

Ethical challenges in health surveillance: a case study on thyroid screening after Fukushima

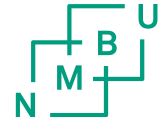


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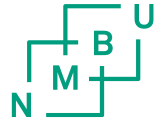
SHAMISEN
Nuclear Emergency Situations
Improvement of Medical and
Health Surveillance



OBJECTIVE

Build upon lessons learned from Chernobyl, Fukushima and other radiation accidents, in order to develop recommendations for medical and health surveillance of populations ... that respond to their needs and concerns.

Fukushima Thyroid Cancer Screening



Fukushima's children at centre of debate over rates of thyroid cancer

Three years after the worst nuclear accident in a generation, the Japanese prefecture is reporting a rise in the number of children showing cancer symptoms. But is this directly related to the disaster, or is the testing more rigorous?

theguardian

Tsuda, et al. 2014/2015: «An excess of thyroid cancer has been detected by ultrasound among children and adolescents in Fukushima Prefecture within 4 years of the release, and is unlikely to be explained by a screening surge» Epidemiology



In Iwaki, a town south of the Fukushima nuclear plant, a doctor conducts a thyroid examination on 4-year-old Maria Sakamoto. Scientists are puzzled over a high number of thyroid abnormalities observed so soon after the accident.

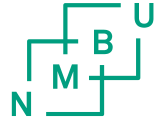
© Toru Hanai/Reuters

Mystery cancers are cropping up in children in aftermath of Fukushima

By **Dennis Normile** | Mar. 4, 2016, 10:45 AM

Science

Fukushima Thyroid Cancer Screening



Prefecture wide screening – offered to all 18 years old and under

- Baseline screening 2011 - 2014
 - 300,456 participants (81,7%)
 - 113 suspicious or malignant cases
- Full survey 2014 -
 - 169,455 participants (44,7%)
 - 25 suspicious or malignant cases
- 106 children had undergone surgery (June 2015).



Reuters



Ethics of Health Screening and Surveillance:



Thyroid Screening - a text book case in medical ethics

- False positives/false negatives/overdiagnosis – unnecessary surgery or worry

Box 1: Classic overdiagnosis, narrowly conceived, precise, and condition specific

Thyroid cancer provides a useful example of the narrow sense of overdiagnosis^{26 27} In the US, the rate of diagnosis of thyroid cancer has tripled over the past 30 years, from 3.6 cases/100 000 in 1973 to 11.6 cases/100 000 in 2009, with most of the extra diagnoses being of papillary cancer. This rise in thyroid cancer diagnosis has been linked to the increased use of portable ultrasound machines for screening asymptomatic people. Before ultrasonography was available lesions were identified by clinical examination, usually when patients presented with symptoms. Now lesions as small as 2 mm can be identified and biopsied. If malignant cells are found, patients are offered thyroidectomy, the rates of which in the US have increased by 60% over the past 10 years. Despite the rise in diagnoses and treatment, the death rate from thyroid cancer has remained stable.²⁶ This suggests that the extra diagnoses and treatments are not reducing morbidity or mortality.

To tackle this example of overdiagnosis we need to understand the natural course of these very small lesions, which may grow too slowly to become symptomatic during the person's lifetime. Are they one end of a spectrum of tumour behaviour ranging from indolent to aggressive, and if so, can we identify which will remain indolent? Or are they a separate pathological phenomenon? What are the relevant histopathological and genomic features that might answer these questions?

Carter et al. *BMJ* 2015;350

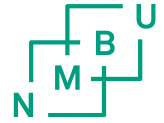
ICRP TG94: The Ethical Foundations of the ICRP System of Radiological Protection

Objective: To develop an ICRP Publication presenting the ethical foundations of the system of radiological protection.

To clarify the rationale for recommendations, to assist in implementation, identify potential conflicts and to provide a basis for communication on radiation risk.

Could this provide insight into the challenges with the Fukushima thyroid screening case?

ICRP TG94: Historical Context

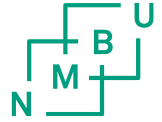


Evolution of the System of Radiological Protection: Science, Ethical Values, and Experience

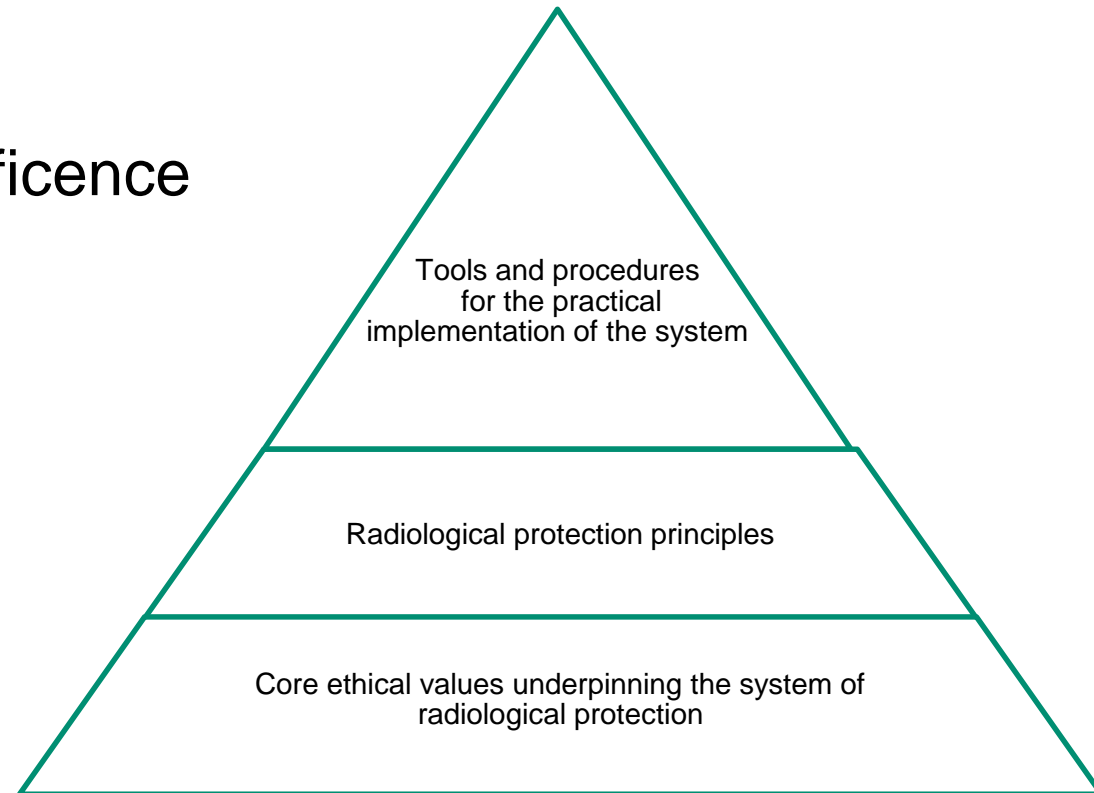
- Influence of scientific developments
- Influence of different applications – medical, energy, accidents, ...
- Influence of changes in societal and cultural attitudes



Four Core Ethical Values Underpinning the ICRP System

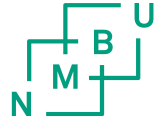


- Beneficence/Non-maleficence
- Prudence
- Dignity
- Justice



ICRP (2016) *The Ethical Foundations of the ICRP System of Radiological Protection*,
Draft out for consultation on www.icrp.org

Beneficence/Non-maleficence (Well-being)

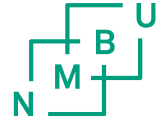


Are we doing more good than harm?

- Will the procedure reduce incidence, severity or mortality related to the disease?
- Overdiagnosis and unnecessary surgery
- Relieving or increasing anxiety?
- Highlights the complexity of balancing benefits and risks

“Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity”
(WHO, 1948)

Prudence

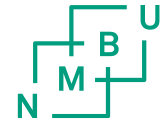


“Prudence is the ability to make informed and carefully considered choices without the full knowledge of the scope and consequences of actions” ICRP 2017, Ethical Foundations....

- Links to precautionary approach
- Should not be taken to be synonymous with zero risk or over conservatism

Thyroid Screening: Careful consideration of the uncertainties and potential negative consequences of surveillance and evaluation of measures to reduce negative consequences

Communication of Screening Results

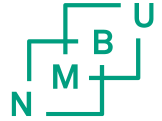


Total number of children whose results are confirmed		FY2011 41,339	FY2012 136,936	FY2013 47,262			
Assessment classification	Assessment result description	Number	Proportion	Number	Proportion	Number	Proportion
A	(A1) No nodules or cysts	26,187	63.3%	74,920	54.7%	20,418	43.2%
	(A2) Nodules 5.0 mm or smaller or cysts 20.0 mm or smaller	14,936	36.1%	61,045	44.6%	26,472	56.0%
B	Nodules 5.1 mm or larger or cysts 20.1 mm or larger	216	0.5%	970	0.7%	372	0.8%
C	Immediate need for secondary examination	0	0.0%	1	0.001%	0	0%

Initially: results sent by mail



Midorikawa et al 2016. *Asia Pacific Journal of Public Health*



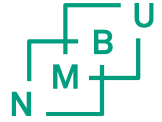
Fukushima: Uncertainty is the new norm

Living with the 'known unknowns' for three years is taking its toll on residents near the damaged Daiichi



*«... a panel of prefectural workers, physicians with Fukushima Medical University and the national health insurance company each presented their findings [on thyroid screening]. **There seemed to be some confusion as to what they were looking for and what they had found, and, indeed, why they were looking for it in the first place»***

Dignity and Autonomy



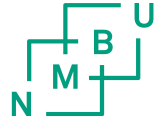
Screening (in part) responds to requests from parents – it recognises their autonomy

But:

- Free Informed Consent of Children – participation was not always seen to be voluntary
- Privacy and confidentiality issues
- Screening for reassurance, epidemiology, research ??



Justice and Fairness



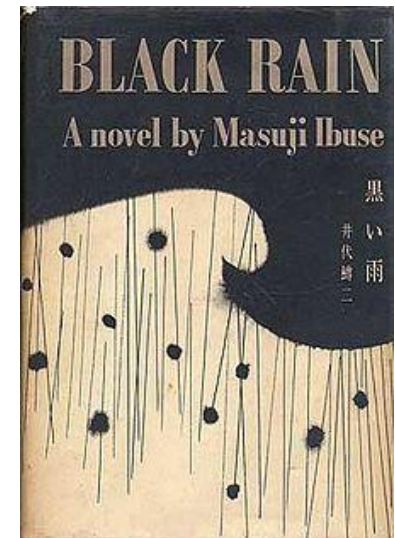
Distributive Justice - Fairness in the distribution of advantages and disadvantages among groups of people

Procedural Justice – Fairness in the rules and procedures in the processes of decision making

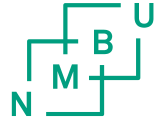
Screening recognises vulnerability of children

But:

- Risk of stigma and discrimination – both from participation or non-participation
- Challenges with the selection of participants – location, not dose; control groups
- Limited stakeholder participation in screening planning



Practical Recommendations



Transparency

- Clarity on expectations and purpose of screening
- Clarity on voluntariness of screening
- Communication strategy for participants, media, public health officials, ...

Stakeholder Engagement – in design of screening programmes

- Critical for success and legitimacy of screening programmes
- Who: medical and public health professionals, community representatives, parents, schoolchildren, public, ...

Full Shamisen recommendations:
www.isglobal.org/en/-/shamisen



Thank You!

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