Clinical Safety & Effectiveness Session # _1__

Safe use of Radiation during Fluoroscopy Procedures

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  - Dr. Michael McCarthy – Department of Radiology Chairman
  - Dr. Pam Otto – Director of Radiology, UHS
  - Michelle Ryerson – Associate Administrator

Our Aim Statement

To ensure that all patients' radiation exposure is below 2Gy for each fluoroscopy procedure by 3months.

Background

- **Radiation:** ionizing energy that can affect biologic tissues.
- **Fluoroscopy:** real-time X ray imaging that is especially useful for guiding a variety of diagnostic and interventional procedures.
- X ray exposure needed to produce one fluoroscopic image is low (compared to radiography), high exposures to patients can result from the large series of images that are encountered in fluoroscopic procedures.

Radiation

- **Absorbed Dose:** The energy imparted per unit mass by ionizing radiation to matter at a specified point. The SI unit of absorbed dose is the joule per kilogram. The special name for this unit is the Gray (Gy).
- **Effective Dose** *:* The sum, over specified tissues, of the products of the equivalent dose in a tissue and the tissue weighting factor for that tissue. Effective dose is measured in Sieverts (Sv). Stochastic risk factors are usually stated relative to effective dose.
- **Equivalent Dose:** A quantity used for radiation protection purposes that takes into account the different probability of effects that occur with the same absorbed dose delivered by radiations with different radiation weighting factors. Effective dose is measured in Sv.
- **Peak Skin Dose (PSD):** The highest dose at any portion of a patient's skin during a procedure.
- **Fluoroscopy Time***:* The total time that fluoroscopy is used during an imaging or interventional procedure

Quality Improvement Guidelines for Recording Patient Radiation Dose in the Medical Record, JVIR, Volume 20, Issue 7, Supplement, Pages S200-S207 (July 2009)

Radiation Side effects

- **Stochastic Effect:** A radiation effect whose probability of occurrence increases with increasing dose, but whose severity is independent of total dose.

- **Deterministic Effect:** A radiation effect characterized by a threshold dose. The effect is not observed unless the threshold dose is exceeded. (The threshold dose is subject to biologic variation.) Once the threshold dose is exceeded in an individual, the severity of injury increases with increasing dose.

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Radiation Side effects

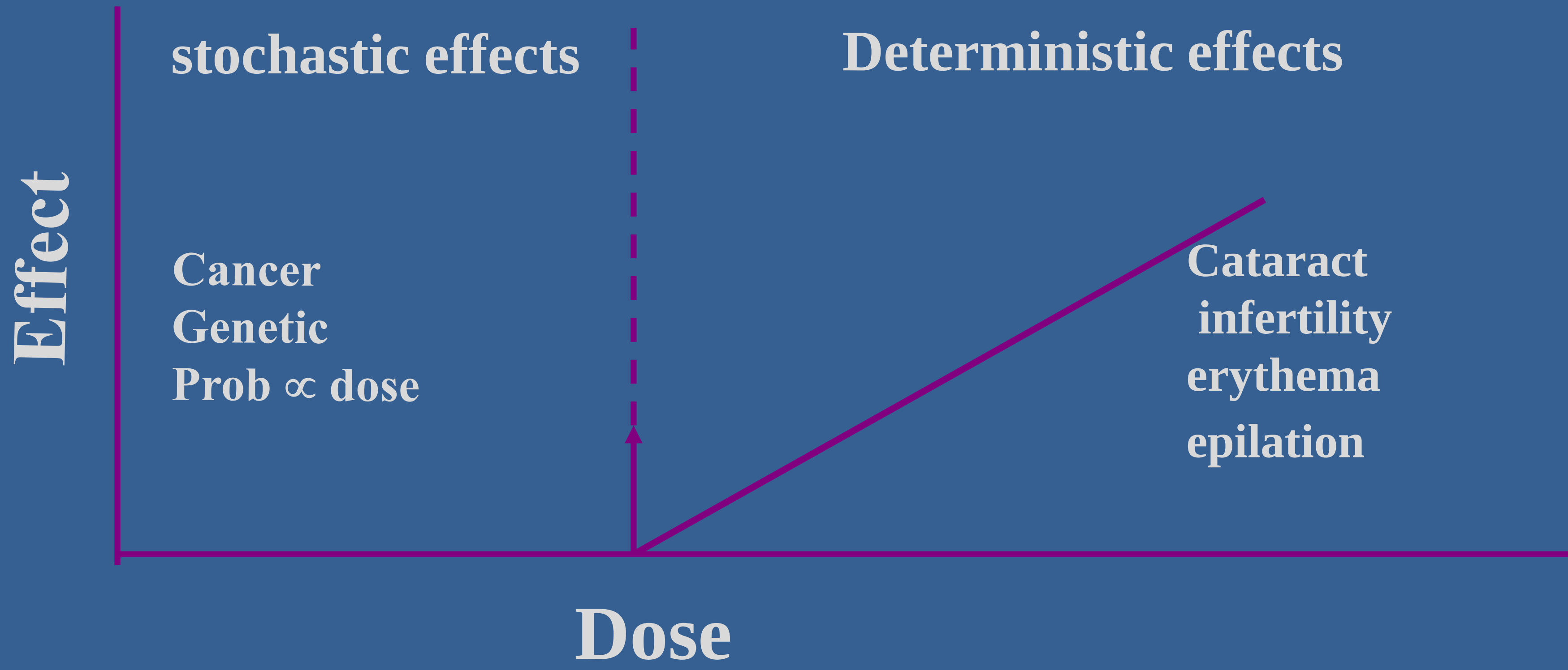
Stochastic (Random) Effects:

- Cancer
- Mental Retardation
- Genetic Effects

Deterministic Effects:

- Sterility
- Cataracts
- **Skin Erythema**
- Hemopoietic Syndrome
- Gastrointestinal (GI) Syndrome
- Central Nervous System Syndrome

Radiation side effects



Radiologists may be at increased cataract risk

Pippa Wysong
in Phoenix, Arizona

INTERVENTIONAL radiologists appear to have an increased risk of developing cataracts because of on-the-job radiation exposure, warned researchers at the annual meeting of the Society for Interventional Radiology.

The cataracts interventional radiologists are at risk for differ markedly from aged-related cataracts and can be identified by their location, reported Ziv Haskal MD, Professor of radiology and surgery at Columbia University, New York.

"The characteristic changes and injury that we get is a posterior subcapsular cataract (PSC)," he said. Age-related cataracts occur between the nucleus and the capsule instead of in the posterior aspect of the lens.

The findings come from an ad hoc study conducted during an earlier conference, the Advanced Interventional Management symposium in New York held in November 2003. Dr Haskal and colleagues announced what they were doing at the opening session, set up a booth in the exhibit hall, and offered free testing of attendees' eyes.

The interventional radiologists lined up and volunteered to be screened. All underwent slit-lamp examination and Scheimpflug imaging. The median age of the radiologists was 45 years and they had been in practice for a median of 11 years, ranging from one to 39 years. Initial findings showed that 22 of the 59 volunteers had small dot-like opacities in the PSC region of the lens, which is consistent with radiation damage.

> "The characteristic changes and injury that we get is a posterior subcapsular cataract" - Ziv Haskal MD

"Standard slit lamp exam, not imaging, in the hands of an ophthalmologist aware of the problems should be able to detect early PSC changes, but will not provide good documentation. Scheimpflug images in combination with retroillumination would be first choice for imaging and documentation," co-investigator ophthalmologist Anna Junk MD, told EuroTimes.

For the most part, while the changes were detectable in the images, the radiologists didn't notice any change in vision, Dr. Haskal said. With age-related cataracts, visual acuity drops while posterior subcapsular cataracts can lead to decreased contract sensitivity.

The lens of the eye consists of some of the most radiation sensitive tissue of the body. Interestingly, other studies have shown that if the nucleus is removed and radiated no cataract forms. The damage from ionising radiation occurs in the germinate zone at the edge of the lens, Dr. Haskal explained.

Dr. Junk pointed out that the daily close proximity to radiation sources of interventional radiologists in the study differs from that of other types of radiologists, such as those who do diagnostics only.

The findings are early and there are still a lot of unanswered questions. There are still hundreds of images to sort through to look for changes, and the numbers of PSCs found may change, said Dr. Haskal. He also pointed out there were some confounders in the study, such as the fact that seven of the subjects had received steroids at some point which can also lead to PSC cataracts.

Just what the rates are of cataracts among interventional radiologists overall, or what the actual risk to this physician group is not yet known. There are also questions about what the cataract risks for other radiologists and technicians might be. The study's compelling findings highlight the need for further studies involving larger groups of radiologists, Dr. Haskal said.

The researchers are currently collecting additional information from the study's participants. They want to find out details such as where each radiologist stands when performing interventional procedures. If a radiologist tends to stand to one side, then there could be a sidedness to the eye damage, such as in the left eye only, he said.

The findings of this study support the idea that interventional radiologists should have an annual eye exam, Dr. Junk advised.

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- The median age of the radiologists was 45 years
- In practice for a median of 11 years, (range1 to 39)
- Initial findings showed that 22 **(37,2%)** of the 59 volunteers had small dot-like opacities in the PSC region of the lens, radiation damage.

Radiation Measurement

- Deterministic Effects - **Peak Skin Dose (PSD):** The highest dose at any portion of a patient's skin during a procedure.
- Stochastic (Random) Effects - **Dose–Area–Product (DAP):** The integral of air kerma (absorbed dose to air) across the entire x-ray beam emitted from the x-ray tube. DAP is a surrogate measurement for the entire amount of energy delivered to the patient by the beam. DAP is measured in Gy·cm2.

Quality Improvement Guidelines for Recording Patient Radiation Dose in the Medical Record, JVIR, **Volume 20**, **Issue 7, Supplement**, Pages S200-S207 (July 2009)

Factors that Increase Entrance Dose

- Long duration of fluoroscopy
- Use of high-intensity mode
- Maintenance of a single angle of view
- Patient obesity
- Cranio-caudal angulation of the X-ray beam
- High image magnification
- No dose monitoring
- X-ray machine defects

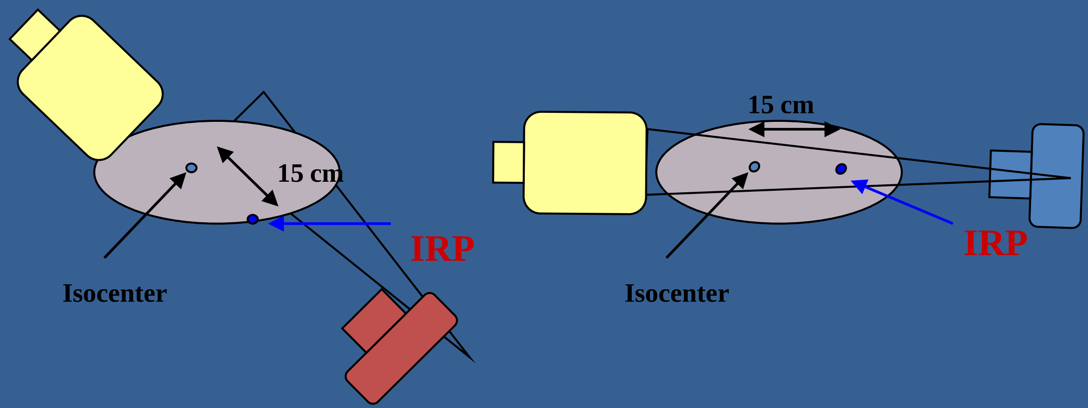
Radiation Burns as a Severe Complication of Fluoroscopically Guided Cardiological Interventions, JIC, Volume 17, Issue 3, Pages 131-142

Maximum local skin dose (MSD or PSD) assessment

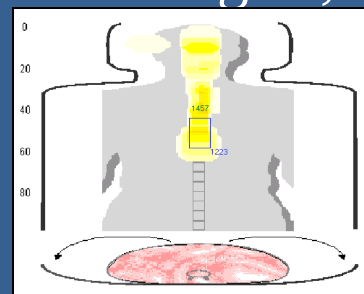
- On-line methods
- Off-line methods

MSD: on-line methods

- Zinc-Cadmium based sensor, Linked to a calibrated digital counter, Position sensor on patient, in the X ray field, Real-time readout in mGy
- Point detectors (ion chamber, diode and Mosfet detectors)
- Dose to Interventional Radiology Point (IRP) via ion chamber or calculation



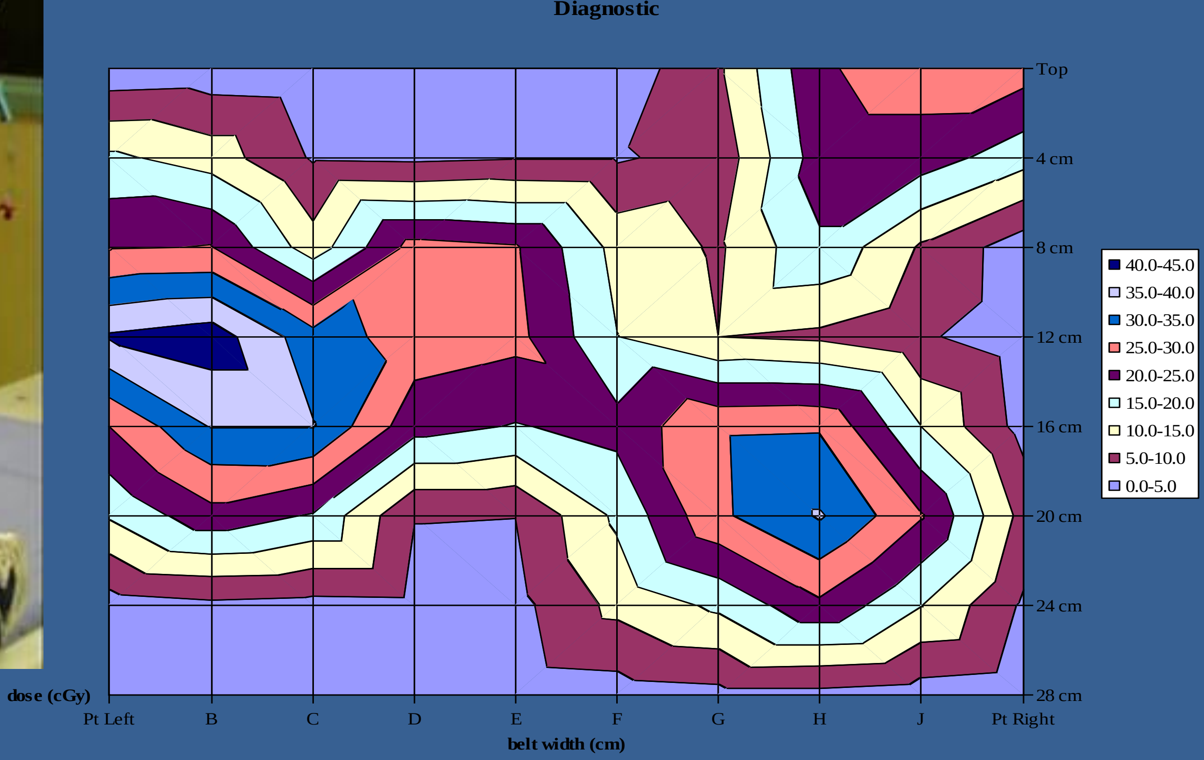
- Dose distribution calculated by the angio unit using all the geometric and radiographic parameters (C-arm angles, collimation, kV, mA, FIID, …)



MSD: off-line methods

– Area detectors: TLD grid

- Dose distribution is obtained with interpolation of point dose data



Threshold Skin Entrance Doses for Different Skin Injuries

Effect	Single-Dose Threshold (Gy)	Onset
Early transient erythema	2	Hours
Main erythema	6	~10 d
Temporary hair loss	3	~3 wk
Permanent hair loss	7	~3 wk
Dry desquamation	14	~4 wk
Moist desquamation	18	~4 wk
Secondary ulceration	24	>6 wk
Late erythema	15	~6–10 wk
Ischemic dermal necrosis	18	>10 wk
Dermal atrophy (1st phase)	10	>14 wk
Dermal atrophy (2nd phase)	10	>1 yr
Induration (invasive fibrosis)	10	
Telangiectasia	10	>1 yr
Late dermal necrosis	>12?	>1 yr
Skin cancer	not known	>5 yr

d: day(s), Gy: gray, wk: week(s), yr: year(s).

Radiation Burns as a Severe Complication of Fluoroscopically Guided Cardiological Interventions, JIC, Volume 17, Issue 3, Pages 131-142

Effects of radiation on skin and hair

Effect	Approximate Threshold (Gy)	Initial Occurrence	Note
Early transient erythema	2	Hours	Inflammation of the skin caused by activation of a proteolytic enzyme that increases the permeability of the capillaries
Acute ulceration	20	<2 weeks	Early loss of the epidermis that results from the death of fibroblasts and endothelial cells in interphase
Epilation	3	2 to 3 weeks	Hair loss caused by the depletion of matrix cells in the hair follicles; permanent at doses exceeding 6 Gy
Dry desquamation	8	3 to 6 weeks	Atypical keratinization of the skin caused by the reduction of the number of clonogenic cells within the basal layer of the epidermis
Main erythema	3	Days to weeks	Inflammation of the skin caused by hyperemia of the basal cells and subsequent epidermal hypoplasia
Moist desquamation	15	4 to 6 weeks	Loss of the epidermis caused by sterilization of a high proportion of clonogenic cells within the basal layer of the epidermis
Secondary ulceration	15	>6 weeks	Secondary damage to the dermis as a consequence of dehydration and infection when moist desquamation is severe and protracted
Late erythema	20	8 to 20 weeks	Inflammation of the skin caused by injury of the blood vessels; edema and impaired lymphatic clearance precede a reduction in blood flow
Dermal necrosis	20	>10 weeks	Necrosis of the dermal tissues as a consequence of vascular insufficiency
Invasive fibrosis	20	Months to years	Method of healing associated with acute ulceration, secondary ulceration, and dermal necrosis, leading to scar tissue formation
Dermal atrophy	10	>26 weeks	Thinning of the dermal tissues associated with the contraction of the previously irradiated area

Centers for Disease Control and Prevention, *Cutaneous radiation injury: fact sheet for physicians* (2006) Available at: http://www.bt.cdc.gov/radiation/criphysicianfactsheet.asp. Accessed October 6, 2006..

Factors that may lower the threshold for radiation-induced skin injury

1. Previous radiation to the area
2. Diseases
• Diabetes mellitus
• Hyperthyroidism
• Collagen-vascular disease
• Ataxia telangiectasia
3. Drugs
• Actinomycin D
• Adriamycin
• Bleomycin
• Fluorouracil
• Methotrexate
• Simvastatin

T.R. Koenig, D. Wolff, F.A. Mettler and L.K. Wagner, Skin injuries from fluoroscopically guided procedures: part 1, characteristics of radiation injury, *AJR Am J Roentgenol* **177** (2001), pp. 3–11

6-8 weeks after multiple coronary angiographic and angioplasy procedures

Injury approximately 16-21 weeks after procedure

18-21 months after procedure. Tissue necrosis is evident

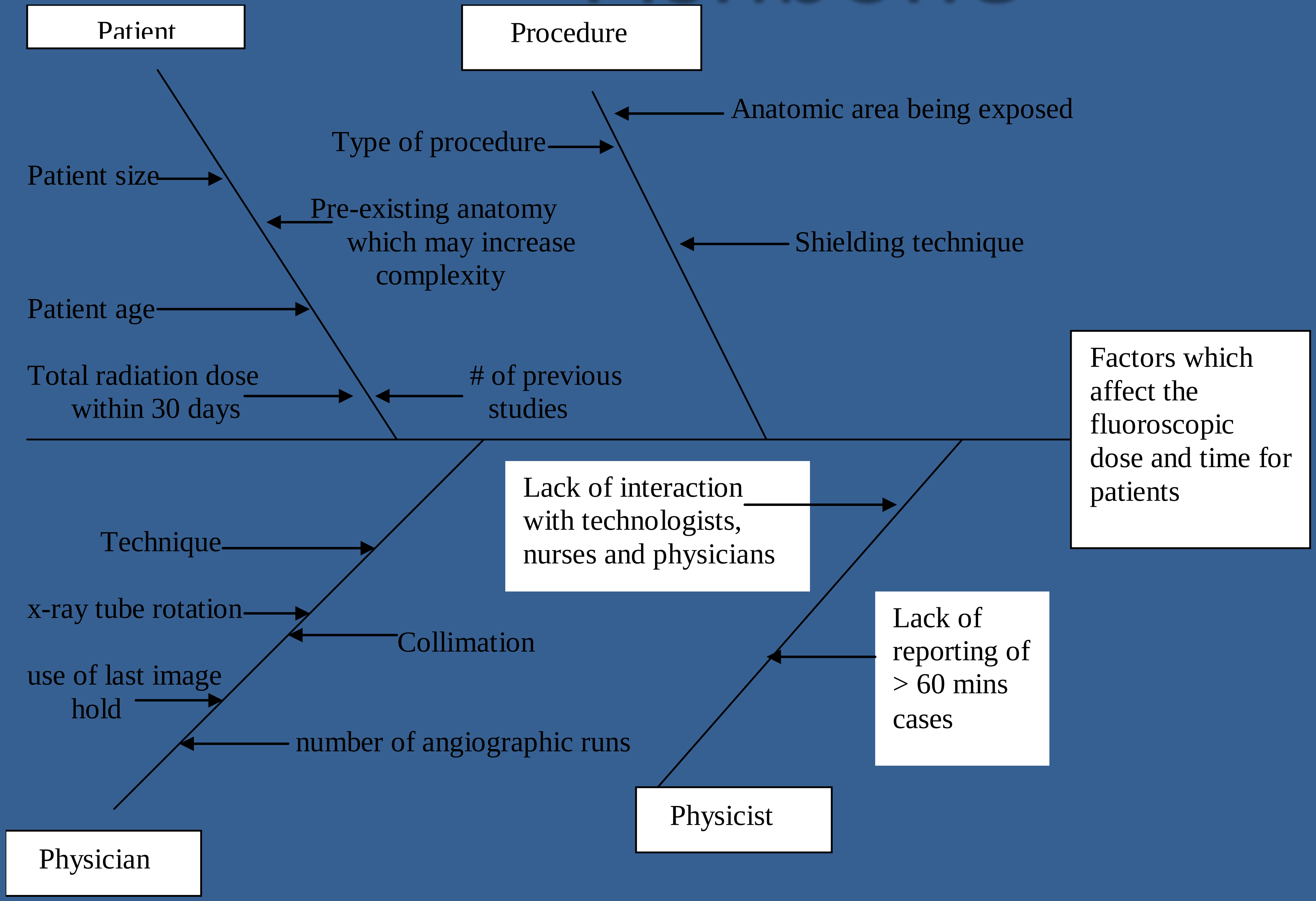
Radiation-induced skin injuries from fluoroscopy. T B Shope September 1996 Imaging & Therapeutic Technology, Vol 16:5, 1195-1199.

Close up of last photograph in previous slide

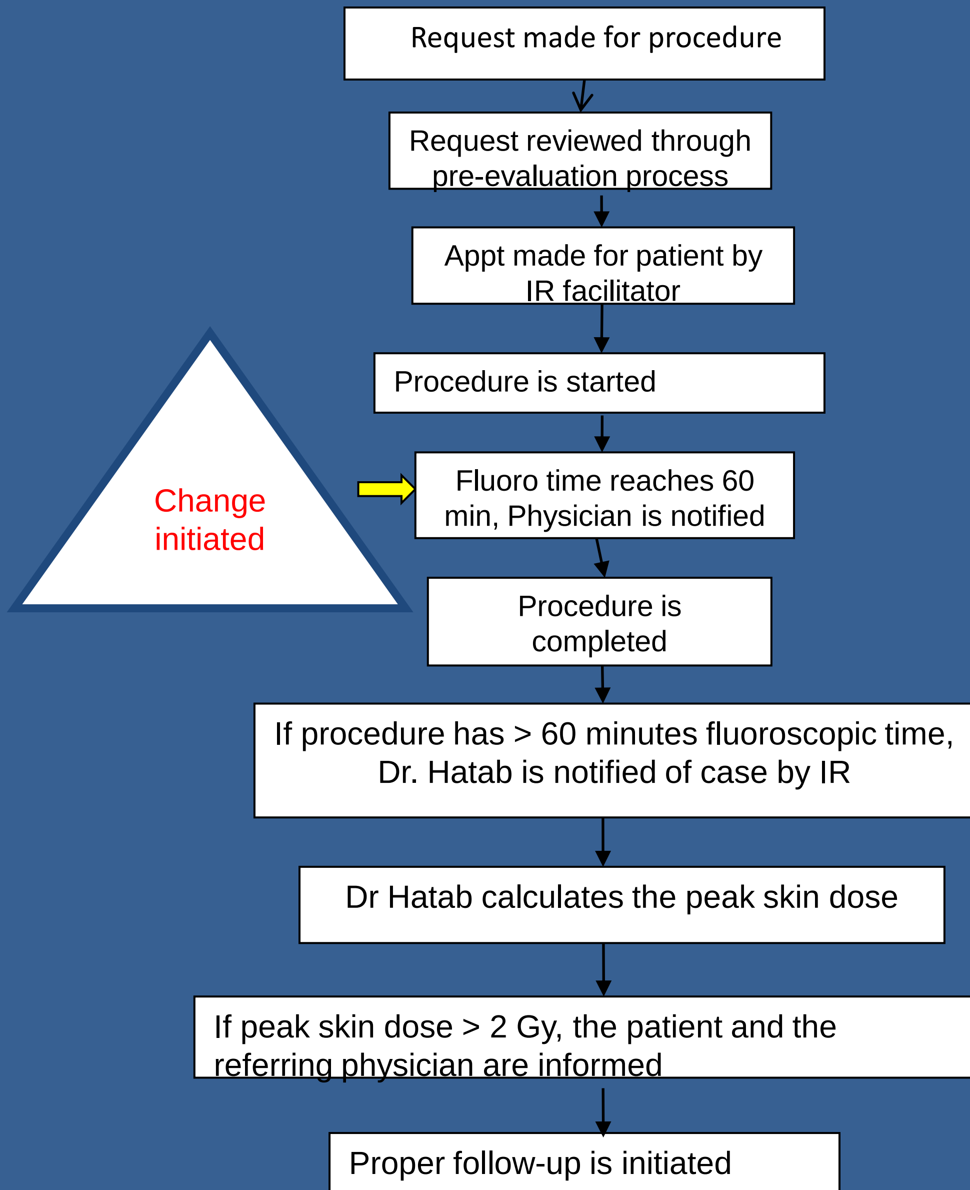
Area of back after skin grafts

Radiation-induced skin injuries from fluoroscopy. T B Shope September 1996 Imaging & Therapeutic Technology, Vol 16:5, 1195-1199.

Fishbone

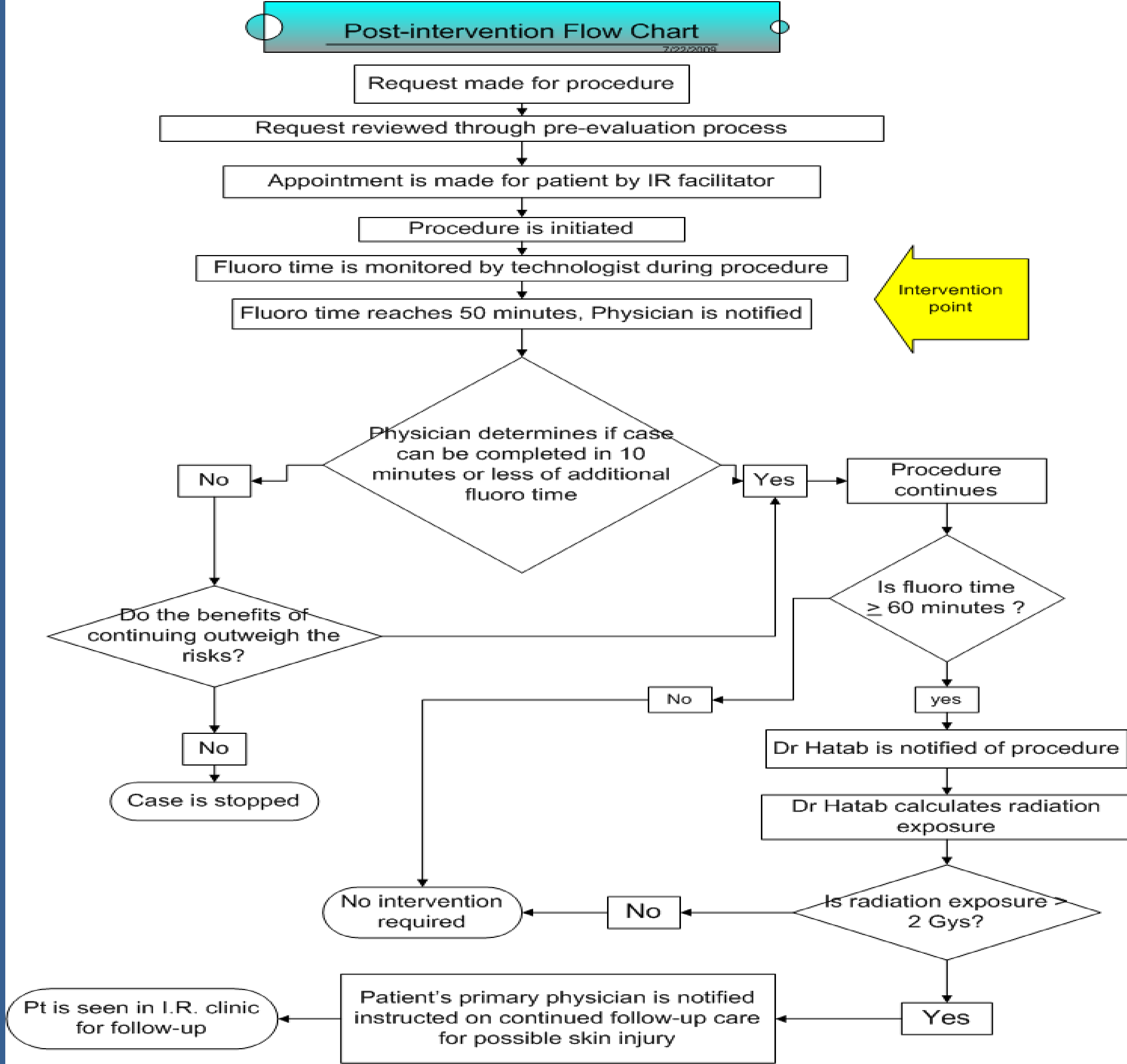

Patient
Procedure
Anatomic area being exposed
Type of procedure
Patient size
Pre-existing anatomy which may increase complexity
Shielding technique
Patient age
Total radiation dose within 30 days
# of previous studies
Factors which affect the fluoroscopic dose and time for patients
Lack of interaction with technologists, nurses and physicians
Technique
x-ray tube rotation
Collimation
Lack of reporting of > 60 mins cases
use of last image hold
number of angiographic runs
Physicist
Physician

Pre-intervention Flow Chart



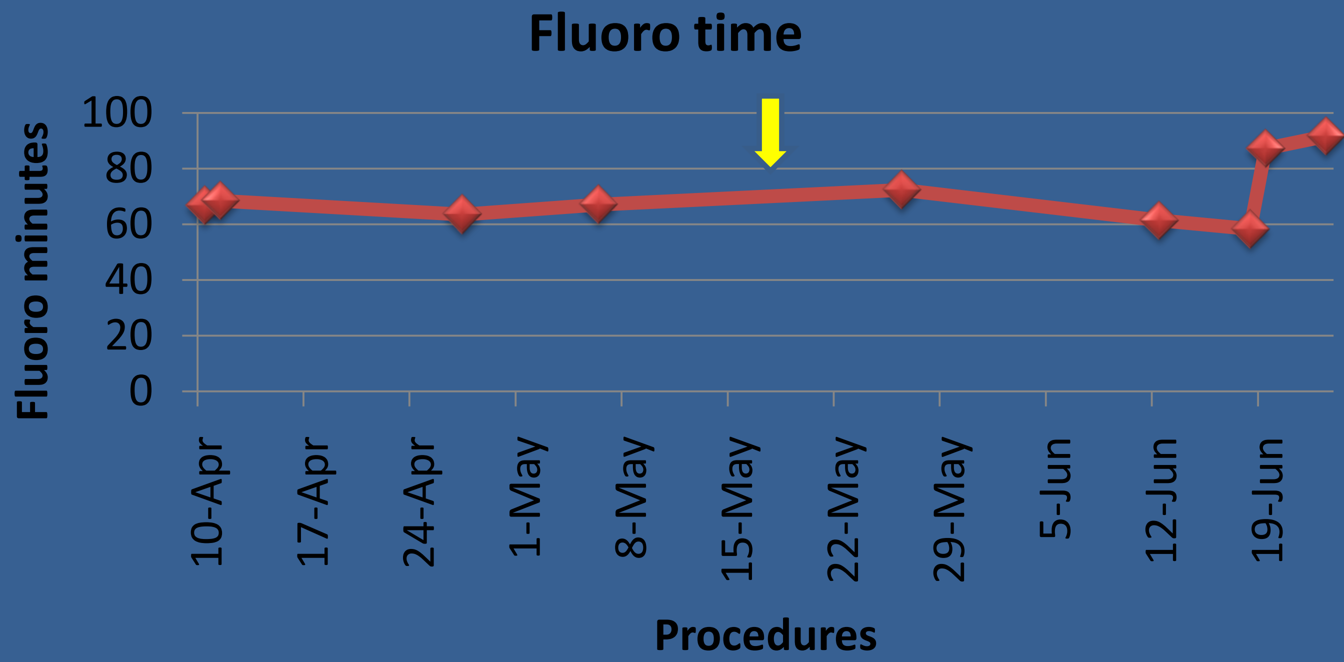
Intervention

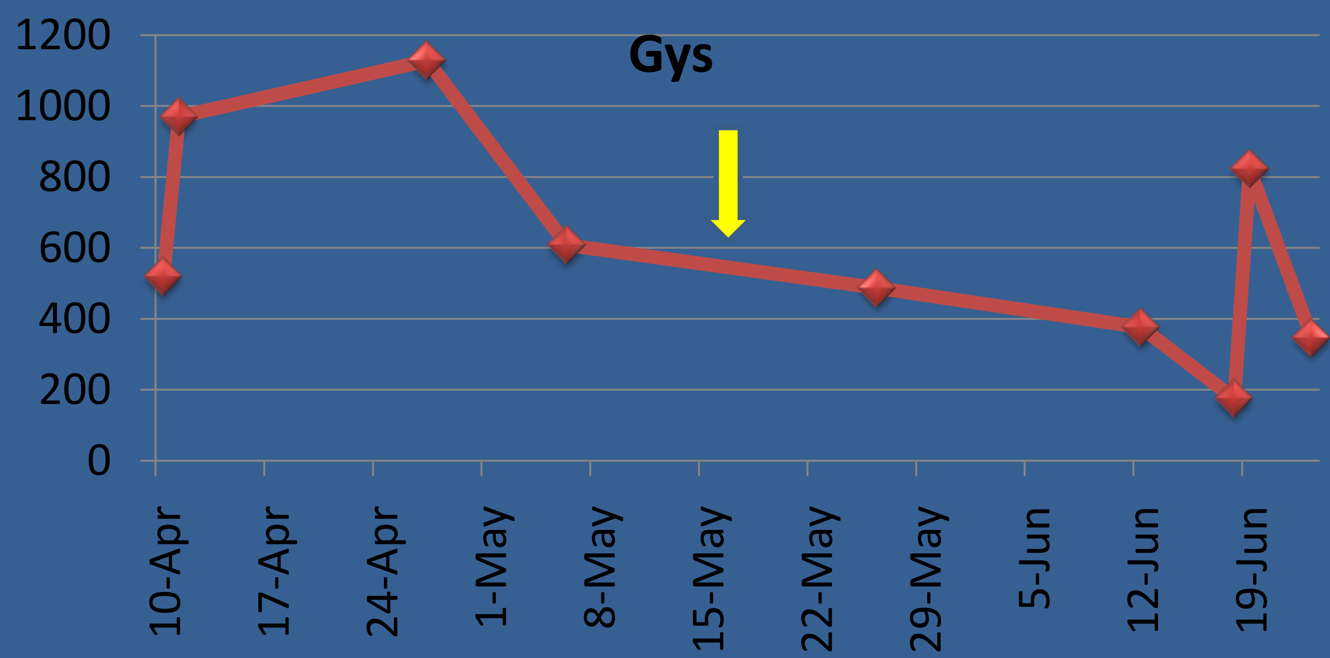
- Monitoring real time fluoro time
- Notification to Physician of 50 minute flouro time
- Education of proper techniques of radiation use
- Establishing proper clinical follow-up of patients exposed to >2 Gy dose


Post-intervention Flow Chart
Request made for procedure
Request reviewed through pre-evaluation process
Appointment is made for patient by IR facilitator
Procedure is initiated
Fluoro time is monitored by technologist during procedure
Fluoro time reaches 50 minutes, Physician is notified
Intervention point
Physician determines if case can be completed in 10 minutes or less of additional fluoro time
No
Yes
Procedure continues
Do the benefits of continuing outweigh the risks?
Is fluoro time ≥ 60 minutes ?
No
yes
No
Case is stopped
Dr Hatab is notified of procedure
Dr Hatab calculates radiation exposure
No intervention required
No
Is radiation exposure > 2 Gys?
Pt is seen in I.R. clinic for follow-up
Patient's primary physician is notified instructed on continued follow-up care for possible skin injury
Yes

Implementing the Change

- Implemented new protocol for real time monitoring and notification by technologist during procedures.
- One-to-one in-services done with technologist concerning dose reaction
- Active involvement of physicians in the prevention, recognition and management of radiation side-effects.





= Indicates time of intervention

Return on Investment

Implementation of this new process:

- Did not increase the cost to the health institute or to the patient
- Was easily implemented into the current department processes
- May potentially prevent any additional health care cost the patient may incur related to radiation exposure injuries.

Expansion of Our Implementation

Our hope is to develop a template that can be implemented in other areas of health care where live fluoroscopy is used, such as:

- cardiology
- rehab medicine
- vascular and thoracic surgery

Conclusion

Benefits:

- To the patient
- To the team
- To the hospital

Thank you!

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