Research needs, requirements for good quality studies and challenges; policy implications

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summary of evidence and limitations

- From 1956 to present epidemiological studies linked diagnostic x-rays with cancer increase in patients:
  - *in utero* exposure – continued debate whether 10 mGy could give rise to cancer; additional follow up is needed
  - Children – ambivalent results perhaps due to some methodological limitations and not sufficiently long follow-up to assess risks in adulthood;
    new CT studies are trying to address limitations in dosimetry
  - Adults - dose response associations with breast cancer, limited evidence for CML, limited number of studies, small size; no studies on newer technologies (e.g. CT)
  - Imaging healthy patients (screening) – need for careful assessment since most of the screened patients will not develop the disease of interest: benefit vs. risk approach

summary of evidence and limitations (2)

- Dose response for cancer risks associated with radiotherapy is similar to A bomb survivors but the ERR/Gy is lower likely due to cell killing; complete information on competing treatment modalities is not always available; pooling of existing cohorts in Europe, particularly childhood cancer survivors, would be desirable to address exposure in childhood issue
- For newer treatment modalities (e.g. proton therapy, IMRT) – patients' registries are needed for setting up studies in the future
- Genetically susceptible populations with radiation sensitivity – populations are small, it is essential that future studies are large in size to adequately address variation in demographic factors and include high-quality radiation exposure information

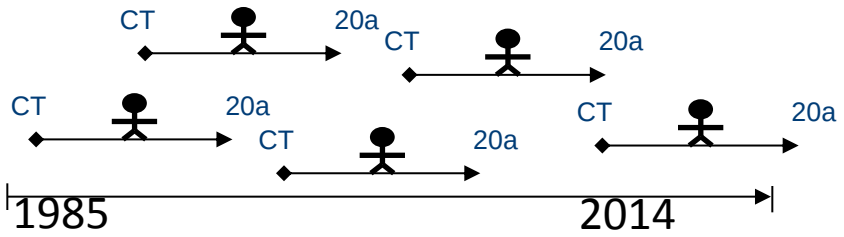
requirements for good radiation studies and challenges

- Large populations (e.g. children with CT scans)
- Non-differential and sufficiently long follow-up through disease registries (cancer and non-cancer)
- Good dosimetry (complete information on all diagnostic procedures = registry/patient's dose passport would be helpful)
- Information of confounding factors (e.g. indication for diagnostic procedure, etc.- not always available)
- Good quality of diagnosis
- Multidisciplinary approach to elucidate mechanisms behind the low does radiation effects

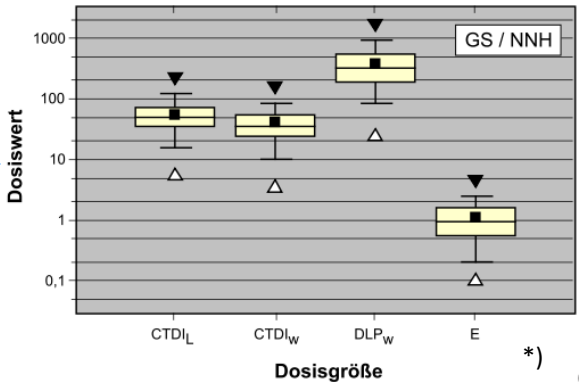
EPI-CT study: overall design

Slide courtesy of L. Krille

1. cohort study



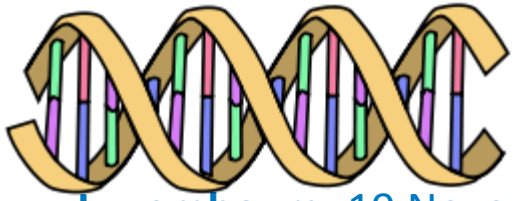
2.: dosimetry study (individual organ doses) and optimization strategies



EPI-CT

http://epi-ct.iarc.fr/

3.: biological pilot study



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World Health Organization

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future plans and lessons learned

- Need for assessment of uncertainties in doses and their impact on risk estimates
- Coordination with ongoing and planned studies outside Europe – future pooling envisaged
- Development of a user-friendly tool for evaluating organ dose from paediatric CT, in collaboration with the US NCI
- Contribution to dose optimization strategies
- Full scale study of biomarkers of radiation sensitivity
- Continuous follow-up (subject to funding):

  After EPI-CT results on childhood leukaemia and all cancers become available in 2016, plans for studying other outcomes (meningiomas, cataracts, cardiovascular disorders, school performance…)

- ***Need for harmonization of ethics guidelines across Europe***