# Considerations on risk-benefit analyses in medical radiation usage

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http://www.lifescanuk.org/our-health-checks/vital-check-new (9.6.2014)

## As seen on TV

## Our locations

With 30 locations around the UK, a Lifescan centre is never very far away.

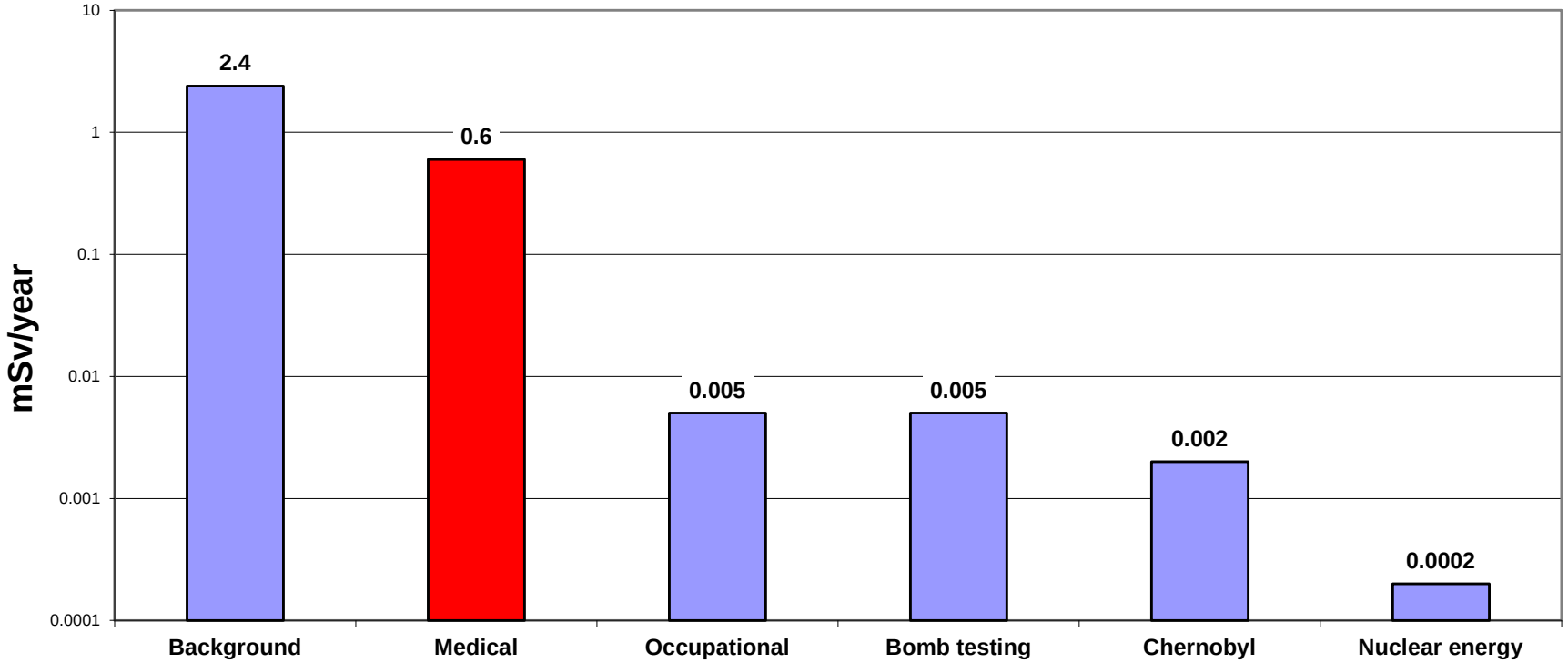
Enter UK postcode

### Do I need a referral from my doctor to have a Lifescan health check?

Generally speaking, no - although we do need to check that you are eligible for the appointment you hav selected against our Clinical Referral Criteria. For those who require a specialised scan (ie not a Lifesca health check) it will be necessary to obtain a referral letter from a GP or Consultant highlighting why the scan is being recommended.

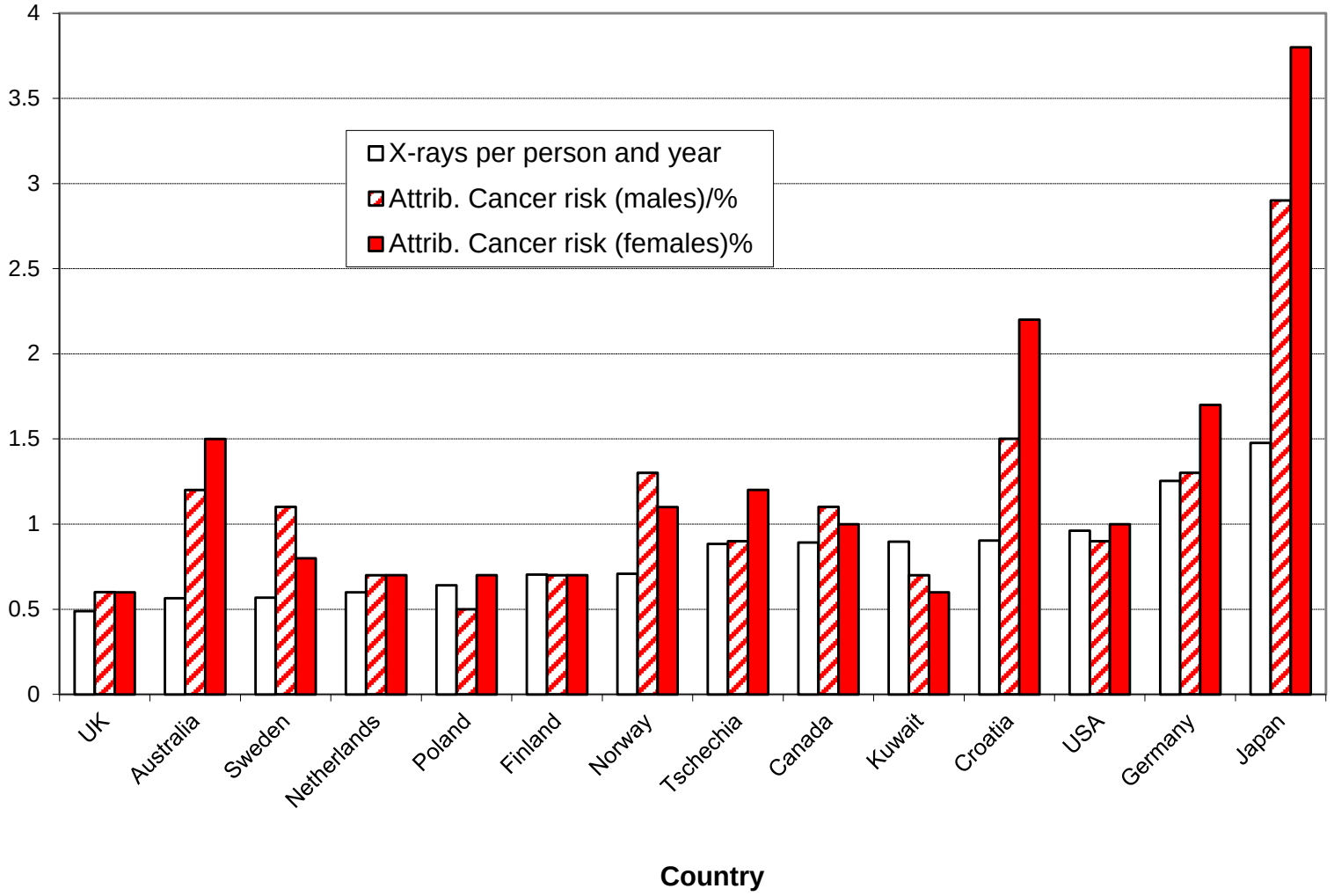
http://www.lifescanuk.org/ (9. 6. 2014

# Average yearly per capita doses worlwide




UNSCEAR 2008 Report Vol. I

## X-ray frequency and attributable cancer risk in different countries (2003)




Berrington de González A, Darby S. Lancet 363(9406):345-51 (2004)

# Risk and benefit

- Population exposure by medical procedures is the second largest contribution of the worldwide radiation load, considerably more than those by nuclear accidents or by the use of nuclear energy.
- Medical radiation usage is a very important tool for diagnosis and treatment of many lifethreatening diseases and possesses a **clear benefit**.
- But there is also undisputably a considerable **health risk.**
- The decision which risk may be acceptable under specific circumstances is not only a technical but even more an ethical issue.

# Oath of Hippocrates

I will prescribe regimens for the good of my patients according to my ability and my judgment and never do harm to anyone. (Hippocrates)

***What is the reality?***

# What does that mean for radiation usage in medicine?

- There are no dose limits for patients
- It is the ethical obligation of the medical doctor to supply the best possible treatment with the lowest achievable risk.
- The patient must receive comprehensive information about benefits and risk taking into account his individual heath situation based on best available scientific evídence.
- This can only be achieved if the doctor is familiar with present state of knowledge.

# Medical radiation usage: Ethical considerations

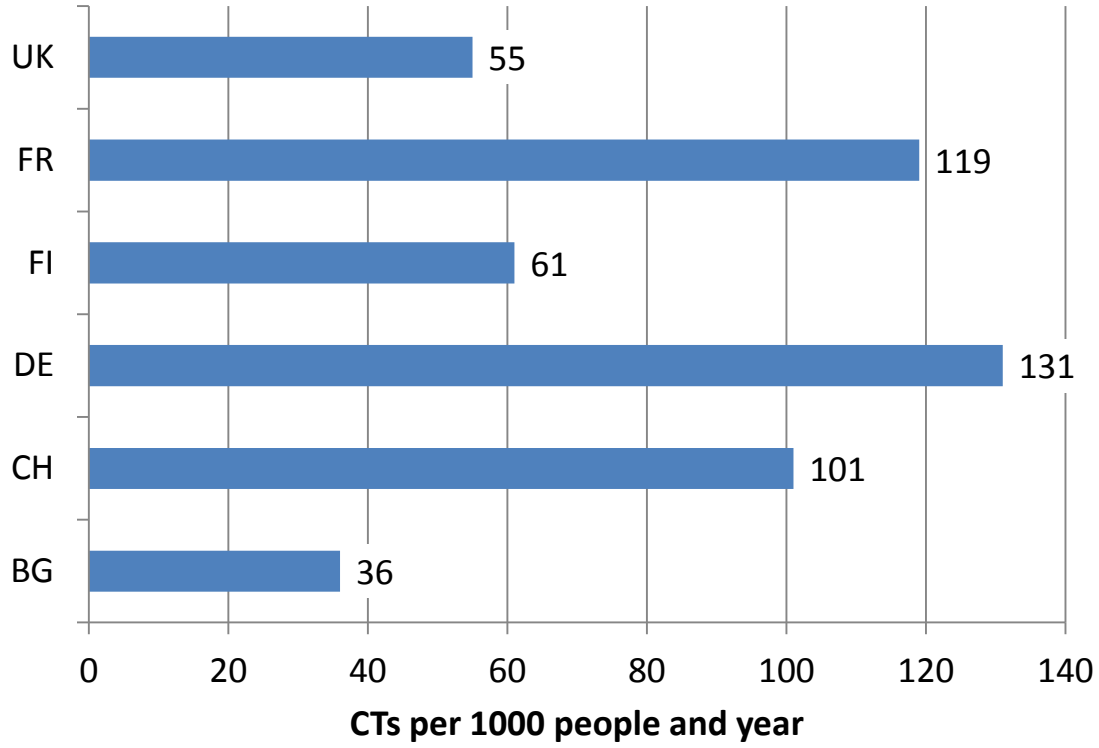
- The patient is entitled to the best diagnosis or treatment
- Decisions have to be based on medical considerations only, never on economical arguments
- Every exposure has to be individually justified. The justification has to take into account the individual situation (health status, age, gender..)
- „Informed consent“ by the patient is mandatory. It requires extensive information on risk and benefit by a knowledgeable physician.
- Anxieties of the patient are to be taken seriously and discussed in detail.

# Medical exposures in Europe and the US

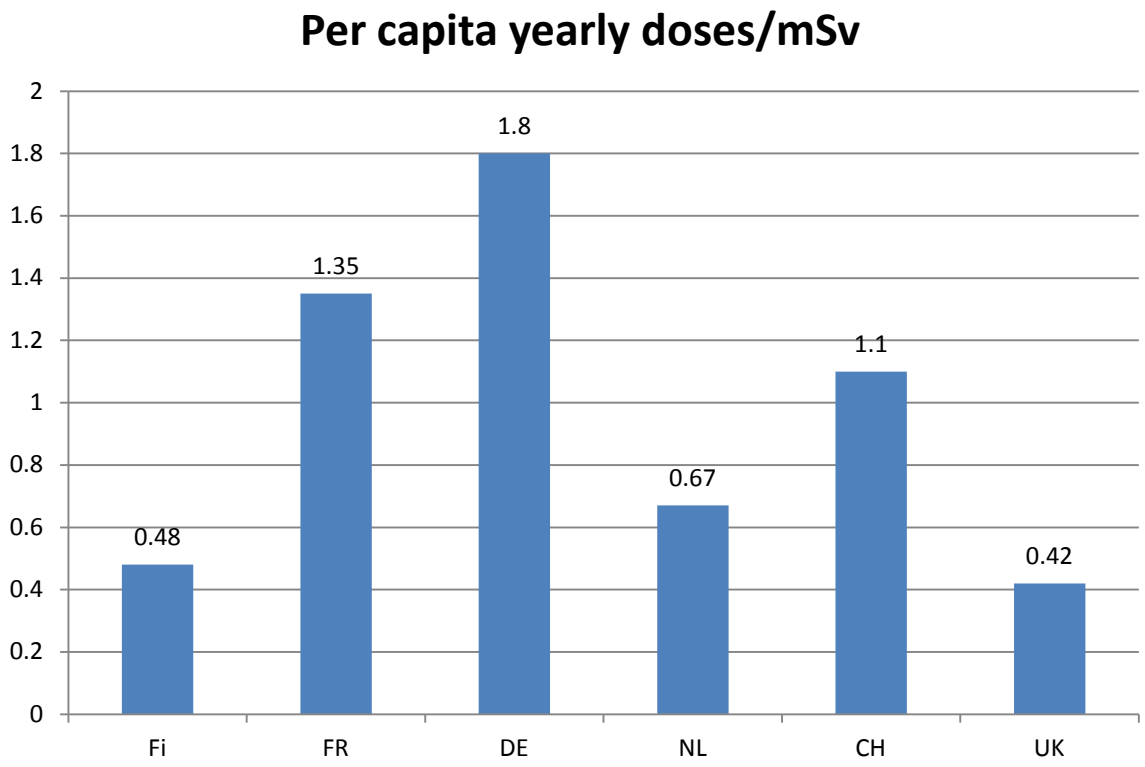
# Radiography in Europe

| Country | Total plain radiography per 1000 population | Total dental procedures per 1000 population | % of dental from total plain radiography |
|---|---|---|---|
| BG | 434 | 62 | 14,4 |
| CH | 1533 | 692 | 45,1 |
| DE | 1248 | 391 | 31,4 |
| FI | 1120 | 469 | 41,9 |
| FR | 1003 | 294 | 29,4 |
| UK | 668 | 204 | 30,5 |
| Mean | 1001 | 352 | 32,1 |

# CT-examinations in Europe (2008)

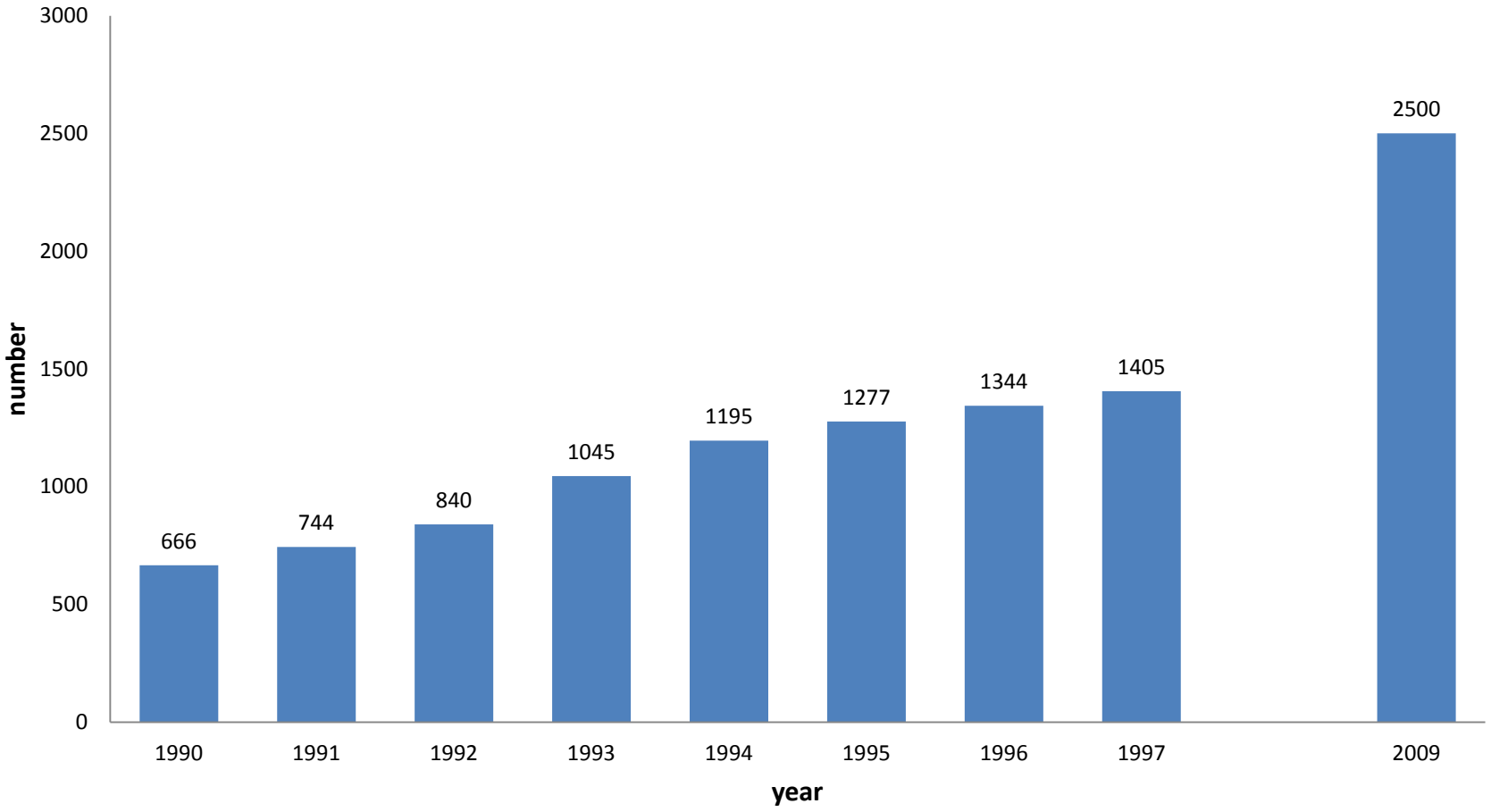


# European Comparison: Average per capita doses by medical applications

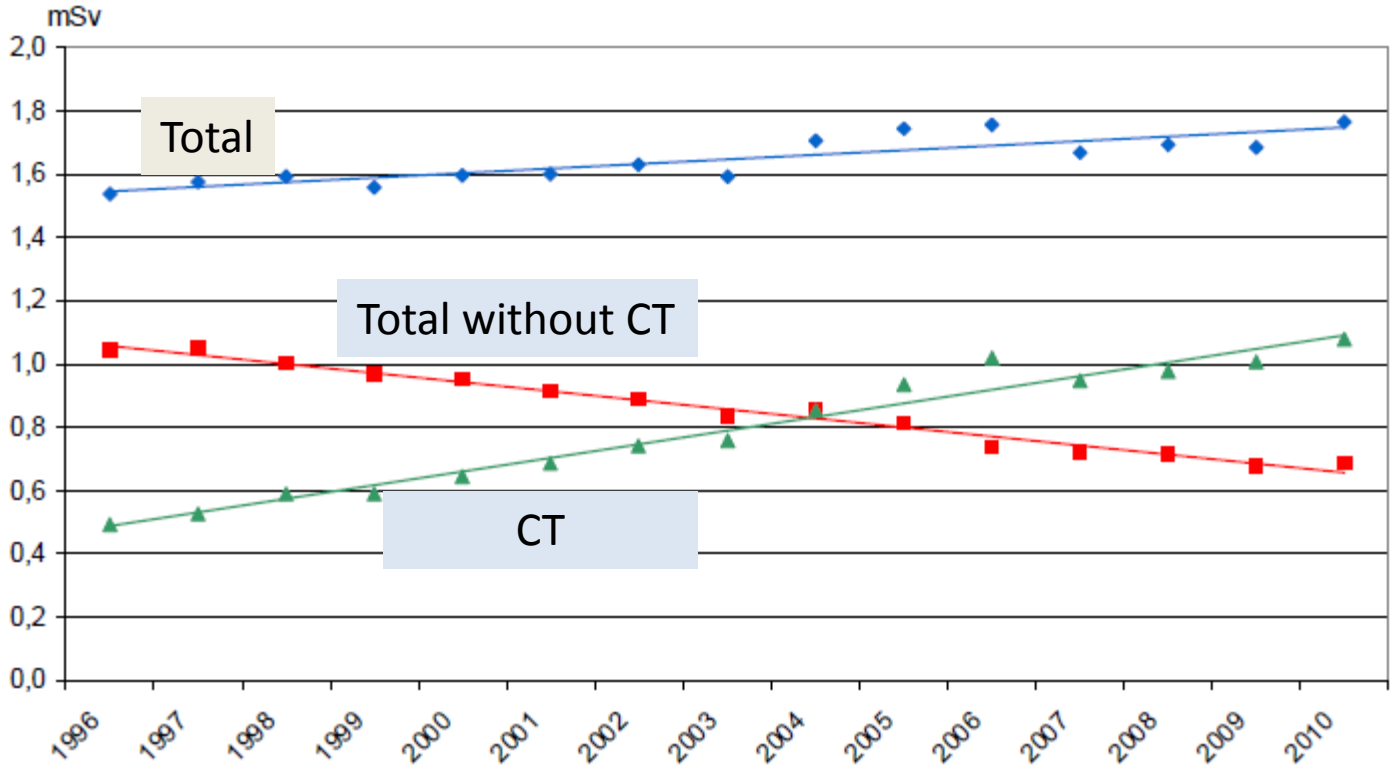


# Germany

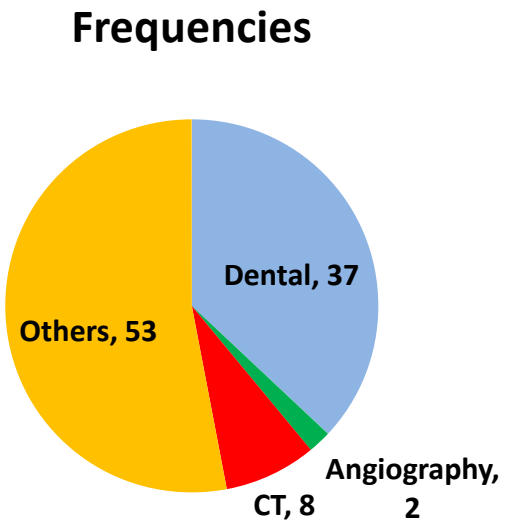
# CT equipments in Germany

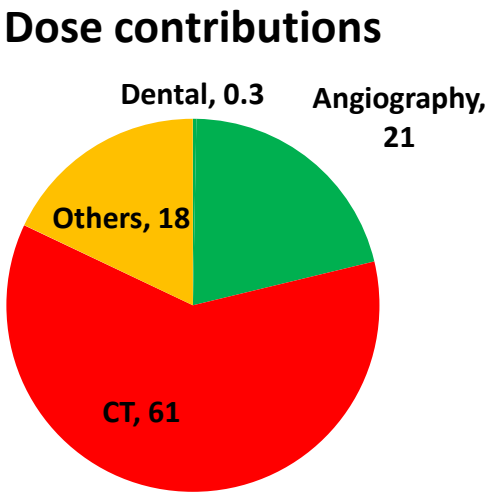


# Per capita doses in Germany

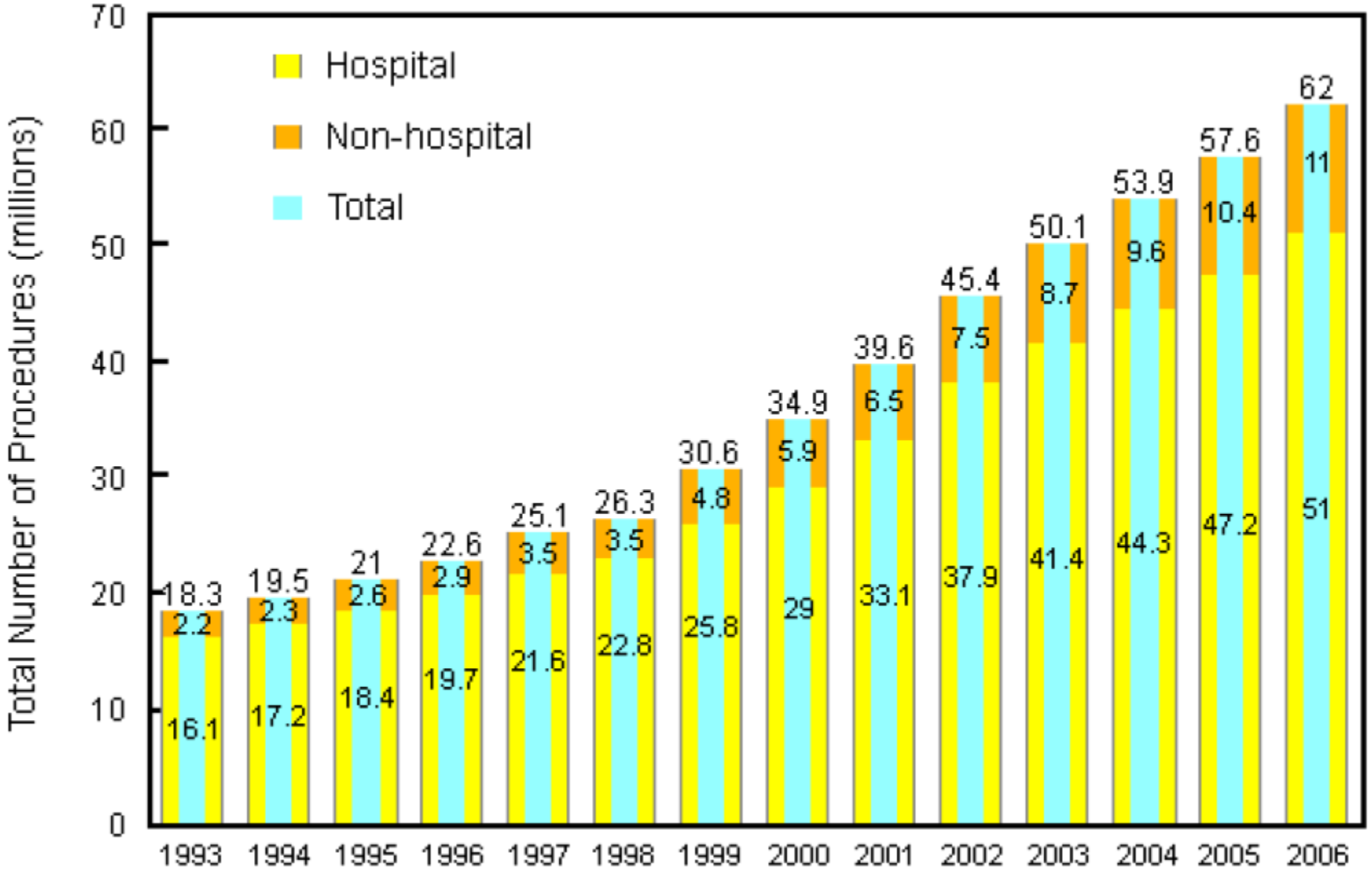


# Distribution of radiological examinations in Germany 2010 (%)



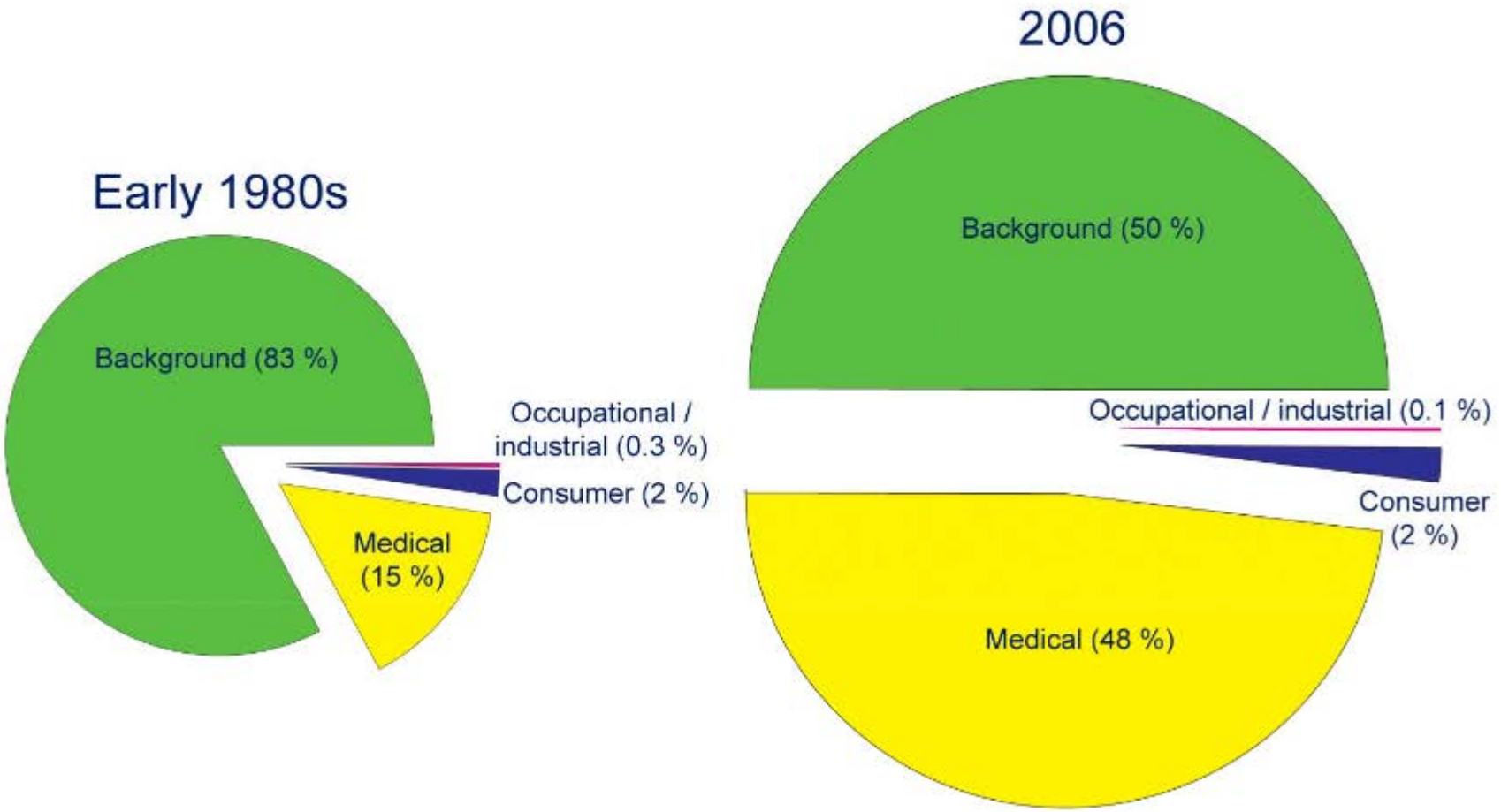



# United States




http://www.ncrponline.org/PDFs/2012/DAS_DDM2_Athens_4-2012.pdf (9.6.2014)

# NCRP Report No. 160, *Ionizing Radiation Exposure of the Population of the United States*




http://www.ncrponline.org/PDFs/2012/DAS_DDM2_Athens_4-2012.pdf (9.6.2014)

- There is a clear tendency to replace plain radiography by CT-scans.
- On an average in this case the patient dose is higher by a factor 10.
- There is also a ten times higher risk.

# Justification

- Every radiation exposure of humans has to be justified.
- In the case of medical application justification is to be based on the specific conditions of the person involved.
- **Different from current practice the use of techniques involving high exposures (e. g. CT-scans) should require an additional special justification** (not yet a part of current legislation)

# The view of ICRP

- The aim of managing radiation exposure is to minimise the putative risk without sacrificing, or unduly limiting, the obvious benefits in the prevention, diagnosis and also in effective cure of diseases (optimisation).

- It should be pointed out that when too little radiation is used for diagnosis or therapy there is an increase in risk although these risks are not due to adverse radiation effects per se. Too low an amount of radiation in diagnosis will result in either an image that does not have enough information to make a diagnosis and in radiation therapy, not delivering enough radiation will result inincreased mortality because the cancer being treated will not be cured.

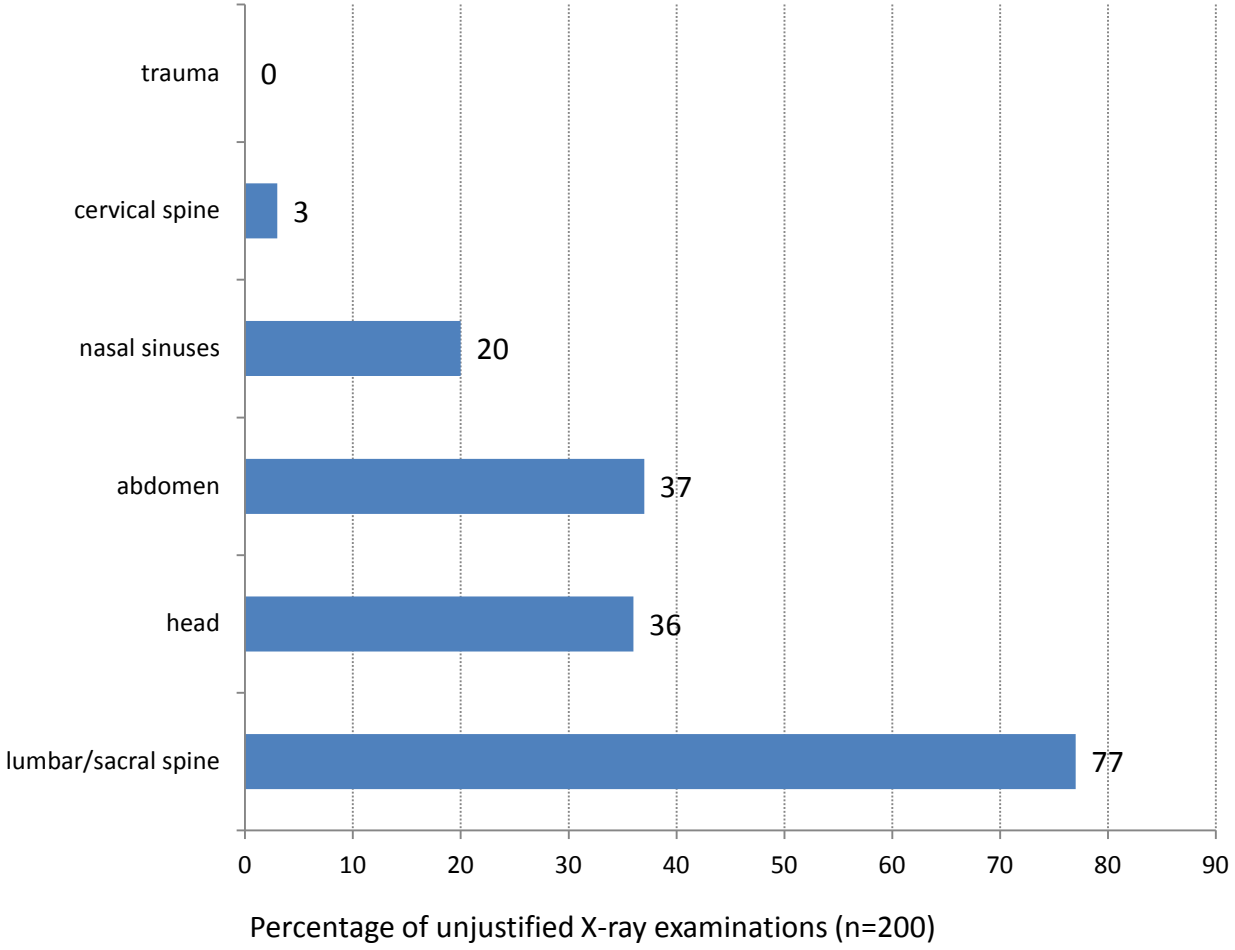
***What is the reality?***

# EU directive 2013

- Member States shall ensure ……..

  …. that all individual medical exposures are justified in advance taking into account the specific objectives of the exposure and the *characteristics of the individual involved*

# Unjustified X-rays in young patients- an example from Finland




Oikarinen et al. Unjustified CT examinations in young patients. Eur Radiol. 19:1161-1165(2009)

Is there a neglegible risk?

# No risk of dental radiology?

Table II. Association between exposure to dental x-rays and risk of thyroid cancer.

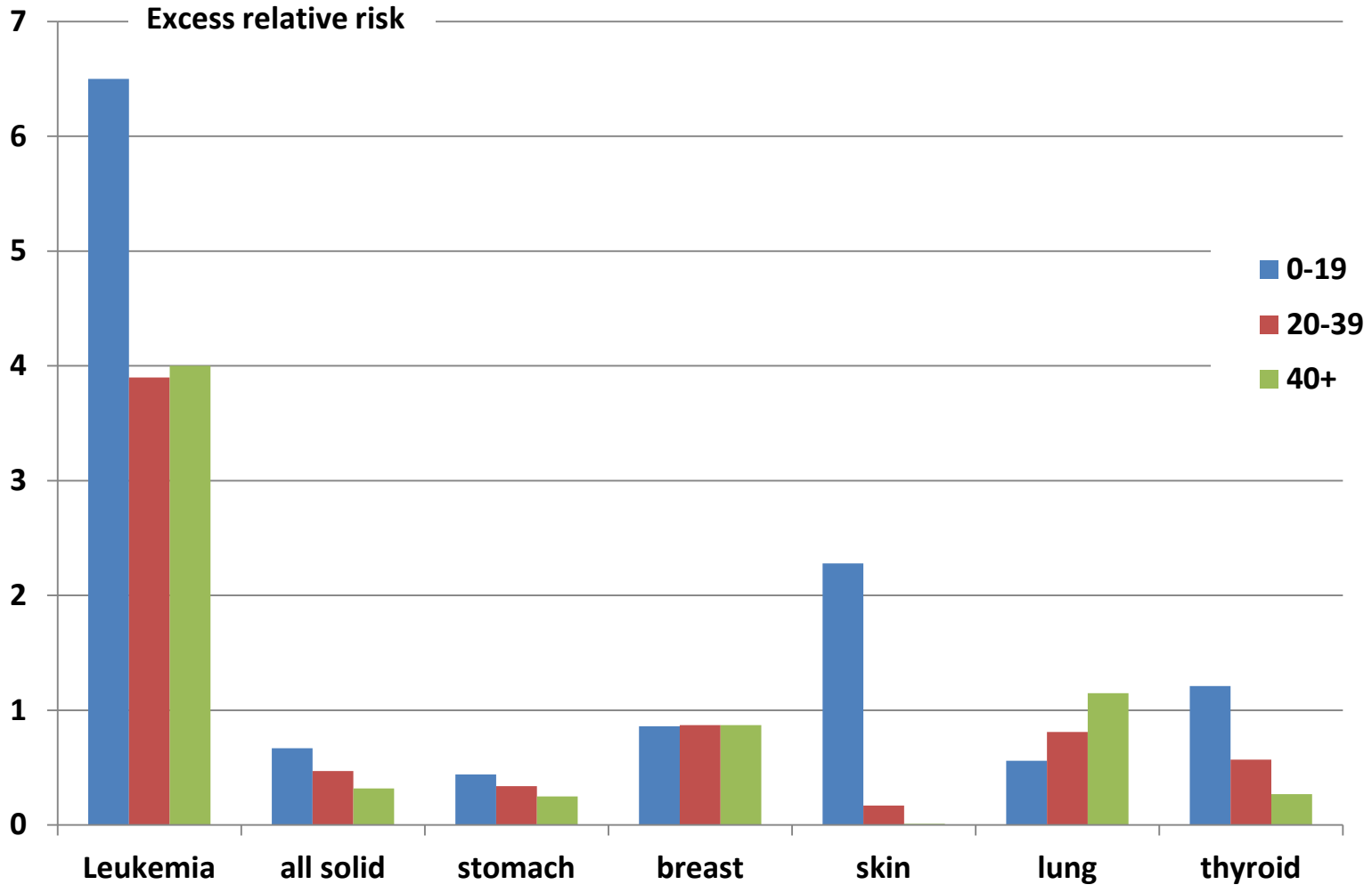
| | Case/Control | Cases % | Controls % | OR | 95% CI | P-value |
|---|---|---|---|---|---|---|
| Dental x-ray | | | | | | |
| No | 208/255 | 66.7 | 81.7 | 1.0 | – | |
| Yes | 104/57 | 33.3 | 18.3 | 2.1 | 1.4–3.1 | 0.001 |
| Number of dental x-rays | | | | | | <0.0001* |
| 1–4 | 75/43 | 72.2 | 75.4 | 2.2 | 1.4–3.5 | 0.001 |
| 5–9 | 16/4 | 15.4 | 7.0 | 4.6 | 1.4–14.7 | 0.01 |
| 10+ | 11/3 | 10.6 | 5.3 | 5.4 | 1.1–26.7 | 0.037 |

Memon et al. Dental x-rays and the risk of thyroid cancer: a case-control study. Acta Oncol. 49:447-53 (2010)

# Special groups

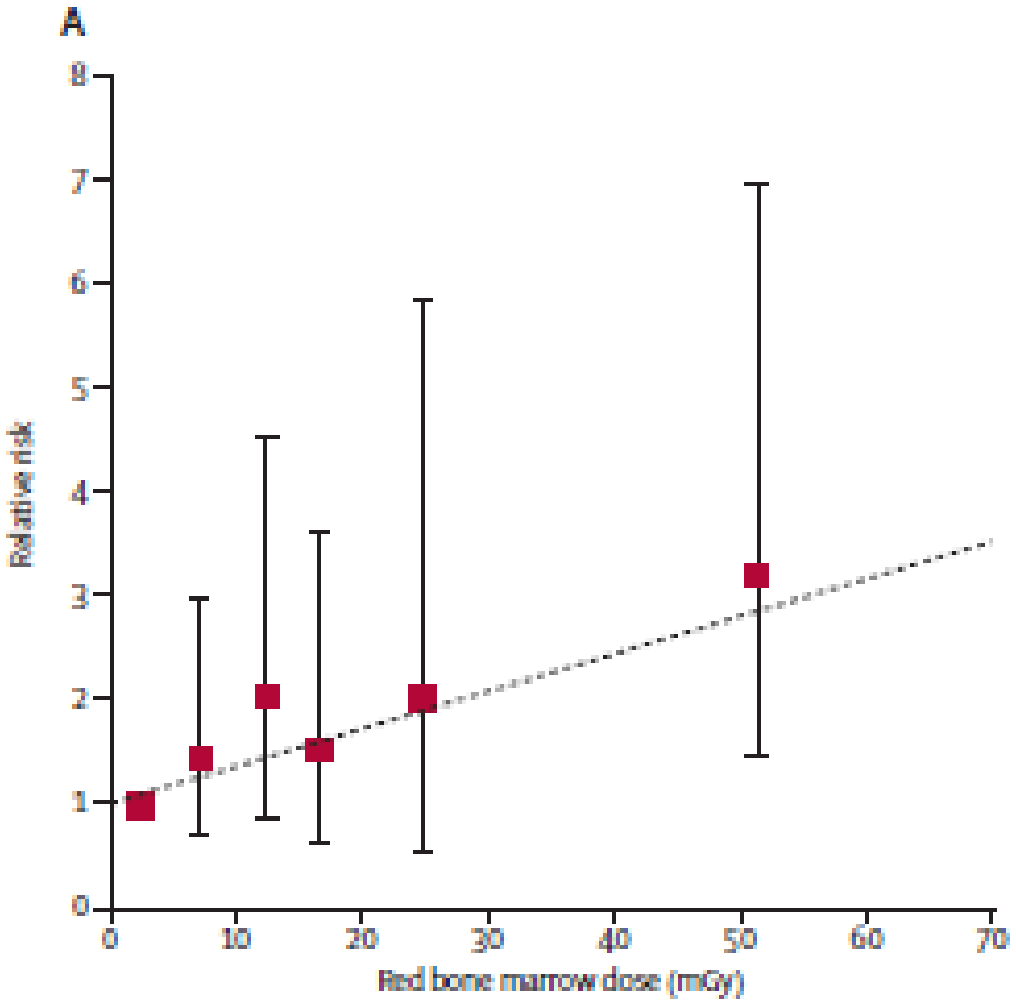
The (very) young

# Incidences of radiation induced tumours for different ages at exposure



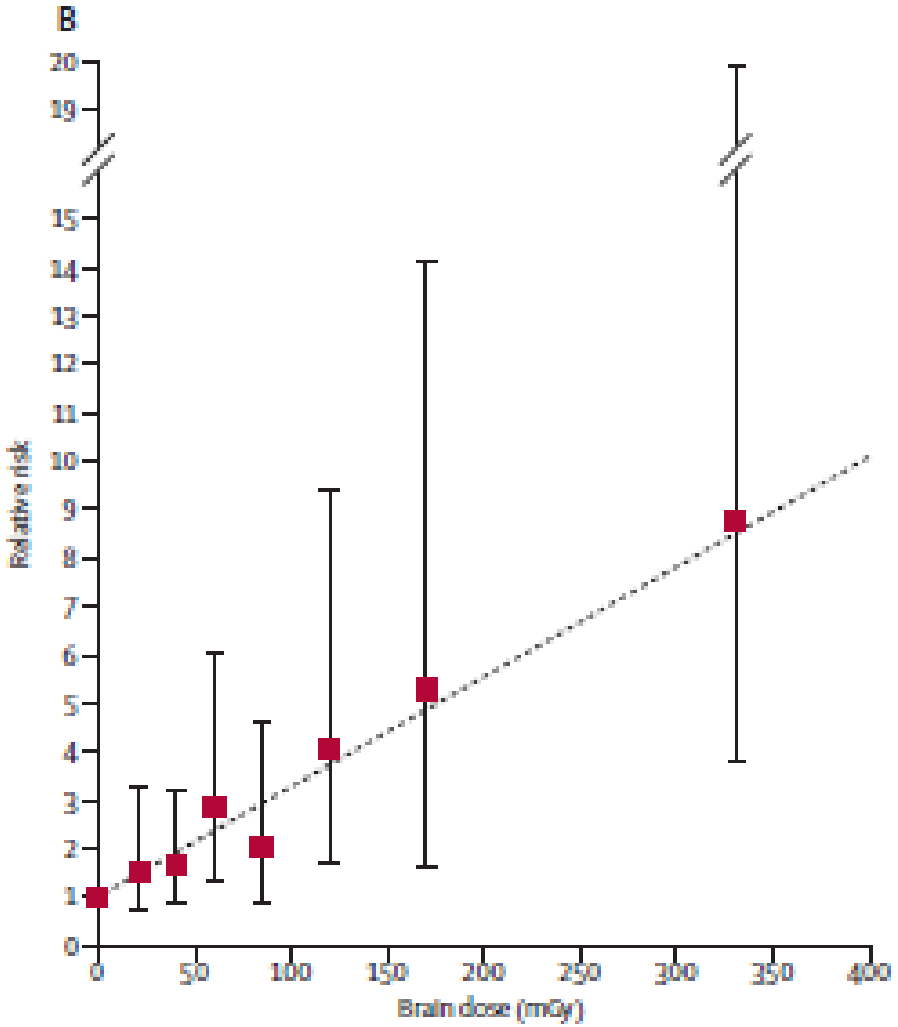

UNCEAR 2013 Report Vol. II

# Excess relative risk of children leukemia due to CT-examinations




Radiation exposure from CT scans in childhood and subsequent risk of leukaemia and brain tumours: a retrospective cohort study. Pearce, M. S. et al. Lancet 2012: 380, 499-505

# Excess relative risk of children brain tumours due to CT-examinations




Radiation exposure from CT scans in childhood and subsequent risk of leukaemia and brain tumours: a retrospective cohort study. Pearce, M. S. et al. Lancet 2012: 380, 499-505

# Special groups

The elderly

# Age distribution of medical exposures in Germany 2007

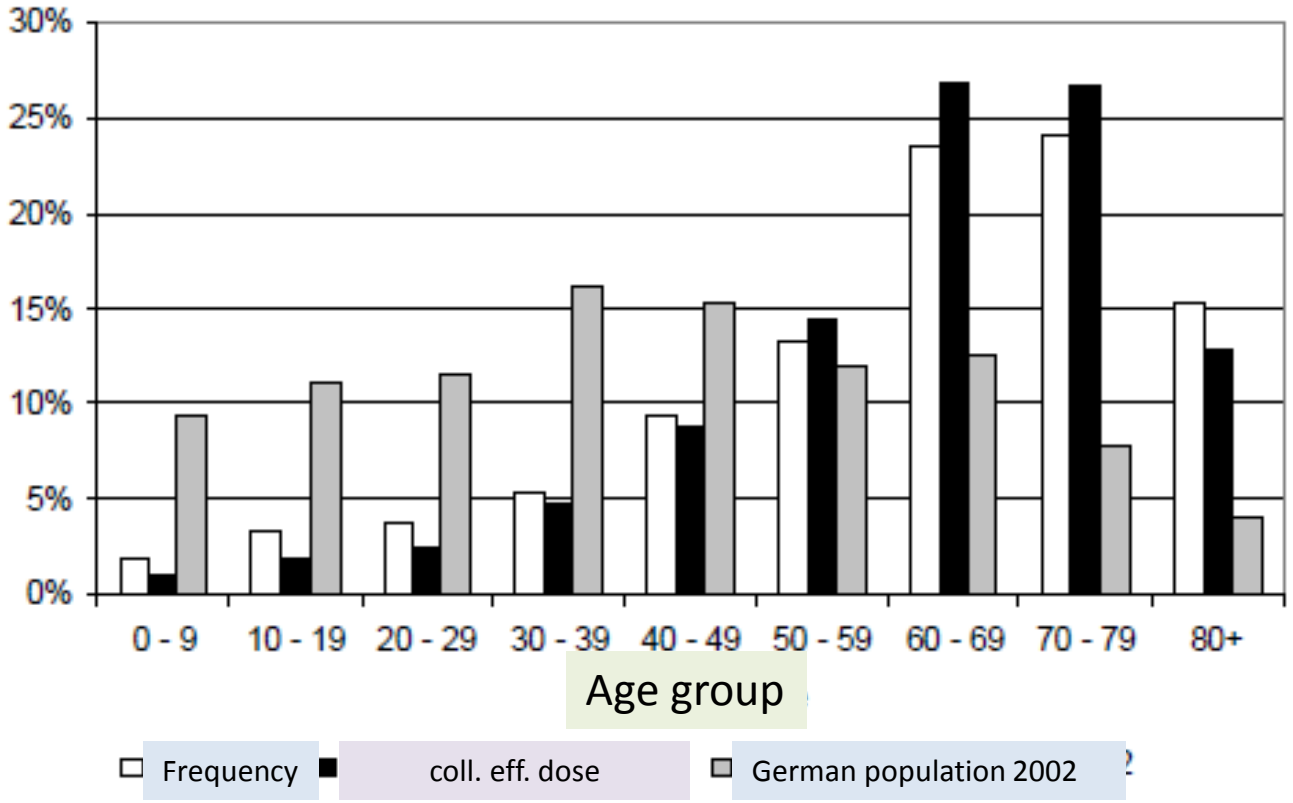


**TABLE 2: Comparison of the Estimated Number of Radiation-Related Cancers With the Number of Colorectal Cancers Prevented by CT Colonography (CTC) Screening Every 5 Years per 100,000 by Microsimulation Model and Age at Screening**

| Microsimulation Model and Age (y) at Screening | Average No. of Screenings per Person | No. of Colorectal Cancers Prevented per 100,000 Persons Screened | Radiation-Induced Cancer Incidence | | Benefit-Risk Ratio (Prevented:Induced) | |
|---|---|---|---|---|---|---|
| | | | Per 100,000 Persons Screened | 95% Uncertainty Interval | Per 100,000 Persons Screened | 95% Uncertainty Interval |
| MISCAN | | | | | | |
| 50–80 | 3.5 | 3580 | 150 | 80–280 | 24:1 | 13:1–45:1 |
| 40–80 | 4.5 | 3740 | 230 | 110–410 | 16:1 | 9:1–34:1 |
| 65–80 | 2.0 | 2700 | 60 | 30–100 | 45:1 | 27:1–90:1 |
| 50–64[a] | 2.3 | 880 | 120 | 70–220 | 7:1 | 4:1–13:1 |
| 40–49[b] | 1.8 | 160 | 110 | 50–210 | 1.5:1 | 0.8:1–3:1 |
| CRC-SPIN | | | | | | |
| 50–80 | 3.5 | 4780 | 150 | 80–280 | 32:1 | 17:1–60:1 |
| 40–80 | 4.5 | 5000 | 230 | 110–410 | 22:1 | 12:1–45:1 |
| 65–80 | 2.0 | 4010 | 60 | 30–100 | 67:1 | 40:1–134:1 |
| 50–64[a] | 2.3 | 770 | 120 | 70–220 | 6:1 | 4:1–11:1 |
| 40–49[b] | 1.8 | 220 | 110 | 50–210 | 2:1 | 1:1–4:1 |
| SimCRC | | | | | | |
| 50–80 | 3.5 | 5190 | 150 | 80–280 | 35:1 | 19:1–65:1 |
| 40–80 | 4.5 | 5680 | 230 | 110–410 | 25:1 | 14:1–52:1 |
| 65–80 | 2.0 | 3390 | 60 | 30–100 | 57:1 | 34:1–113:1 |
| 50–64[a] | 2.3 | 1800 | 120 | 70–220 | 15:1 | 8:1–26:1 |
| 40–49[b] | 1.8 | 490 | 110 | 50–210 | 4:1 | 2:1–10:1 |

Note—Radiation risks from screening individuals 40–49, 50–64, and 65–80 years old do not equal the sum of the risks from screening individuals 40–80 or 50–80 years old because the total number of CTC screening examinations performed differs.

[a]Additional benefit-risk from CTC screening individuals 50–64 years old assuming screening continues at ages 65–80.

[b]Additional benefit-risk from CTC screening individuals 40–49 years old assuming screening continues at ages 50–80.

Berrington de González et al. Radiation-related cancer risks from CT colonography screening: a risk-benefit analysis. AJR Am J Roentgenol. 196:816-23 (2011

# Interim conclusions

- Children and young people are more sensitive and they have a longer life ahead of them. Justification has to be very careful, examinations not absolutely necessary are to be avoided.
- With elderly people the exact diagnosis is often more important than the (then smaller) risk- Justification has to concentrate on diagnostic aspects (but has still to be very careful!)

# Radiation therapy

- Radiation therapy is a powerful method for the treatment (and often cure) of cancer. But severe side-effects may occur which can be considerably reduced by modern techniques (e. g. intensity modulated beams, image guided exposure, particle therapy)
- Not to apply these methods because modern equipment is not available on site is not acceptable.
- In order to receive the best possible treatment patients have to be referred to specialised centres.

# „Informed consent“

- Patients have to be comprehensively informed about radiation risks taking into account the particular application and their personal health status.
- Doctors have to be aware of the current scientific state of knowledge concerning biological and medical radiation effects.
- This requires continuous familiarisation with the scientific literature in regular courses.

# Patient anxiety

- Many patients are afraid of radiation applications although the may be of considerable benefit for them.
- Doctors have to take these anxieties serious and inform in great detail about the pros and cons to build up trust.
- This can only be achieved if the doctors have a solid scientific background in the field.

# Final resumé

- Radiation applications constitute an indispensable and essential part of modern medicine.
- Radiation is dangerous and should be used only on the basis of the best available scientific evidence and with the most advanced technical equipment.
- Doctors must be aware of the current state of risk-benefit estimates to inform patients in a comprehensive way taking into account also their potential anxieties.
- **Radiology is a science, possibly an art, but must never degenerate to a business**