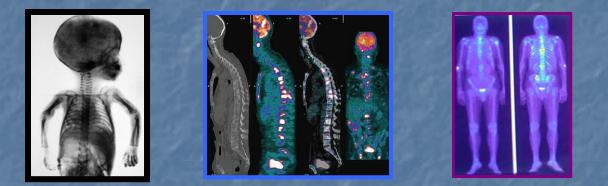


Patient Safety Concerns in Diagnostic Radiology?



Lawrence T. Dauer, PhD, CHP Assistant Attending Health Physicist Department of Medical Physics RAMPS/GNYCHPS Spring Symposium – April 30, 2010

Radiation Dose Associated With Common Computed Tomography Examinations and the Associated Lifetime Attributable Risk of Cancer

Arch Intern Med. 2009;169(22):2078-2086 Rebecca Smith-Bindman, MD; Jafi Lipson, MD; Ralph Marcus, BA; Kwang-Pyo Kim, PhD; Mahadevappa Mahesh, MS, PhD; Robert Gould, ScD; Amy Berrington de González, DPhil; Diana L. Miglioretti, PhD

Projected Cancer Risks From Computed Tomographic Scans Performed in the United States in 2007

Arch Intern Med. 2009;169(22):2071-2077

Amy Berrington de González, DPhil; Mahadevappa Mahesh, MS, PhD; Kwang-Pyo Kim, PhD; Mythreyi Bhargavan, PhD; Rebecca Lewis, MPH; Fred Mettler, MD; Charles Land, PhD



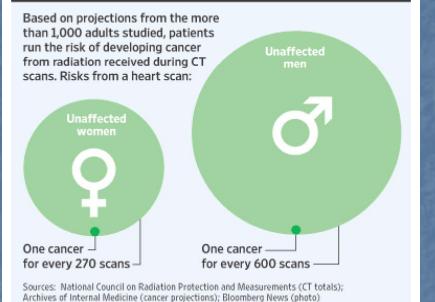
THE WALL STREET JOURNAL

WSJ.com

U.S. NEWS | DECEMBER 15, 2009 CT Scans Linked to Cancer

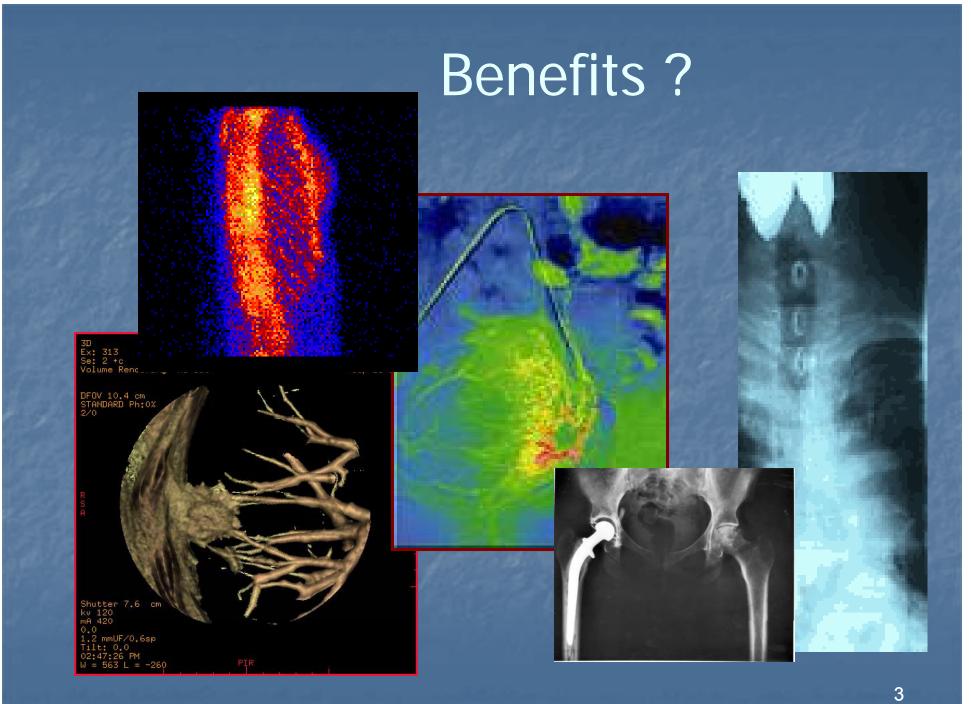
Study Warns Radiation Dose From Single Test Can Trigger Disease in Some People

Potential Risk



msnbc.com 15,000 will die from CT scans done in 1 year

Scans have higher levels of radiation than thought, researchers say



Background Radiation in U.S. ~6.3 mSv/yr ~0.02 mSv/day (~2 mrem/day)

Medical 3.2
Radon 2.0
Cosmic 0.3
Earth 0.3
Internal 0.4
Cons Prod 0.1
Occup 0.002

Absorbed Dose

 $d\overline{\epsilon}$

 $\frac{d}{dm}$

 $H_{\rm T} = \sum w_{\rm R} D_{\rm T,R}$ R **Radiation type Radiation weighting** factor, w_R Photons Electrons^a and muons Protons and charged pions Alpha particles, fission frag-20ments, heavy ions Neutrons Radiation weighting factor 10

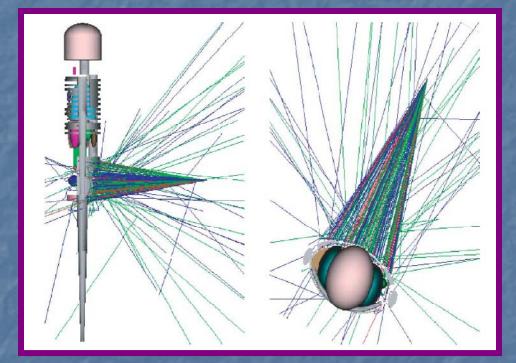
 $10^{.6}$ $10^{.4}$ $10^{.3}$ $10^{.2}$ $10^{.1}$ $10^{.0}$ $10^{.1}$ $10^{.2}$ $10^{.3}$

Neutron energy / MeV

Equivalent Dose

Risk Evaluations

Monte-Carlo transport and energy deposition
Equivalent Dose
Age-Adjusted
Gender-Adjusted
Organ risk factors



Effective Dose

 $\int w_{\rm T} H_{\rm T} = \sum w_{\rm T} \sum w_{\rm R} D_{\rm T,R}$ $E = \sum$

Tissue	w _T	$\sum w_{\mathrm{T}}$
Bone-marrow (red), Colon, Lung, Stomach,	0.12	0.72
Breast, Remainder tissues* Gonads	0.08	0.08
Bladder, Oesophagus, Liver, Thyroid	0.00	0.16
Bone surface, Brain, Salivary glands, Skin	0.01	0.04
	Total	1.00

* Remainder tissues: Adrenals, Extrathoracic (ET) region, Gall bladder, Heart, Kidneys, Lymphatic nodes, Muscle, Oral mucosa, Pancreas, Prostate (\Im), Small intestine, Spleen, Thymus, Uterus/cervix (\Im).

ICRP-103 (2007)

Internal Radionuclide Radiation Dosimetry MIRD Formalism

(Medical Internal Radionuclide Dosimetry)

Absorbed fractions and S factors from reference anatomic phantoms

Energy Emitted per Decay Equilibrium Dose Constant

Fraction of energy emitted in Source Region r_h absorbed in Target Region r_k *Absorbed Fraction*

 $\mathbf{S}(\mathbf{r}_{k} \leftarrow \mathbf{r}_{h})$

<mark>∧</mark>, ¢_i(r_k← r_h)¦

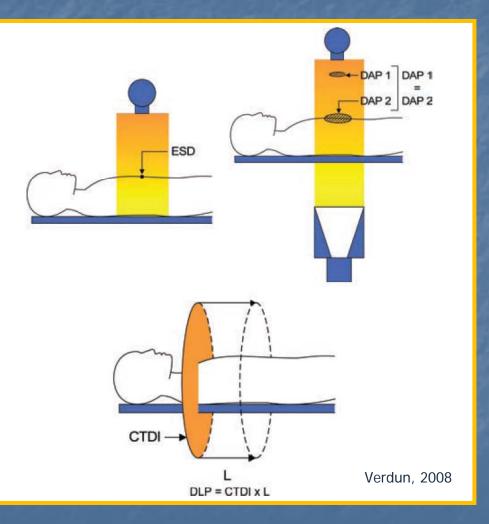
Number of decays in Source Region r_h *Cumulated Activity*

Absorbed Dose from Source Region r_h to Target Region r_k

Mass of Target Region r_k

Doses in CT

ESD $\square DLP = CTDI x L$ • E/DLP for adults: Head 0.0023 Neck 0.0054 Chest 0.017 Abd 0.015 Pelv 0.019



ACR, 2004

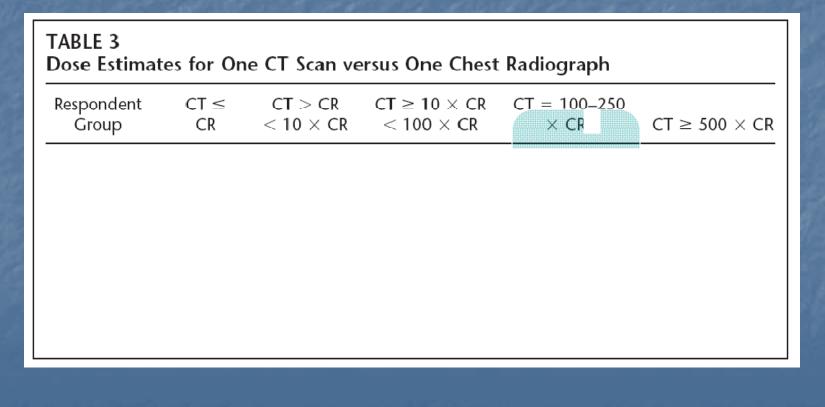
Diagnostic CT Scans: Assessment of Patient, Physician, and Radiologist Awareness of Radiation Dose and Possible Risks¹

Christoph I. Lee, AB Andrew H. Haims, MD Edward P. Monico, MD James A. Brink, MD Howard P. Forman, MD, MBA

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



Radiation Passport 1.0 iPhone application

Edit Expos	ure +		Risk	
Common - 99.187 i	nSv	Personal	Source	Exam
Background	99.187 mSv	8 3		
Exams - 128.417 m	Sv (12)			
nterventional bdominal Angio Potober 11, 2009	12 mSv	- All		
(-Ray Ibow (Unilateral) pril 3, 2009	0.001 mSv	1/23	1/35	1/71
Dental CT Scan Mugust 13, 2006	0.2 mSv	Stoke Cance	ATTUS CICENTE	Incidence (Call
CT Scan Pulmonary Embolism	15 mSv	Sector Street		· · · · · · · · · · · · · · · · · · ·
227.604	mSv 🔳 🔟	18	* Ris	k of cancer caused by i
Exposure Risk	Background	Exposure	Bisk	Background



Typical Radiation Doses - General Radiology			
Examination	Effective Dose mSv		
Dental	0.05 (0.02-0.09)		
Chest	0.1 (0.02-0.81)		
Head	0.1 (0.1-0.22)		
Mammography	0.7 (1-3 gland)		
Abdomen/Pelvis	1.2 (0.7-1.2)		

See <u>http://mskweb5.mskcc.org/intranet/html/65927.cfm</u> For a complete listing of typical radiology doses

Typical Radiation Doses - Computed Tomography			
Examination	Effective Dose mSv		
PET Attenuation (CT Only)	0.72		
Head	2 (0.8-5)		
Chest	7 (4.6-20.5)		
Abdomen or Pelvis	10 (6-27.4)		
CT Angiography	13 (4.6-15.8)		



Typical Radiation Doses - Nuclear Medicine

Examination	Effective Dose mSv	
F-18 FDG 15mCi (Nuclear Med only)	9	
I-131 MIBG 1mCi	7.5	
Tc-99m pertech.	5	
Tc-99m stress	6	
I-131 therapy	270	

RADAR

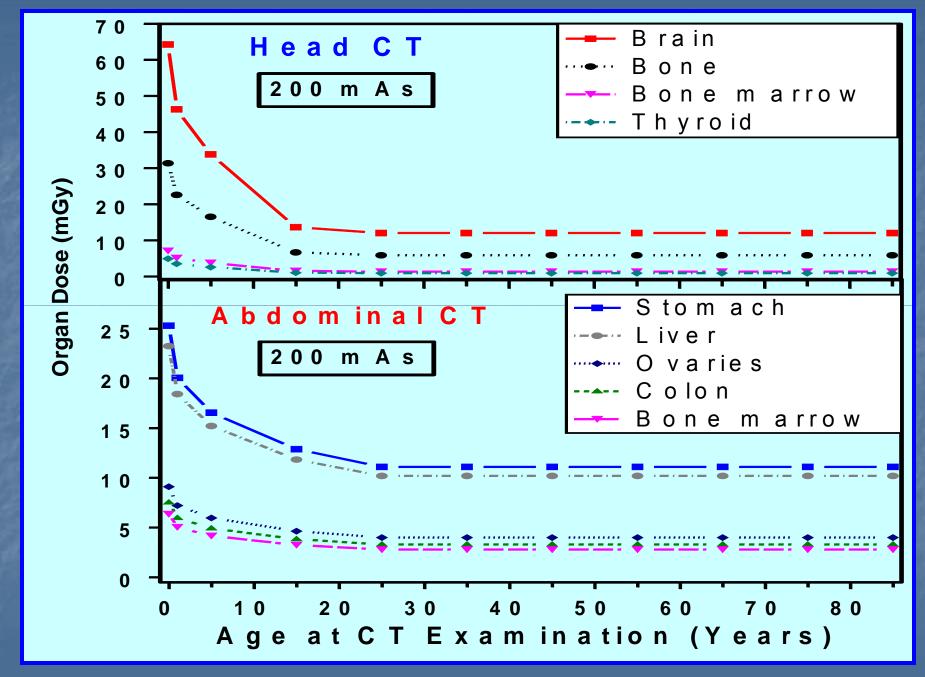
14

Typical Radiation Doses Fluoroscopy Entrance Skin Dose

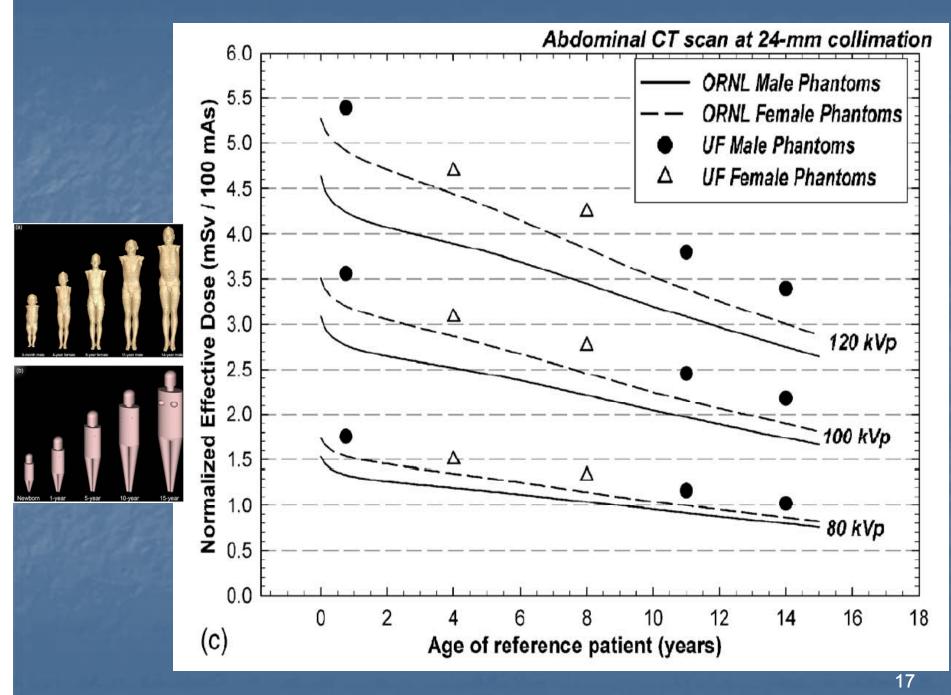
Examination	Skin Dose mGy	
Hepatic Embolization	2000 (1251-9500)	
Arterial	3000 (1761-8073)	
Embolization	ED~60 mSv	
Biliary Drainage	660 (401-3569)	
IVC Filter	260 (162-2686)	
Mediport – Chest	12 (8-620)	



Dauer, Thornton... JVIR 2009



*Adapted from Brenner et al. 2001



Lee, 2007, MedPhys

One size does not fit all...

There's no question — CT helps us save kids' lives! But...When we image, radiation matters! Children are more sensitive to radiation. What we do now lasts their lifetime. So, when we image, let's image gently. More is often not better. When CT is the right thing to do: • Child size the kVp and mA

- One scan (single phase) is often enough
- Scan only the indicated area

A timely message from the Aliance for Radiation Safety in Pediatric Imaging.

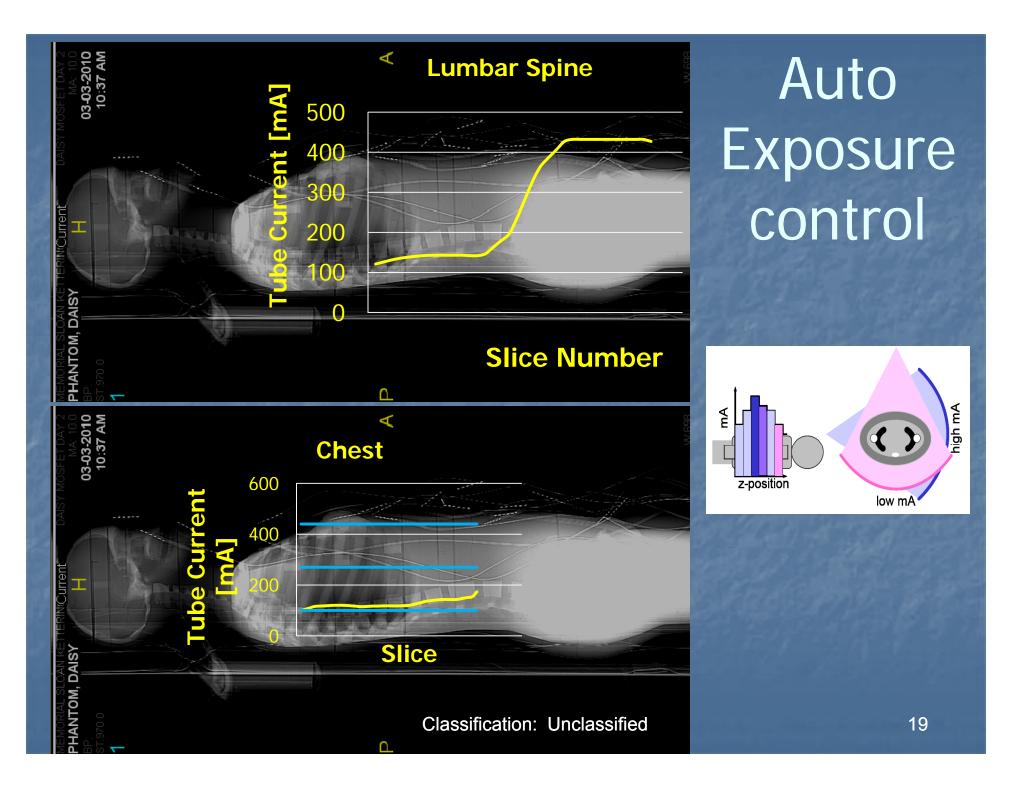




Visit www.imagegently.org. Made possible by an unrestricted educational grant from GE Healthcare.

The Aliance for Radiation Safety in Pediatric Imaging is:

The Society for Pediatric Radiology - American Association of Physicists in Medicine - American Association of Physicists in Medicine - American Registry of Radiology - American Society of Radiologists - American Association of Physicists - American Begistry of Radiologist - American Society of Radiologists - American Society of Radiologist - American Society of Radiologists - American Society of Radiologists

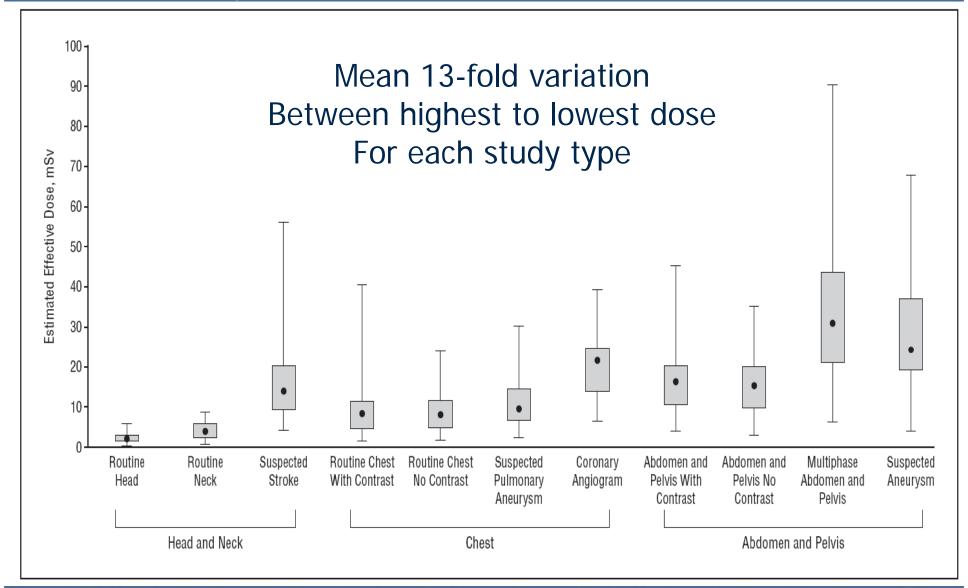


How do we assure quality control on an ongoing basis?

- Medical Physicist verifies CT dose on new equipment prior to 1st patient use, at least 1x per year and at x-ray tube changes.
- CT dose measurements meet American College of Radiology, State, and Local guidelines for dose.
- CT machine settings are developed by Radiologists and Radiology specialists.
 Technique Charts showing machine settings and standard delivered doses are posted at each CT.



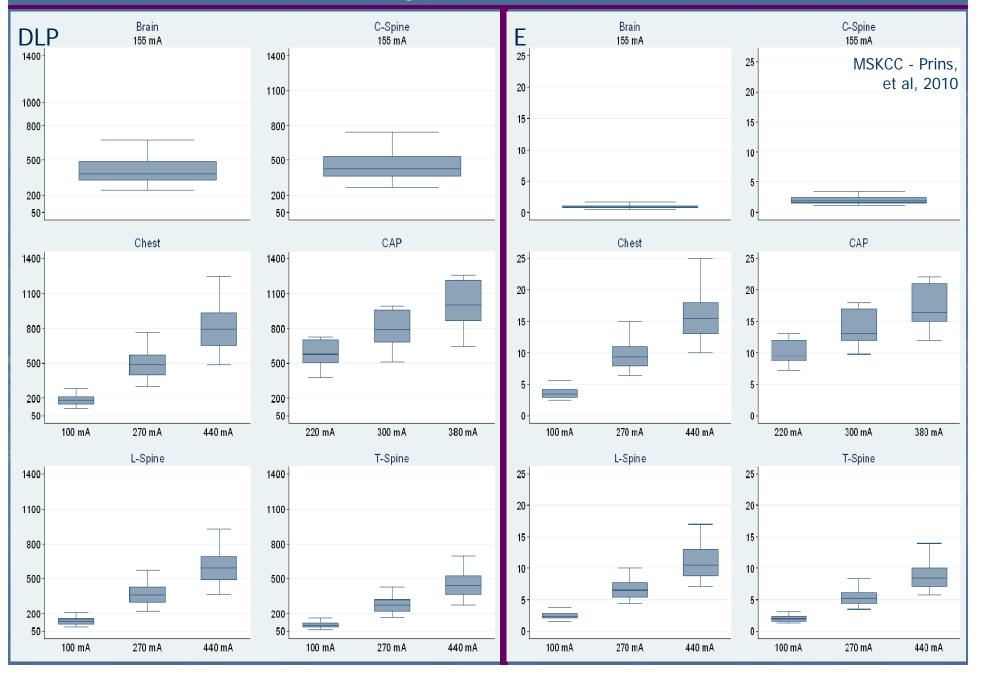
Variability in CT doses for real individuals



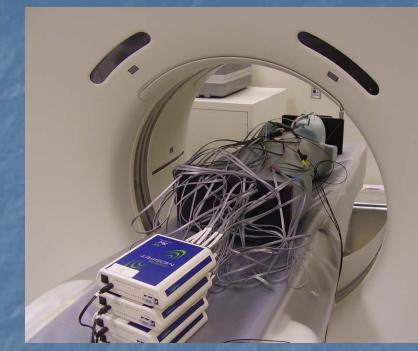
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Machine Model & Type = 2.5 to 5-fold variation



Ongoing Evaluations





Principles of Radiation Safety in Radiology

Justification

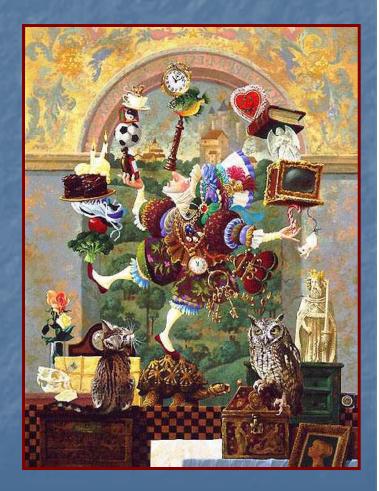
Benefit greater than risk

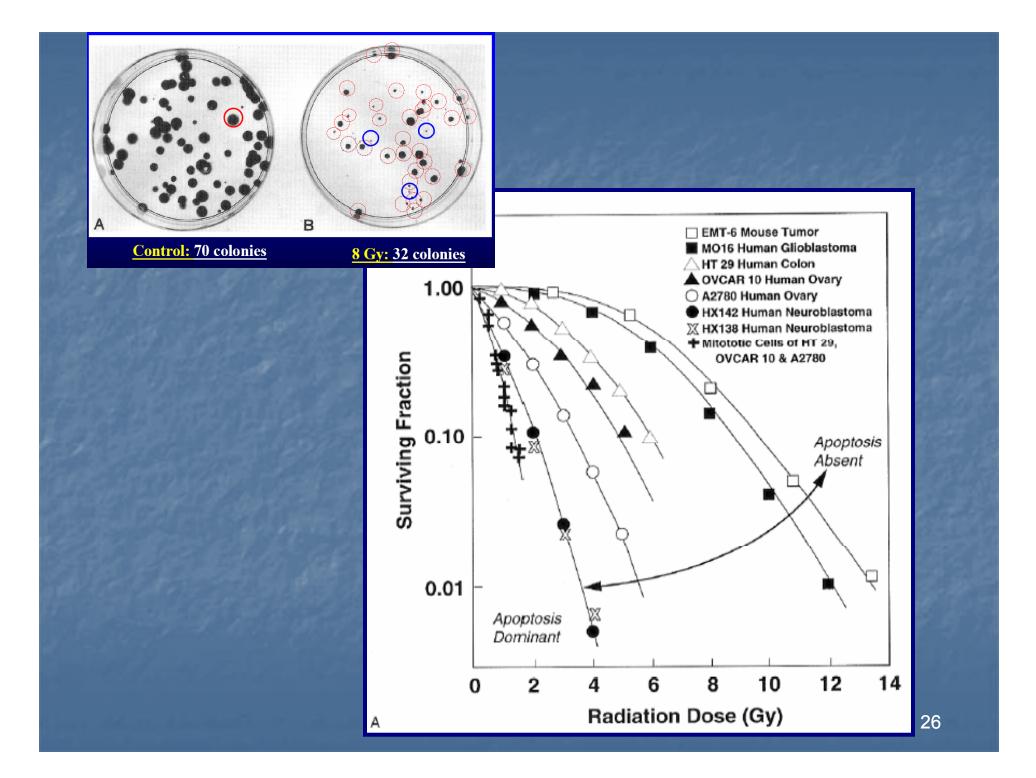
Optimization

Benefit AHARA
Risk ALARA

Limitation

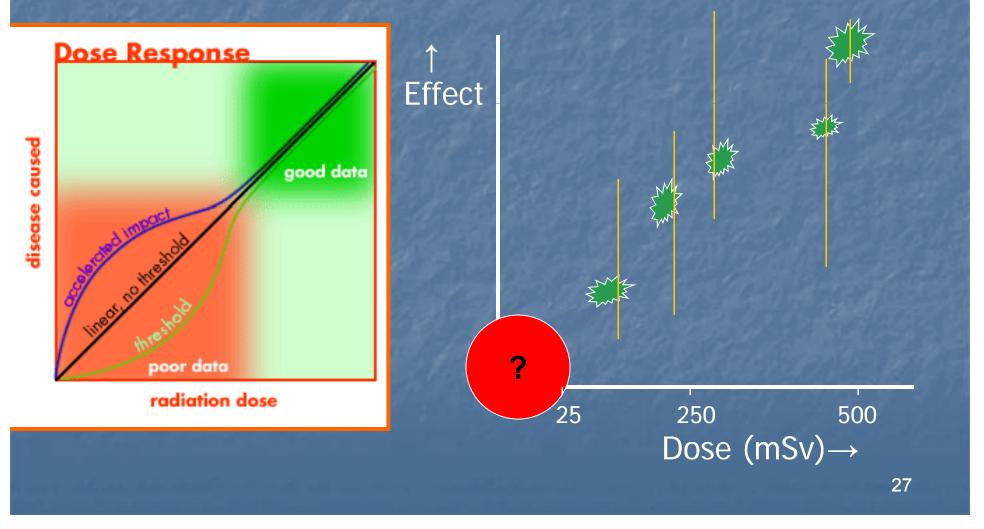
Occupational doses based on risk of safe industries



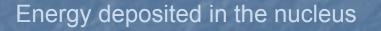


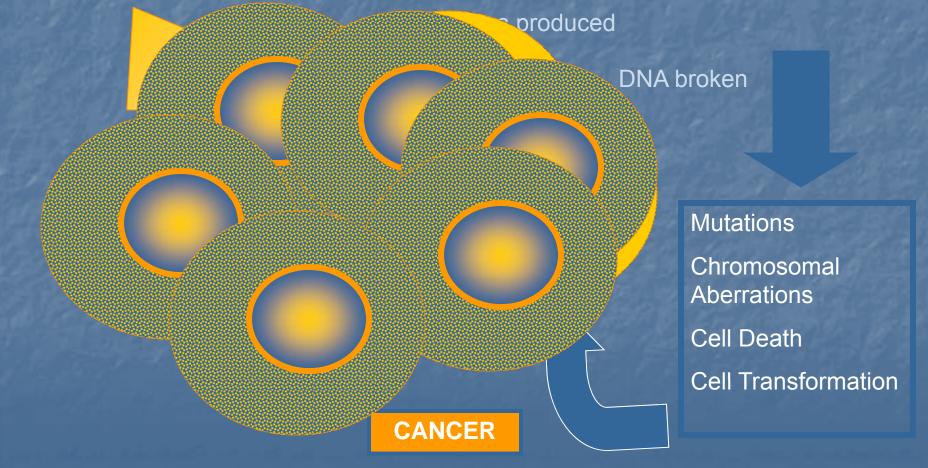
Can We Predict Effects at Low Doses?

While moderate/high doses cause well-documented effects, we cannot measure significant effects at the doses where typical diagnostic or regulated doses occur.

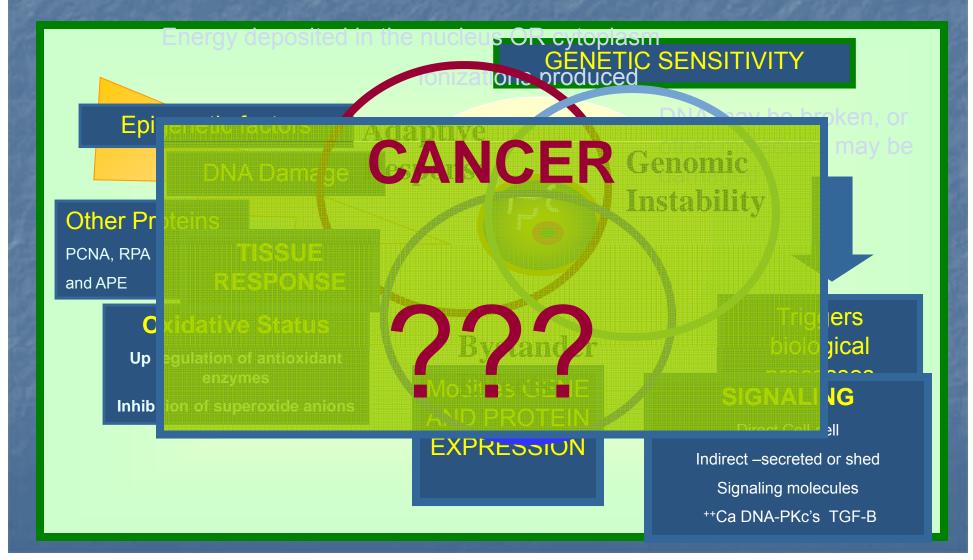


Classic Risk Paradigm





Expanded Risk Paradigm



Need an Expanded Paradigm for Low-Dose Response

Production of damage

Linear processes

- Deposition of energy
- ✓DNA damage

Physics

Responses to damage

Non-linear processes

Induction of Apoptosis

✓ Gene & Protein expression

Biology

Evaluation Conclusions Vary

BEIR VII - NAS

 Available biological and biophysical data supports a linearno-threshold (LNT) risk model.

ICRP 99/103

 While existence of a low dose threshold may be likely for radiation related cancers in some tissues, the evidence does not support a universal threshold. DDREF-modified LNT suggested as prudent.

French Academy

 New radiobiology focus. Biological differences at high vs. low doses. LNT overestimates risk at low doses.

Low Dose - Linear Risk Model (~5% per Sv)

ICRP-103 for cancer and heredity effects

Exposed Population	Cancer	Heredity Effects	Total
Whole	5.5	0.2	5.7
Adult	4.1	0.1	4.2

A statistically significant increase in cancer has not been detected in populations exposed as adults to doses of less than 50 mSv.

No hereditary effects in atomic bomb survivor offspring.

~ Patient Risks

Risk of contracting cancer increased by less than 1/2%	50 mSv
Temporary Sterilization (Men)	150 mGy
Temporary blood count change	250 mSv
Cataract	<1000 mGy
Permanent Sterilization (Women)	2500 mGy
Skin Erythema (reddening)	3000 mGy

Fetal Radiation Risk

- Most Risk 1st Trimester
- No Malformations <100mGy</p>
- No Malformations 100-1000mGy 3rd Trimester
- Termination of pregnancy at <50 mGy is <u>NOT</u> justified based upon radiation risk
- Take care especially during multiple pelvic CTs, long fluoro, or radiotherapy



Most risk





Wagner, ICRP, IAEA, ACOG



ICRP-103 on Individual Risks

"it remains the policy of the Commission that its recommended nominal risk coefficients should be applied to whole populations and <u>not to individuals</u>...[and] believes that this policy provides for a general system of protection that is simple and sufficiently robust" (p.55)



RADIATION RISK IN PERSPECTIVE

POSITION STATEMENT OF THE

HEALTH PHYSICS SOCIETY*

Adopted: January 1996 Reaffirmed: March 2001 Revised: August 2004 If dose is < 100 mSv ...Take Care When Attempting to Assign Quantitative Risk to Individuals

Radiogenic Health Effects Have Not Been Consistently Demonstrated Below 10 Rem

Radiogenic health effects (primarily cancer) have been demonstrated in humans through epidemiological studies only at doses exceeding 5–10 rem delivered at high dose rates. Below this dose, estimation of adverse health effect remains speculative. Risk estimates that are used to predict health effects in exposed individuals or populations are based on epidemiological studies of well-defined populations (for example, the Japanese survivors of the atomic bombings in 1945 and medical patients) exposed to relatively high doses delivered at high dose rates. Epidemiological studies have not demonstrated adverse health effects in individuals exposed to small doses (less than 10 rem) delivered in a period of many years.

Limit Quantitative Risk Assessment to Doses at or Above 5 Rem per Year or 10 Rem Lifetime

In view of the above, the Society has concluded that estimates of risk should be limited to individuals receiving a dose of 5 rem in one year or a lifetime dose of 10 rem in addition to natural background. In making risk estimates, specific organ doses and age-adjusted and gender-adjusted organ risk factors should be used. Below these doses, risk estimates should not be used. Expressions of risk should only be qualitative, that is, a range based on the uncertainties in estimating risk (NCRP 1997) emphasizing the inability to detect any increased health detriment (that is, zero health effects is a probable outcome).

Have we evaluated total imaging doses for our patients?

Cumulative Imaging Radiation Exposure Following Breast-Conservation Therapy

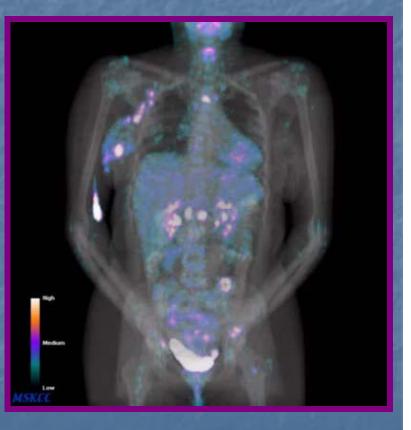
Jennifer L. Marti, MD¹, Lawrence T. Dauer, PhD², Michelle Stempel, MPH¹, Sujata Patil, PhD³, Jennifer B. Kaplan, MD⁴, Leslie L. Montgomery, MD, FACS⁵

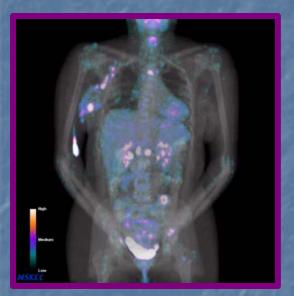
	All patients	1997 cohort	2002 cohort	1997 vs. 2002
	N=68	N=43	N=25	p-value
5y Cumulative	4.56	4.65	4.55	0.56
ED, mSv	(3.3-54.4)	(3.5-62.3)	(3.3-50.2)	
Annual	0.92	0.97	0.91	0.85
ED, mSv	(0.7-11.0)	(0.7-12.5)	(0.7-10.9)	

Annals of Surgical Oncology - pending

Are Diagnostic Doses Really a Concern for Our Patients?

- Risks models based on dose averages and large populations.
- Risk vs. Benefit to Individual.
- Benefit must always be considered.
 Justification and Optimization are paramount

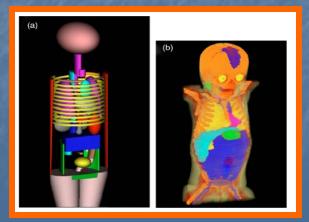




Justification

 In most symptomatic adults, radiation doses for diagnostic radiology procedures, including CT scans, result in extremely small risk, typically well-justified by the medical need.
 Risks are ~ 2-3 x larger

for children.

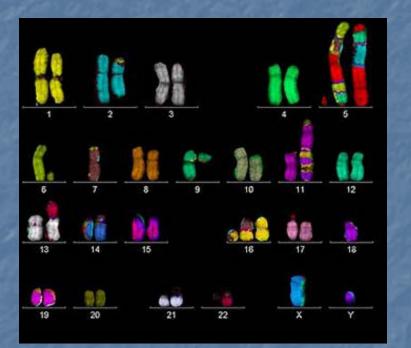


Suggestions

- NO radiation when you don't do the exam! Ensure each exam is justified.
 - Carefully scrutinize screening protocols for 'healthy' subjects and post-therapy screening protocols for pediatric patients and patients with long-term survival expectation.
 - Communicate dose and risk with staff (especially referring physicians) and patients.
- Medical Physics review/testing of final machine std protocols!!



Research Challenges – Some Questions Still Need Answers...



Human Chromosomes Showing DNA Damage From Radiation - Photo Credit: Massey University Molecular markers of DNA damage at low doses? DNA repair fidelity and capacity for double and multiple strand breaks at low doses?

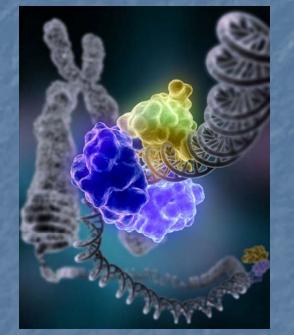
Adaptation, hypersensitivity, bystander effects, hormesis, and genomic instability for radiation carcinogenesis?
How to best communicate risk with patients?
Benefits? 41

Radiation Hazard Index (RHI)

		ED	Background	Typical	Risk
	RHI	Range	Equivalent	Examples	Category
	10	10,000Sv	-	Industrial Uses	10 ⁺² Greater
	9	1000Sv	-	Food Irradiation	10 ⁺¹ Great
	8	100Sv	Centuries	Radiotherapy: dose to tumor	10 ⁰ Major
	7	10Sv	Century	Acute Total Body GI / Bone Marrow	10 ⁻¹ Major
	6	1Sv	Decades	Increased Ca Risk	10 ⁻² Strong
	5	100mSv	Decade	Dose Limits	10 ⁻³ Moderate
	4	10mSv	Years	CT Nuclear Med Diag	10 ⁻⁴ Low
	3	1mSv	Months	Abdominal x-ray	10 ⁻⁵ Very Low
	2	0.1mSv	Weeks	Chest x-ray, Mammography	10 ⁻⁶ Minimal
08	1	0.01mSv	Days	Bone Density, Skull	~0 Negligible

Dauer,200

Research Challenges – What Data are still Needed?



DNA Ligase Repairing Damage

Prospective cohort and nested case-control studies of moderatedose medical exposures. Epidemiological study consortia for medically exposed populations (CTs, Pediatrics, IR). Occupational low-dose studies. **Exposed Population studies.** Current Policies justified and optimized themselves?



Lawrence T. Dauer, PhD, CHP Assistant Attending Health Physicist Department of Medical Physics, MSKCC dauerl@mskcc.org

INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION

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