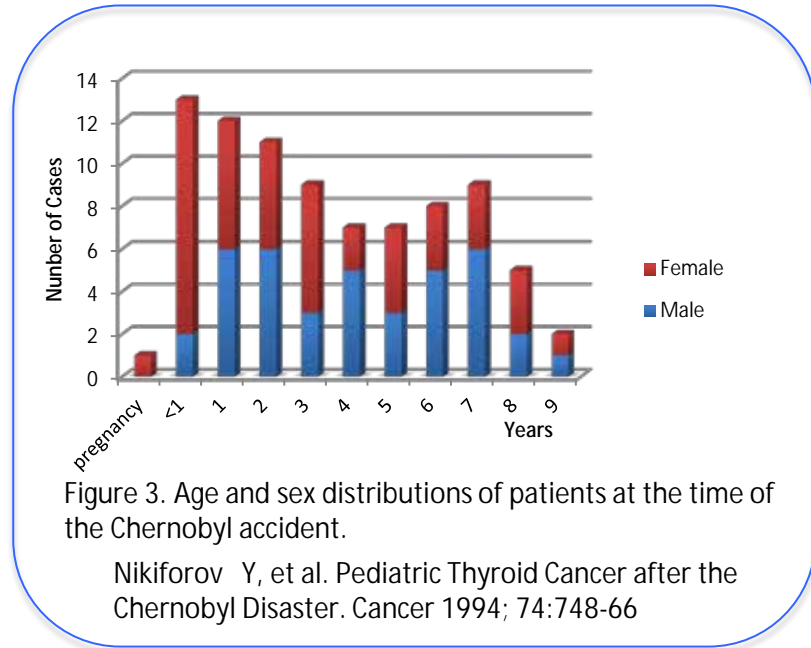
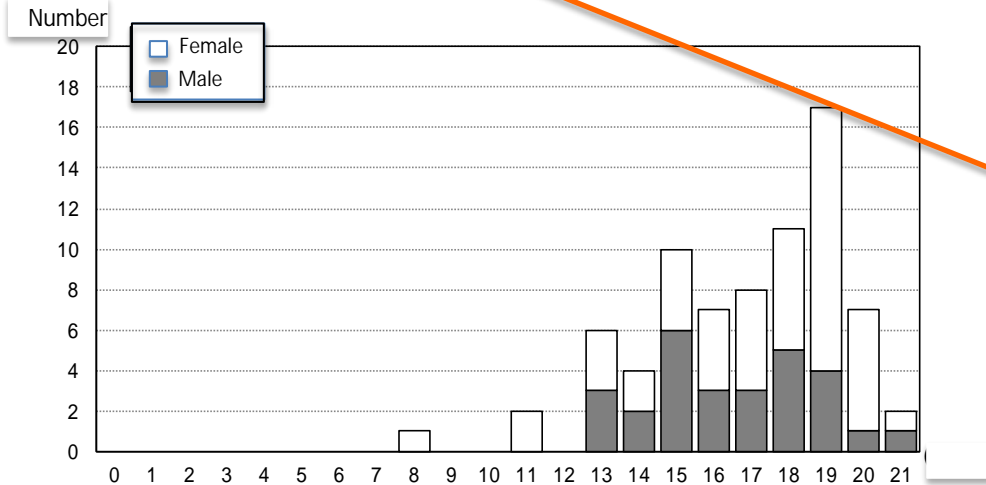


Figure 3. Age and sex distributions of patients at the time of the Chernobyl accident.

Nikiforov Y, et al. Pediatric Thyroid Cancer after the Chernobyl Disaster. Cancer 1994; 74:748-66



Suspicious or malignant cases by age as of the date of confirmatory examination

There was no youngest children of thyroid cancer in Fukushima unlike as Chernobyl children after the accident .

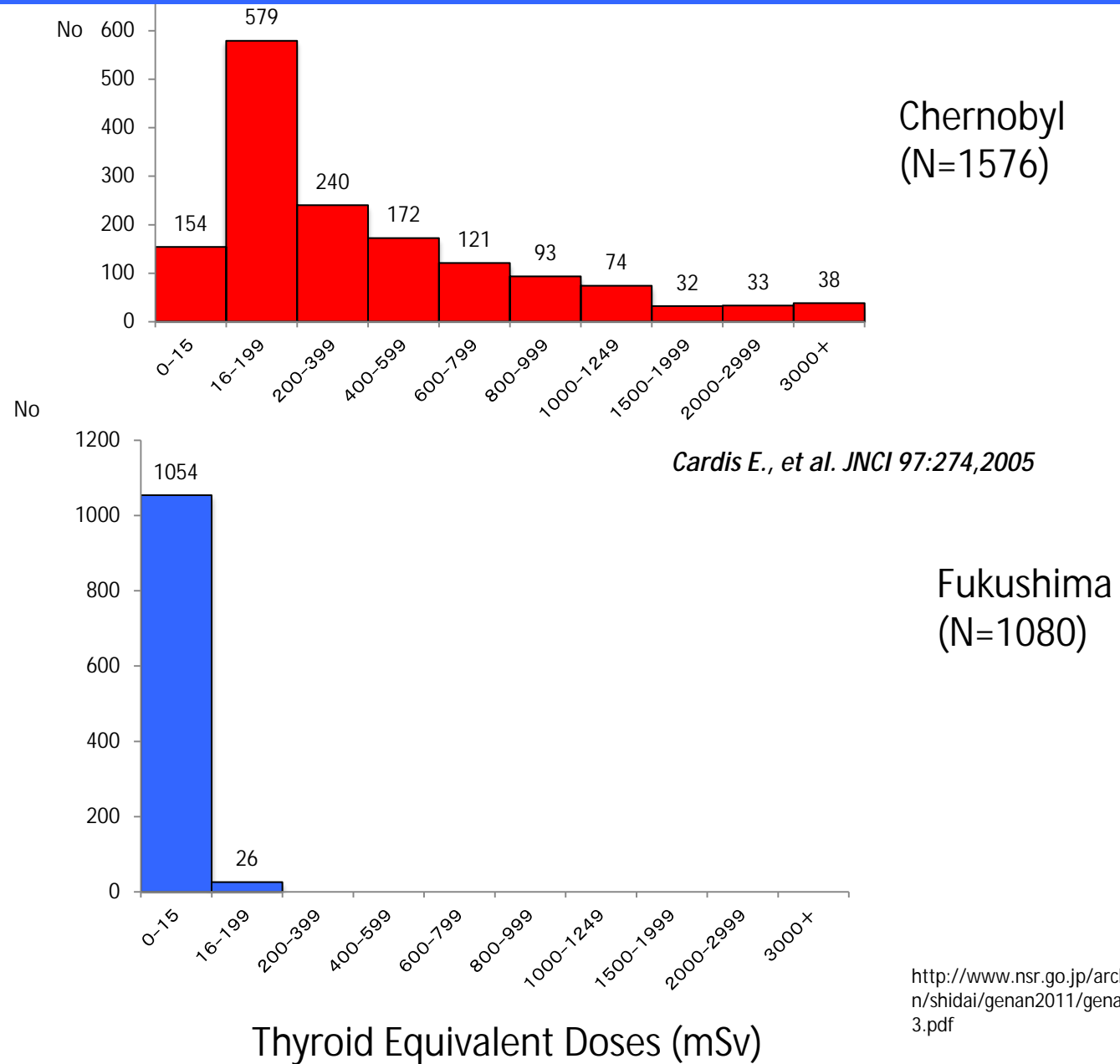
Suspicious or malignant cases on FNAC by estimated radiation dose

Number of suspicious or malignant cases by age and dose

Effective dose (mSv)	Sex	Age at the time of disaster				
		0-5	6-10	11-15	16-18	Total
<0.5	Male	0	0	0	1	1
	Female	0	1	1	3	5
<1.0	Male	0	0	3	1	4
	Female	0	1	0	4	5
<1.5	Male	0	0	2	1	3
	Female	0	0	3	1	4
<2.0	Male	0	0	1	0	1
	Female	0	0	1	0	1
Total	Male	0	0	6	3	9
	Female	0	2	5	8	15

Thirty-one of the 75 cases (41.3%) participated in the Basic Survey (radiation dose estimates), and 24 cases were confirmed, of which 12 (57.1%) had estimated radiation exposure dose below 1 mSv.

Comparison of Thyroid Equivalent Dose between Chernobyl and Fukushima's children after the either accident



Did thyroid cancer occur in these patients as a result of radiation exposure after the Fukushima Daiichi Nuclear Power Plant Accident ?

The answer is no. Because,

1. The exposure level in Fukushima was overwhelmingly low. It is likely that there are no children who have exceeded the maximum exposure level of 50mSv (intervention level) .
2. Radiation induced thyroid cancer will show the symptoms following an incubation period of at least four to five years, however it is still a little less than three years during the period after the accident.
3. The carcinogenic risk would be heightened if the ages of the cases were young at the time of the accident, but the average age of these malignant or suspected malignant cases was 15 years old, and younger children is not accepted .
4. All cases were diagnosed with typical PTC, and there were no solid variant PTCs like in Chernobyl's PTC.

- As mentioned above, a possibility that a thyroid cancer which was accepted by the adult by having performed the highly precise medical examination until now was discovered at an early stage or youth while it was small is high.
- It seems that it had already occurred regardless of radiation exposure.
- This serves as frequency of the thyroid cancer of the baseline of the children of Fukushima.

Conclusion

- This long-term large scale thyroid ultrasound examination (TUE) was started.
- At present, TUE of preliminary survey has been performed on about 270,000 children.
- Among 369 cases where FNAC was performed in confirmatory test of the Preliminary Survey, 75 cases were diagnosed with malignancy or suspected for malignancy, and 34 of these cases were already confirmed as having one benign nodule and 33 thyroid cancers after thyroid surgery.
- This is the interim report of the thyroid examination of the Fukushima Health Management Survey after the Fukushima Daiichi NPP accident, which potentially serves as baseline frequency of the childhood thyroid nodules/cysts in Fukushima discovered by newly introduction of the sophisticated ultrasound screening.
- These results will become the golden standard of the future comparative TUE in Fukushima, Japan whether the risk of childhood thyroid cancer will increase or not in future on a basis of well designed epidemiological study.

Thank you for your attention