Benefit/(Radiation)Risk in Medical Radiological Diagnosis and Intervention

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Objectives:

•To define and to quantitate risk associated with medical imaging in the presence of:

1. Uncertain risk estimates
2. Differing patient populations (age, sex, life expectancy)

•To review different levels of benefit.

•To explore creative ways to assess benefit-risk or to demonstrate how dose reduction improves benefit-risk.

HANDOUTS CAN BE DOWNLOADED FROM:

http://www.uth.tmc.edu/radiology/presentations/

Benefit

Benefit = the positive effect on medical status

- Preventing certain death
- Preventing unnecessary interventions
- Defining necessary interventions
- Easing or preventing pain and suffering
- Hastening recovery
- Making physicians more confident in diagnosis
- Defining termination of medical care

CT Screening for Lung Cancer

Spiraling Into Confusion?

William C. Black, MD
John A. Baron, MD

IN THIS ISSUE OF *JAMA*, BACH ET AL[1] REPORT THEIR ANALYsis of computed tomographic (CT) screening for lung cancer based on 3 single-arm studies, those from the In-

pants. To assess the effectiveness of CT screening, they then compared the observed numbers of lung cancer outcomes with the numbers of expected cases. They observed more than a 3-fold increase in the number of new lung cancer cases (144 observed vs 44.5 expected) and a 10-fold increase in lung cancer resections (109 observed vs 10.9 expected). However, there was no decrease in advanced lung cancer cases (42 observed vs 33.4 expected) or in lung cancer deaths (38 observed vs 38.8 expected).

- **This study finds no change in mortality**

cent International Early Action Lung Cancer Program (I-ELCAP),[2] which reported that low-dose CT screening resulted in a 10-year survival of 88% for patients with stage I disease. The investigators argued that CT screening of high-risk individuals could prevent 80% of lung cancer deaths.

- **This study says screening CT can save up to 80% of deaths**

How is it possible that 2 large studies published within 6 months of each other could lead to such dramatically different conclusions about the effectiveness of CT screening? For a cancer that accounts for more deaths than the 4 next most deadly cancers combined,[3] one group of investigators[1] suggests that CT screening will have no effect on mortality, while the other group[2] suggests that the intervention will reduce mortality by 80%. At least 5 possible ex-

- **Editorial asks - how can two studies be so different?**

What is Radiation Risk

- Induced medical detriment to patient
  - Neoplasm
  - Malignancy
  - Mortality
  - Other

- Induced detriment to progeny
  - Genetically heritable effect
  - Gestationally induced malformation or cancer

The British Journal of Radiology, *76* (2003), 309–320
DOI: 10.1259/bjr/64009424

Analysis of benefit:risk ratio and mortality reduction for the UK Breast Screening Programme

[1]J R BECKETT, PhD, [1]C J KOTRE, PhD and [2]J S MICHAELSON, PhD

[1]*Regional Medical Physics Department, Newcastle General Hospital, Newcastle-upon-Tyne NE4 6BE, UK and* [2]*Departments of Pathology and Radiology, Massachusetts General Hospital and Department of Pathology, Harvard Medical School, Boston, MA, USA*

Abstract. A quantitative analysis has been performed to predict the benefit:risk ratio and associated mortality reduction for the UK National Health Service Breast Screening Programme. The analysis is based on the results of an established biological simulation method coupled with dosimetric information and population statistics applicable to the UK breast screening programme. As well as the general breast screening population, the benefit:risk ratios for specific subgroups of women thought to be at higher risk are estimated. The effects of alterations in screening strategy are also investigated. The results indicate favourable benefit:risk ratios and mortality reductions for all women in the programme, with a breast cancer mortality reduction of approximately 9% over the whole UK female population, equivalent to a breast cancer mortality reduction in the region of 25% for the age range 55–69 years.

Things not considered:

- False positive rate and impact on women
- Biopsy rate and impact on women
- Increased or decreased quality of life
- Cost

Terms to Know

aka Buzz Words

- Benefit/Risk => Justification
- ALARA => Optimization

- **U.S. Residents' Exposure to Medical Radiation 6 Times Higher than in 1980** presented by Dr. Fred A. Mettler, Jr., National Council on Radiation Protection & Measurements (NCRP), April, 2007

U.S. Residents' Exposure to Medical Radiation is infinitely Higher than in 1895

- **Without medical radiation we would have zero benefit with zero radiation risk.**
- **At what point is the benefit/risk at its greatest and increasing medical radiation to the population starts to decrease benefit/risk?**

- **1895 – 0 mSv to population**
- **1980 – 0.54 mSv to the population**
- **2007 – 3.2 mSv to the population**

The British Journal of Radiology, 80 (2007), 639–647

Effective dose: how should it be applied to medical exposures?

C J MARTIN, PHD, FIOP, FIPEM

- E may be used as a generic indicator related to the risk of health detriment to a reference patient for classifying different types of medical procedure into broad risk categories: low, very low, minimal and negligible

What is the real issue?

- The real issue is: How should we behave in light of the fact that we cannot know everything about radiation risk?

Counterproductive Mantra

- **There is no safe dose!**

- There is no safe:
  - Hot dog
  - Steak
  - Vegetable
    - In 2000, 160 children ages 14 years or younger died from an obstruction of the respiratory tract due to inhaled or ingested foreign bodies. Of these, 41% were caused by food items and 59% by nonfood objects (CDC, unpublished data).
  - Shower
  - Bath tub
  - House
    - Years of life lost due to unintentional falls: 66,250 YPLL 2005 (CDC)
  - Swimming pool
    - Years of life lost due to unintentional drowning: 114,212 YPLL 2005 (CDC)

What is Safe?

- <u>Nothing</u> is <u>completely</u> safe
- Safety is a matter of making something far more beneficial to life than the risks imposed on our well-being by the action:
  - Drinking purified water rather than non-purified water;
  - Driving or flying to this meeting;
  - Pumping gasoline into your car;
  - Placing friction mats in a bathtub with hand supports to hold onto while getting up and down and in and out;
  - Keeping medicines out of the reach of children and in child-proof containers while providing the medicine for improved health;
  - Securing swimming pools from unintentional intrusion
  - **Keeping exposures to medical X rays to levels sufficiently low to provide necessary medical care without excess.**

- Benefit/Risk > 1 is necessary (Justification) but not sufficient

- Must apply ALARA (Optimization)

What is the real issue?

- The real issue is: How should we behave in light of the fact that we cannot know everything about radiation risk?

Remember radiology's response to risk from scoliosis x-rays? Here's some history ---

1. **We learned that multiple scoliosis studies might increase risk for thyroid and breast cancers.**
2. **Mayo Clinic recommended doing studies PA to reduce dose to breasts and thyroid**
3. **Afterwards, NCI and others found that earlier scoliosis radiography did increase cancers**
4. **Conclusion – Mayo's recommendation had merit with forethought!**

Good Message Bad Headlines

Radiation overdose common in CT scans of children

Children who are given computed tomography (CT) scans may receive doses that are "at least five times greater than necessary", says Lane Donnelly (Children's Hospital Medical Center of Cincinnati, OH, USA). "Radiologists can reduce the dose [significantly] without compromising image quality, but this isn't being done", he warns.

Donnelly is a coauthor of two papers that underscore the problem and offer strategies to reduce risk. "The bottom line from the first study is that in adult and mixed practices, the mA [tube current] is not being adjusted at all for paediatric patients", he says. "This hasn't been emphasised enough in the radiology literature." In the second study, the team present a "sliding scale" approach in which the CT dose is cut proportionately to the size of the patient. For example, for a CT of a baby's chest, an mA of 40 (about 0·79 rads) would be used, whereas

More scans than are required?

200 mA is typically used for adults, explains Donnelly (*Am J Roentgenol* 2001; **2:** 297–301, 303–06).

"The number of indications we use CT scans for in children has increased dramatically as CT scanners have improved in quality", he continues. In the USA, CT is the primary imaging technique for children with abdominal pain, suspected appendicitis, abdominal trauma, a suspected mass, or complicated pneumonia. "There's never been a documented case of anyone developing cancer [from the standard adult dose], but there is a risk and we want to make it as small as we can."

Key points for managing CT dose in patients:

- Doses can often approach or exceed levels known to increase the probability of cancer
- CT examinations are increasing in frequency
- Referring physicians and radiologists should make sure that the CT examination is indicated
- Newer CT techniques often increase doses compared with standard CT
- The most important way to manage dose is by reducing mA [tube current]
- Paediatric patients should have specific protocols with lower exposure factors (especially mAs)

Adapted from a report by the International Commission on Radiation Protection (www.icrp.org/pr01.htm)

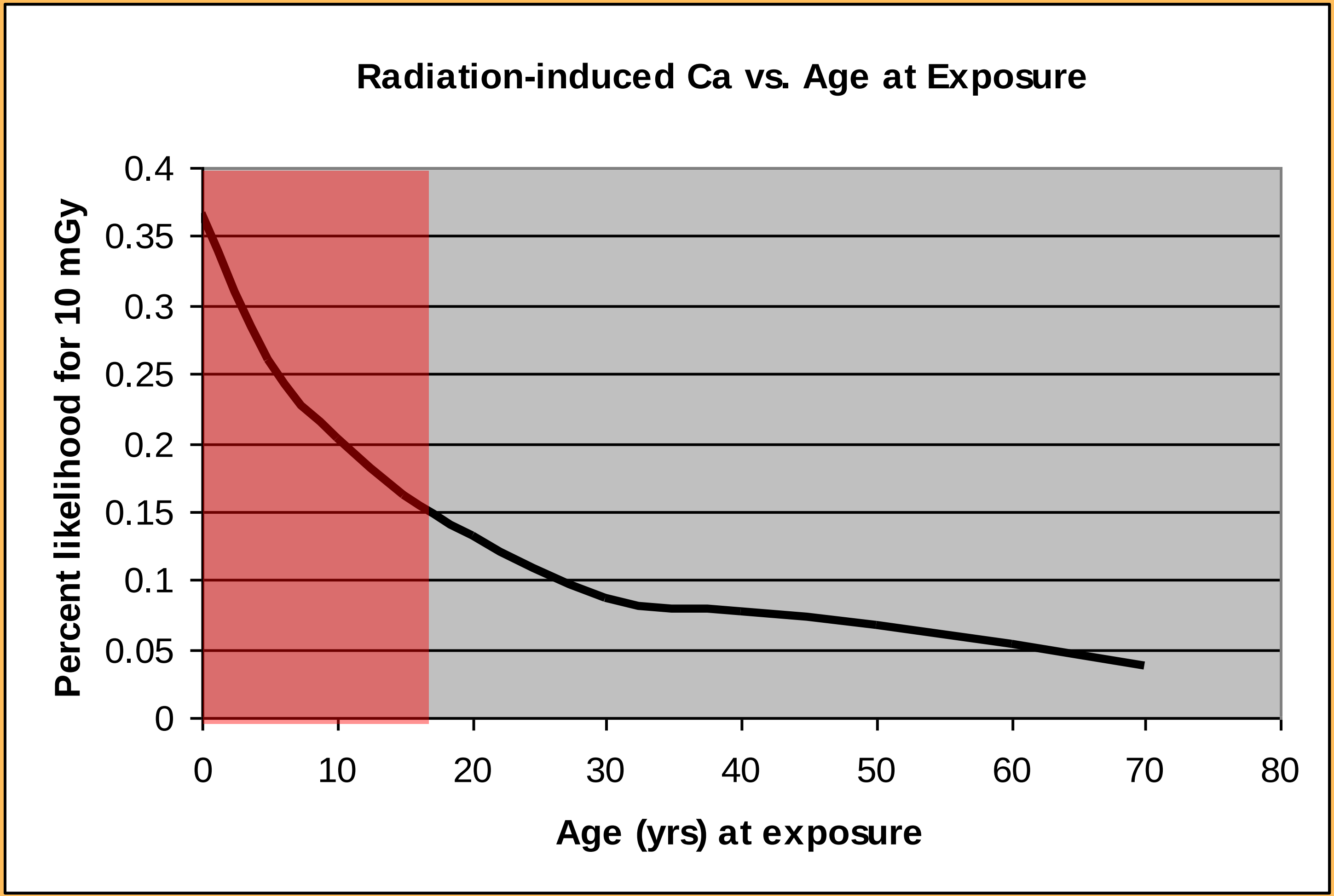
"It's true that nobody has shown an increased risk from cancer, but that's because you'd have to study children being exposed now and it would take 30 years to do it. Just because nobody has found cancer yet, there's no reason to keep on doing this and then 30 years from now say, yes, there is a connection", asserts Fred Mettler, chair of radiology at the University of New Mexico (Albuquerque, NM, USA) and chair of the International Commission on Radiation Protection (see panel). At his institution, CT scans account for "11% of procedures and 70% of the radiation dose", he says.

"The dose for a chest CT is about the same as for 20 mammograms —roughly 2 to 3 rads, compared with a chest X-ray, which is only about 0·1 rad." Japanese children exposed to a single dose of about 5 rads during World War II are at four times greater risk for breast cancer, he says, "so if a child were to have two or three scans of the same area, he or she would get doses that over the long term have been shown to significantly increase cancer risk."

Referring physicians should make sure a CT examination is indicated for a child and find out how it will be done. "Ask 'what factors do you use on adults' and 'what will you use on a child?' If they look the same, I would go elsewhere", advises Mettler.

Marilynn Larkin

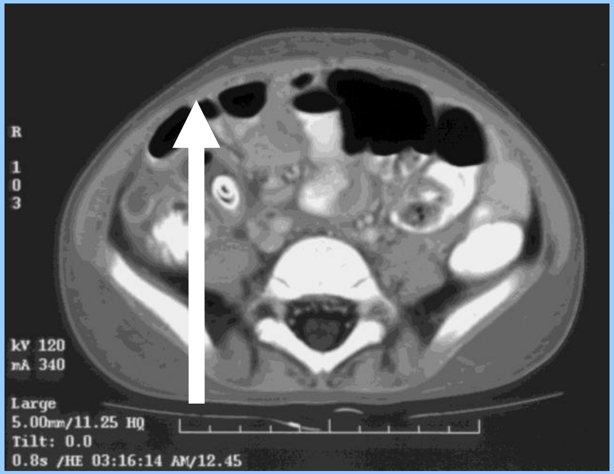
Cancer incidence potentially caused by diagnostic radiation



BEIR VII projections

Crude sense of confidence interval: -50% to plus 100%

CT Dose – How is it controled?



1 year 3 mos

120 kV, 80 mA, 0.8 s

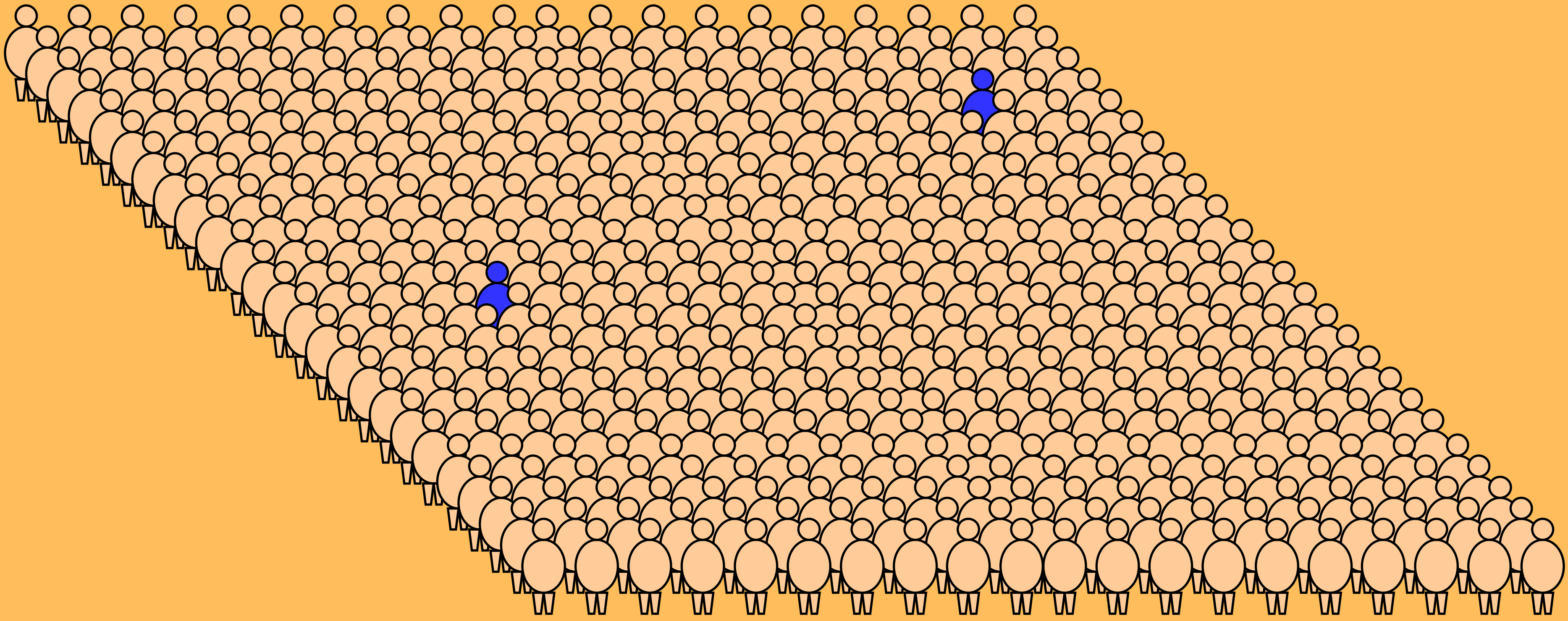
5 mm, pitch > 1

3 year 6 mos

120 kV 340 mA, 0.8s

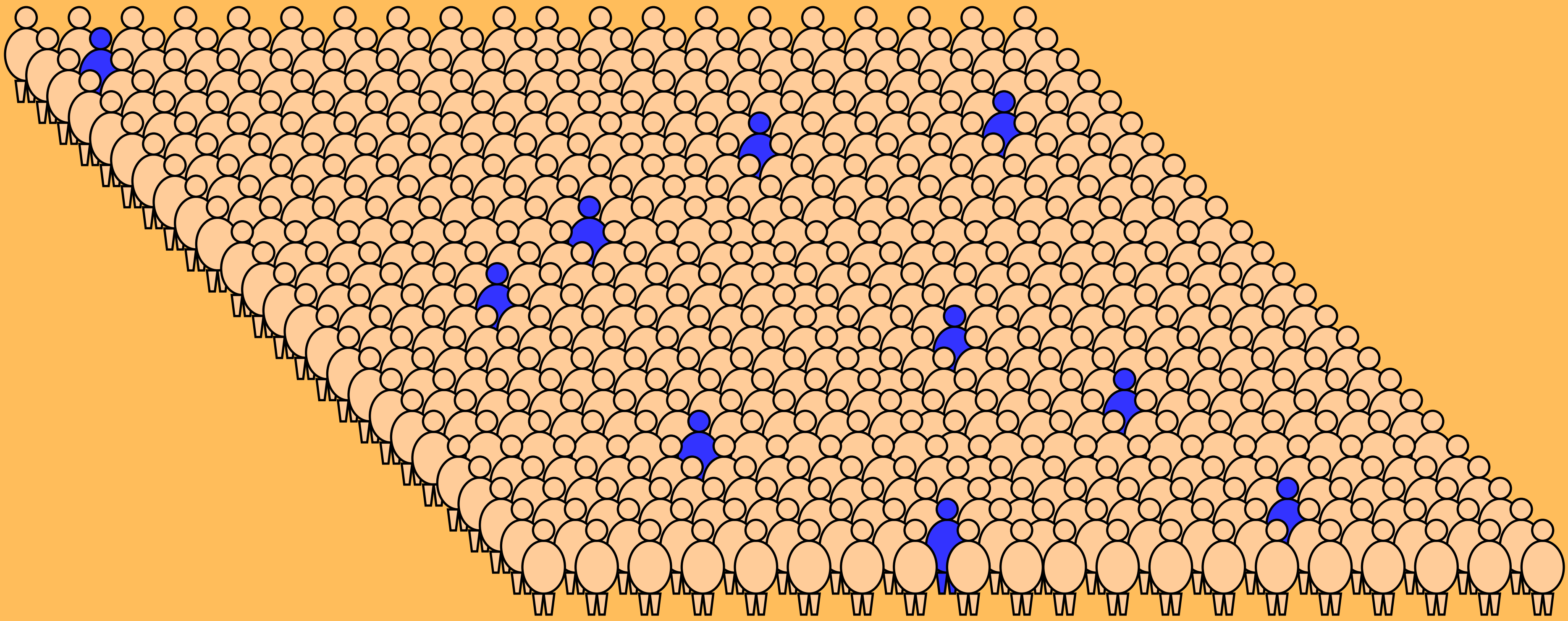
5mm, pitch < 1

Estimated risk to newborn from CT scan of 10 mGy (entire torso) is 0.4%, ………………….but



Note: Assumes all patients will potentially live long lives

Estimated risk to newborn from CT scan of 50 mGy (entire torso) is 2%.

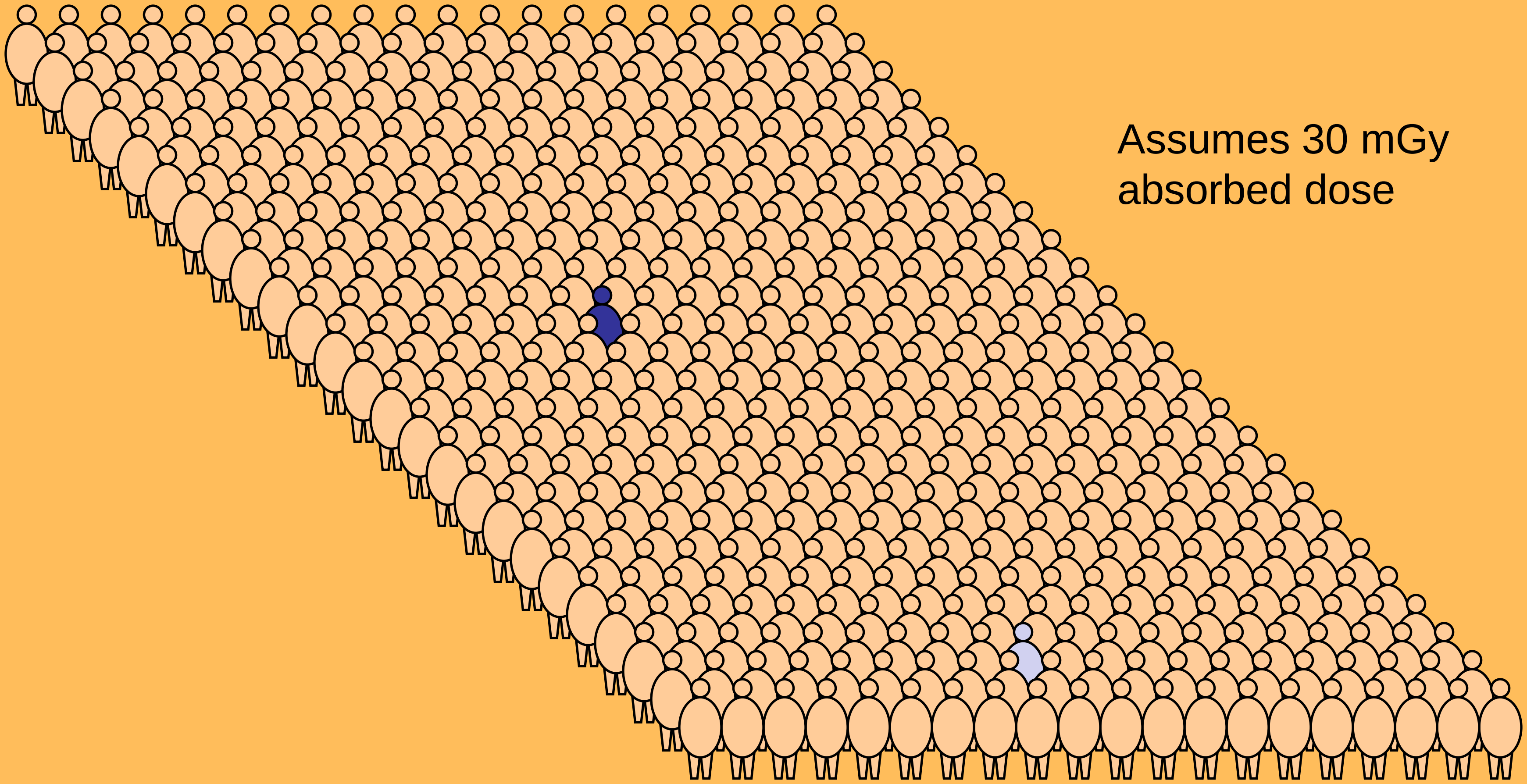


Note: Assumes all patients will potentially live long lives

ACR $CTDI_{vol}$ Criteria

- Pediatric Abdomen not to exceed 25 mGy, reference value is 20 mGy;
- Pediatric normalized to 5-year-old child;
- Five-year-old average is 40 lbs at 43” tall;

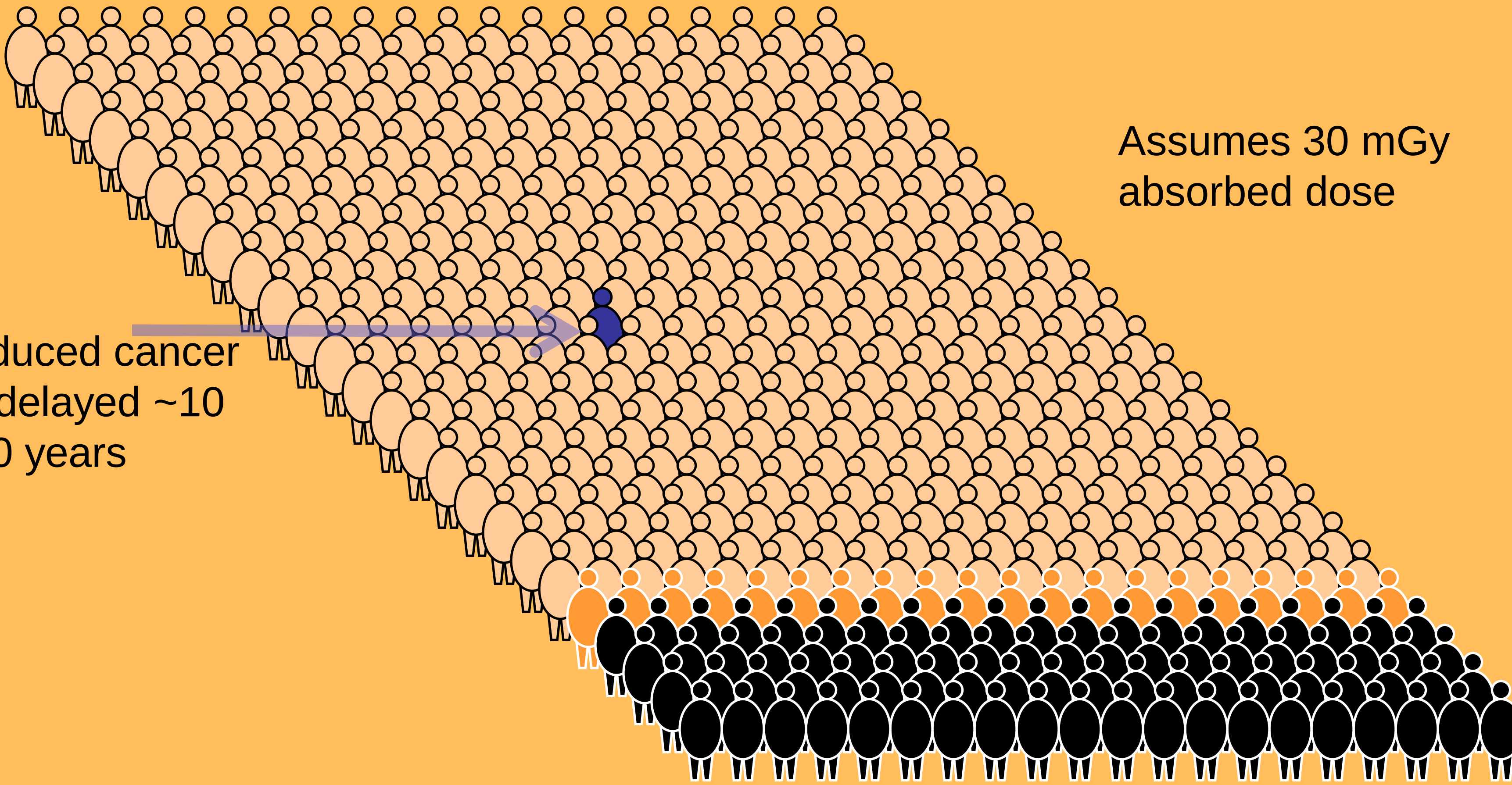
Induced cancers in twenty-eight-year-old adults undergoing Chest-Abdomen-Pelvis CT



Assumes 30 mGy absorbed dose

Note: Assumes all patients will potentially live long lives

Induced cancers in twenty-eight-year-old adults undergoing Chest-Abdomen-Pelvis CT

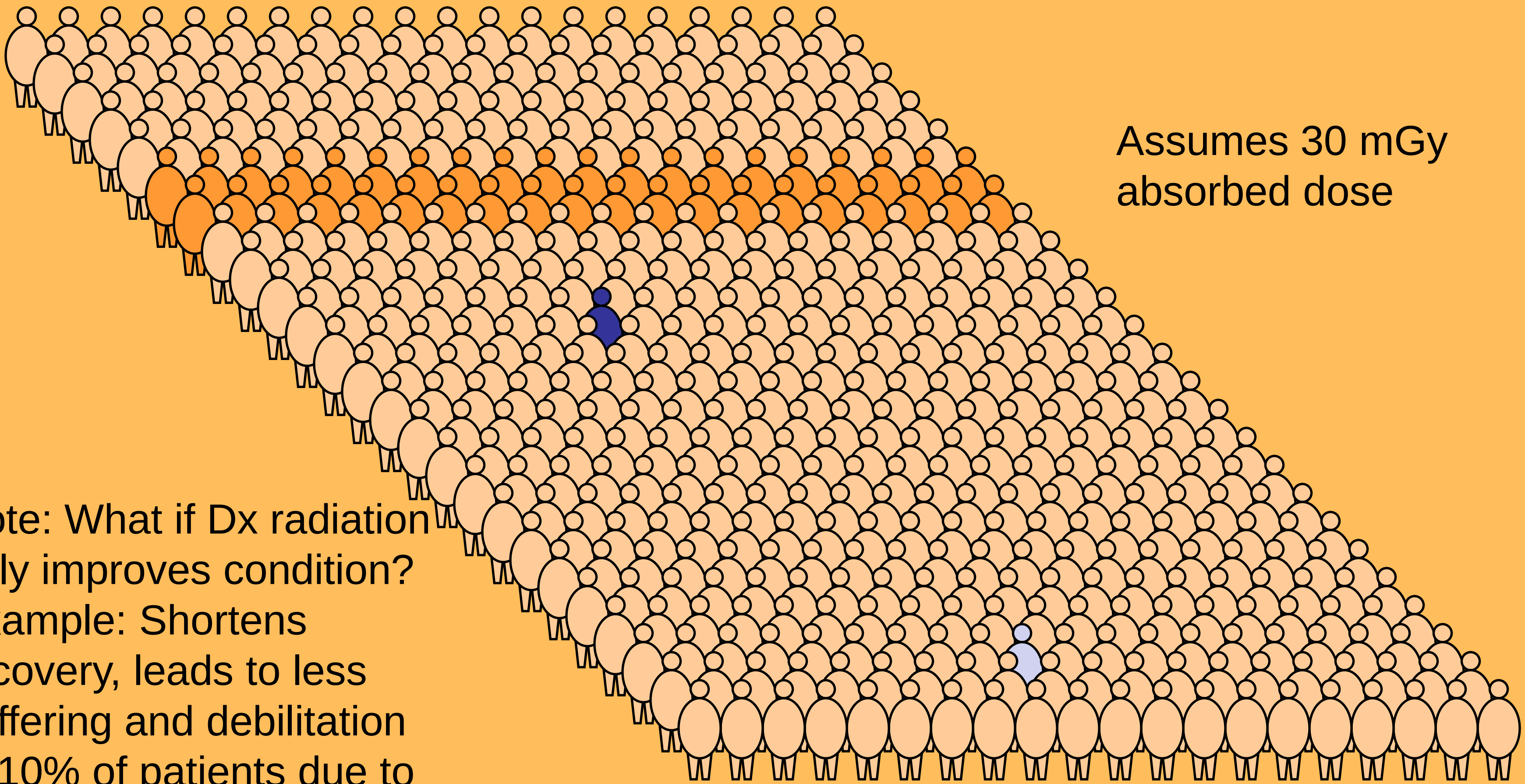


Assumes 30 mGy absorbed dose

Induced cancer is delayed ~10 -30 years

Note: What if survival for patient’s condition is 80% without the study and 85% with the study?

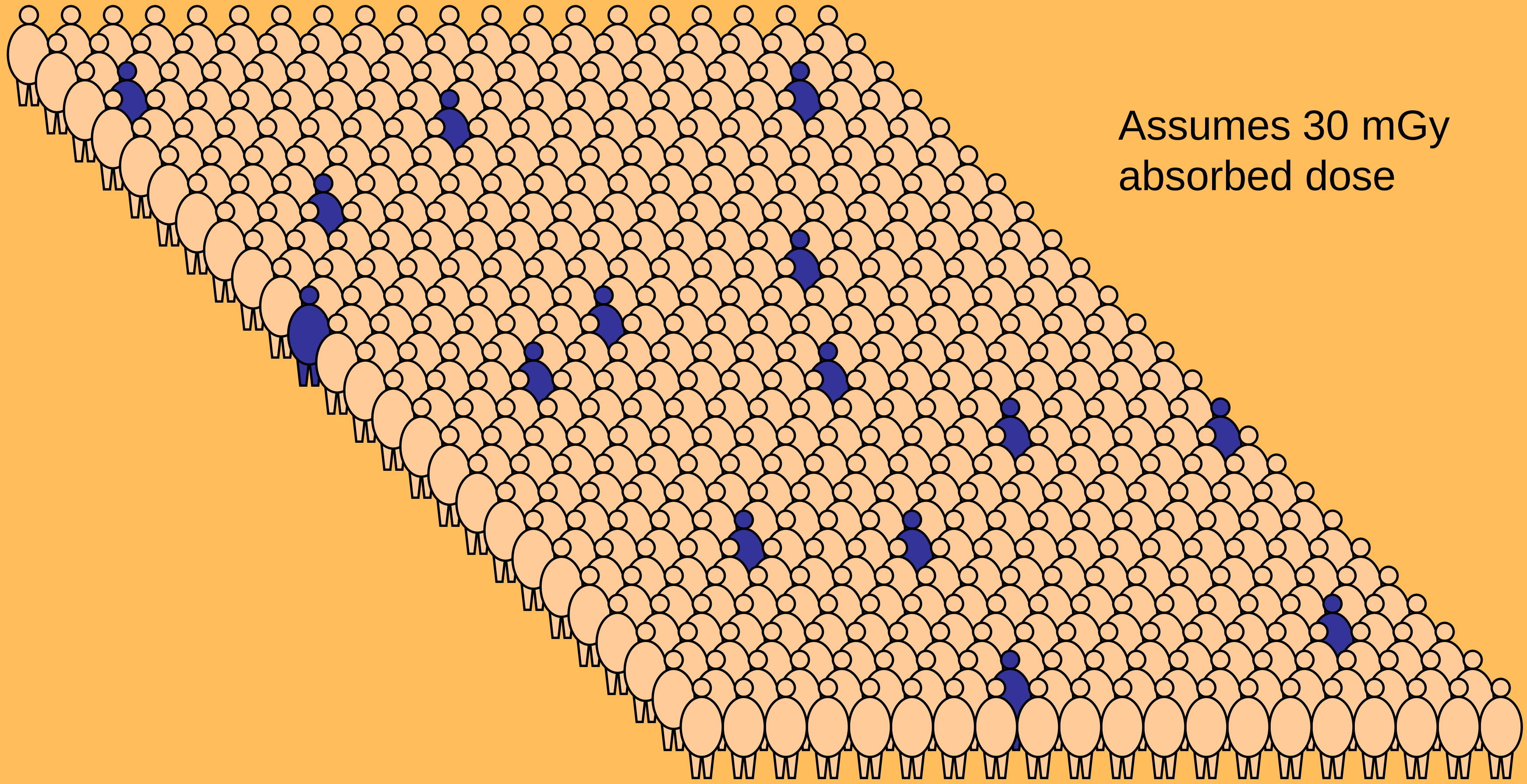
Long term risk of induced cancer must always be considered in light of short-term and long-term benefits!



Assumes 30 mGy absorbed dose

Note: What if Dx radiation only improves condition? Example: Shortens recovery, leads to less suffering and debilitation in 10% of patients due to early discovery and treatment, etc.

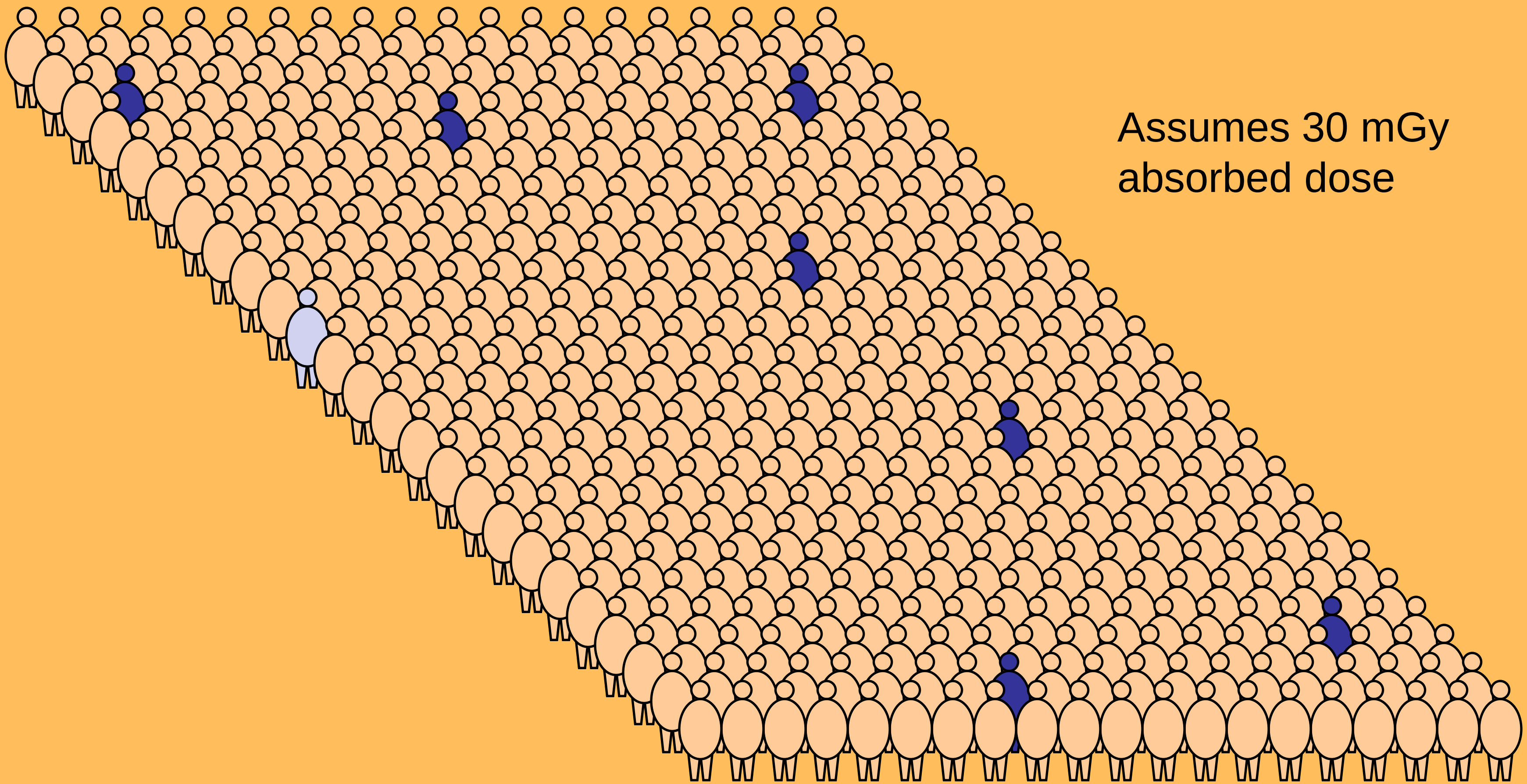
Induced cancers in twenty-eight-year-old adults undergoing 10 Chest-Abdomen-Pelvis CTs



Assumes 30 mGy absorbed dose

Note: Assumes all patients will potentially live long lives

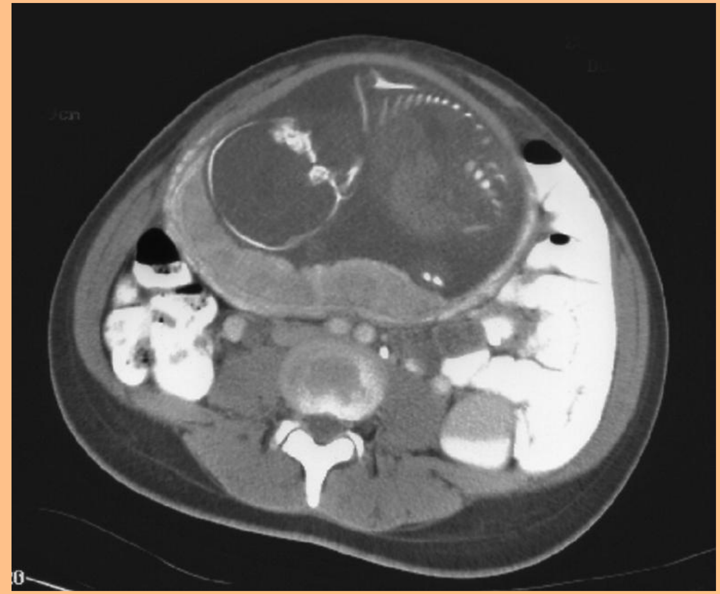
Induced cancers in sixty-year-old adults undergoing 10 Chest-Abdomen-Pelvis CTs

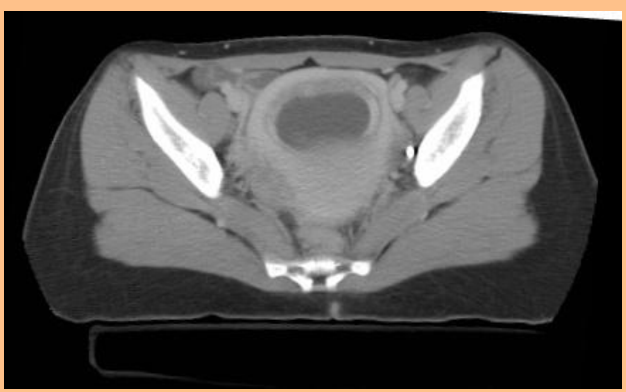


Assumes 30 mGy absorbed dose

Note: Assumes all patients will potentially live long lives

Estimation of Absorbed Dose to the Conceptus





ACR PRACTICE GUIDELINE FOR IMAGING PREGNANT OR POTENTIALLY PREGNANT ADOLESCENTS AND WOMEN WITH IONIZING RADIATION

IV. SCREENING FOR PREGNANCY

The purpose of screening patients for the possibility of pregnancy is to reasonably minimize the number of unexpected exposures of pregnant patients who have entered a potentially vulnerable stage of gestation. In developing a screening policy it must be realized that no screening policy will guarantee 100% detection. The effort made to identify unsuspected pregnancy must be commensurate with the risk of not detecting a pregnancy. Therefore, different screening policies might apply for high-dose procedures versus low-dose ones, such as an interventional procedure in the pelvis versus planar radiography of the pelvis. The vast majority of routine diagnostic studies deliver less than 20 mGy to the uterus, and single-phase acquisition computed tomography (CT) of the abdomen including pelvis usually delivers less than 35 mGy [6-8]. Because fluoroscopically guided interventional procedures in the pelvis might deliver doses above the teratogenic threshold (~100 mGy), a stricter method to screen for pregnancy might apply than that for a diagnostic procedures.

ACR PRACTICE GUIDELINE FOR IMAGING PREGNANT OR POTENTIALLY PREGNANT ADOLESCENTS AND WOMEN WITH IONIZING RADIATION

- **Multiple scans of the pelvis (typically ~3-4) can result in a conceptus dose in excess of the suspected teratogenic threshold of 100 mGy.**
- **Two scans of pelvis can result in dose in gray zone for undetectable effects.**
- **This is a deterministic, not stochastic effect.**
- **Probability and severity increase with dose beyond the threshold.**
- **Risks depend on gestation age.**

ACR $CTDI_{vol}$ Criteria

- Adult Abdomen not to exceed 30 mGy, reference value is 25 mGy;
- Adult head not to exceed 80 mGy, reference value is 75 mGy.

Risk

Actual Risk

PERCEIVED RISK

PERCEIVED RISK

Things that need to change

Radiology

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Index terms:
Computed tomography (CT), radiation exposure
Radiations, exposure to patients and personnel

Published online before print
10.1148/radiol.2312030767
Radiology 2004; 231:393–398

Diagnostic CT Scans: Assessment of Patient, Physician, and Radiologist Awareness of Radiation Dose and Possible Risks[1]

PURPOSE: To determine the awareness level concerning radiation dose and possible risks associated with computed tomographic (CT) scans among patients, emergency department (ED) physicians, and radiologists.

CONCLUSION: Patients are not given information about the risks, benefits, and radiation dose for a CT scan. Patients, ED physicians, and radiologists alike are unable to provide accurate estimates of CT doses regardless of their experience level.

Sometimes Benefit/Risk is Better understood

Medical interventions for certain conditions result in immediate results that not only ease pain and suffering but save lives.

But there are risks:

PSD Band	Range Gy	Prompt < 14 d	Early 2 - 7 w	Mid Term 1 - 12 m	Long Term > 9 M
A1	< 2	- - - - - - - No effects expected - - - - - - -			
A2	2 - 5	Transient erythema	Epilation	- Recovery from hair loss	None expected
B	5 - 10	Transient erythema	Erythema, epilation	- Recovery. - At higher doses; prolonged erythema permanent epilation	- Recovery - At higher doses: skin changes
C	10 - 15	- Transient erythema - Possible skin complaints	- Erythema, epilation, - Possible dry or moist desquamation	- Recovery from desquamation possible - Prolonged erythema - Permanent epilation	- Telangiectasia, - Induration - Skin likely to be weak.
D	> 15 Some effects may occur sooner than noted and be more evident above 20 Gy.	- Transient erythema - Probable skin complaints - After very high doses; edema and acute ulceration	- Erythema, epilation - Moist desquamation - Skin breakdown	- Dermal atrophy - Secondary ulceration - At higher doses; dermal necrosis	- Recovery with telangiectasia, dermal atropyy, induration - Possible late skin breakdown - Wound might be persistent and progress into a deeper lesion - Surgical intervention likely

- This table is applicable to the normal range of patient sensitivities in the absence of mitigating or aggravating factors.
- This table does not apply to the skin of the scalp.
- Abrasion or Infection of the irradiated area is likely to exacerbate radiation effects.
- The dose and time bands are not rigid boundries. Signs and sympmptoms are expected to appear earlier as skin dose increases.
- This table refers to radiation-induced telangiectasia. Telangictesia resulting from skin healing may be present at an earlier stage.

TABLE IS PRELIMINARY AND NOT FOR PUBLICATION AT THIS TIME!!!

Injuries have occurred in a wide variety of anatomical locations

Provided with permission

Granel et al,
Ann Dermatol
Venereol 1998;
125; 405 - 407

Granel et al, Ann Dermatol Venereol
1998; 125; 405 - 407

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Granel et al, Ann Dermatol Venereol
1998; 125; 405 - 407

From:
Koenig et
al. AJR

Courtesy: T. Shope, FDA

Air kerma at reference (AK)	Alert level	Alert interpretation
3000 mGy	1	FYI – to assist physician in projecting how much radiation might be required to complete procedure.
6000 mGy	2	Alert – to assist physician in projecting how much radiation might be required to complete procedure.
9000 mGy	3	Warning – benefit/risk decision must be dictated in report; doses are nearing level that requires mandatory review by medical staff and radiation safety.
12000 mGy	4	Warning – dose level is at level requiring mandatory review by medical staff and radiation safety.
15000 mGy	5	Dose is at level defined by JCAHO as a reviewable sentinel event
All additional +3000 mGy		For the information of the physician

What are the risks?

Risk of cancer from diagnostic X-rays: estimates for the UK and 14 other countries

Lancet 2004; **363:** 345–51

Amy Berrington de González, Sarah Darby

Attributable risk is that % of all cancers to age 75 that is caused by radiation, **not** % likelihood of developing cancer.

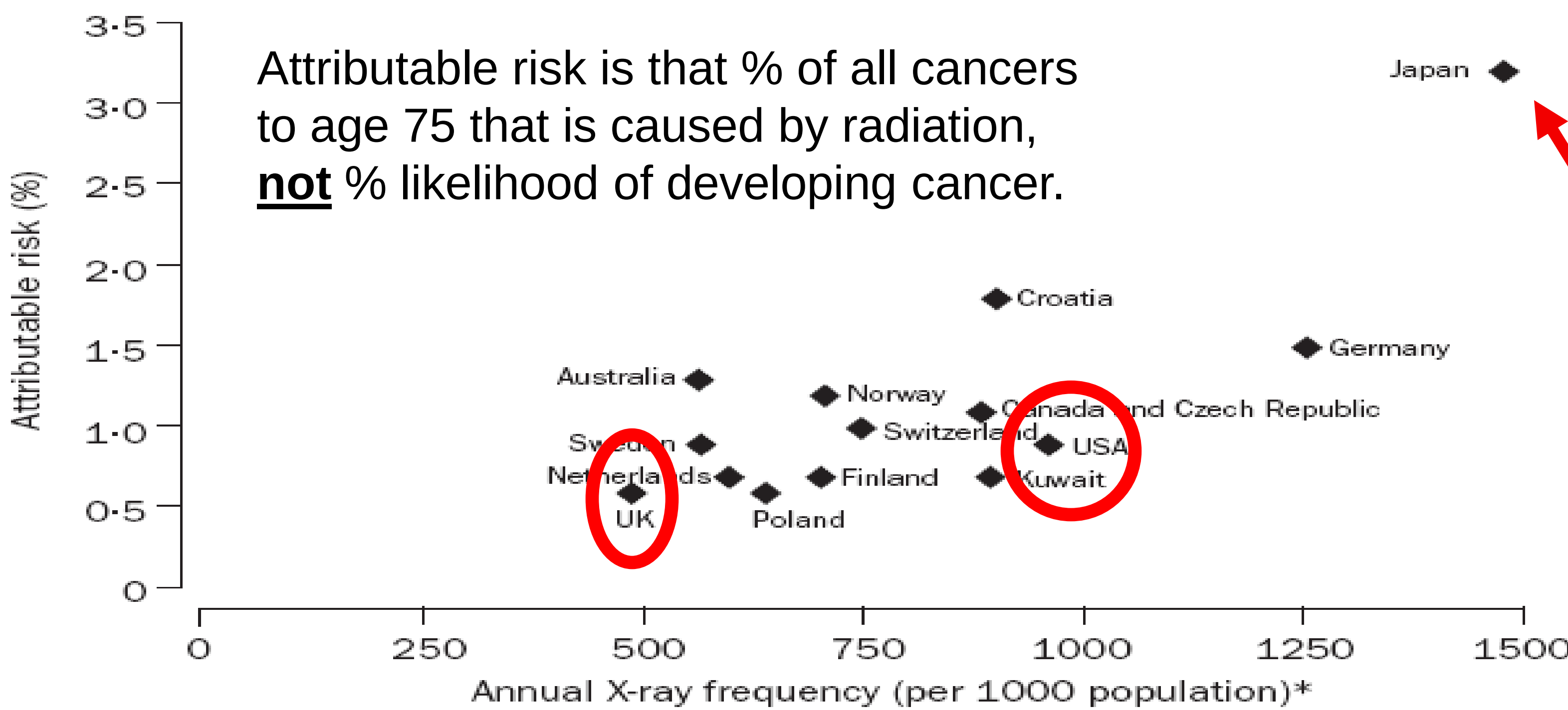


Figure 3: **Risk of cancer attributable to diagnostic X-ray exposures versus annual X-ray frequency**

*Taken from worldwide survey.[1]

What are the risks?

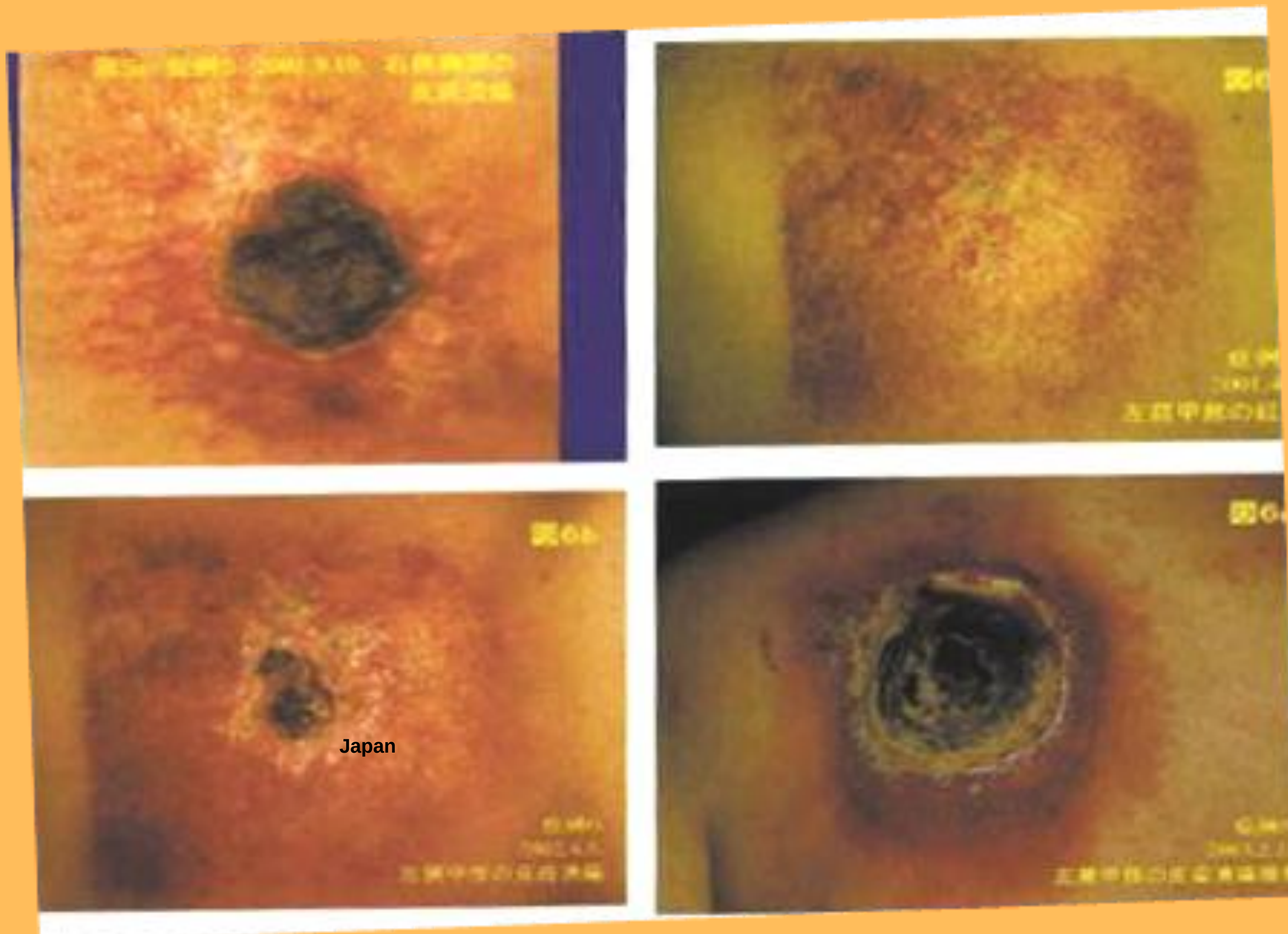
Risk of cancer from diagnostic X-rays: estimates for the UK and 14 other countries

Lancet 2004; **363:** 345–51

Amy Berrington de González, Sarah Darby

	Men	Women
Japan 2003	78.4	85.3
Great Britain 2004	75.7	80.4
United States 2006	75.4	80.7

Fluoroscopically induced radiation injury in Japan



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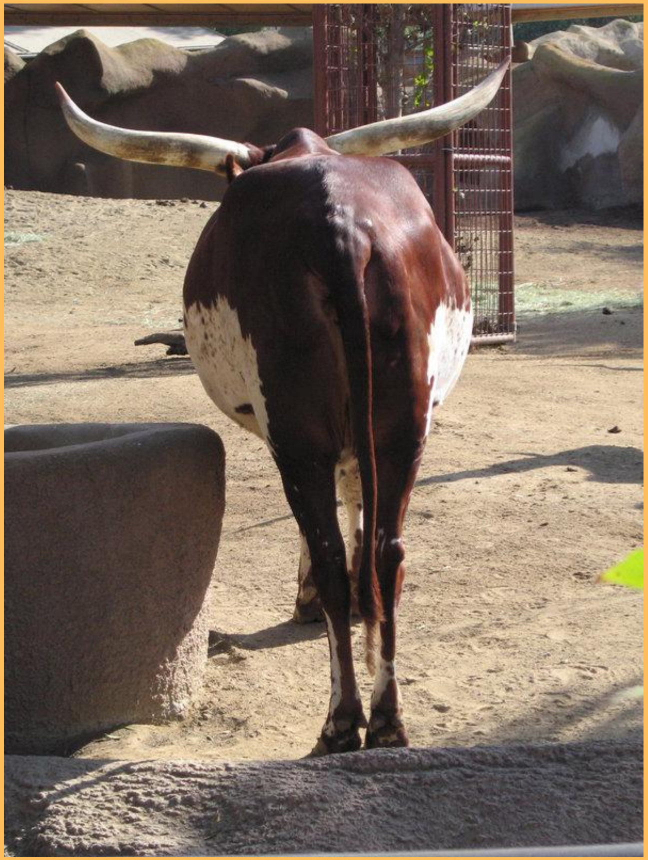

The end