Reducing Unnecessary Medical Imaging Exposure

U.S. Food and Drug Administration
Center for Devices and Radiological Health
April, 2010
Initiative Motivation

Over the past three decades, there has been an increase in the U.S. population’s total exposure to ionizing radiation, largely due to medical imaging.

In 2006, the majority of medical imaging exposure was from CT, nuclear medicine, and interventional fluoroscopy.

Initiative Scope

- High-dose medical imaging procedures
  - Computed tomography
  - Interventional fluoroscopy
  - Nuclear medicine
Initiative Goal

- *Each patient should get the right exam, at the right time, with the right dose*

- **Dose optimization**
  - Minimize the individual’s exposure to radiation for each exam while maintaining image quality

- **Exam justification**
  - Ensure that only medically necessary examinations are performed
Initiative Overview

- Promote Safe Use of Medical Imaging Devices
- Support Informed Clinical Decision Making
- Increase Patient Awareness
Promote Safe Device Use

Establish safety requirements for CT and fluoroscopic devices

- Dose display, recording, reporting
- Access controls
- Alerts
- Optimized default settings
- Training for users
Promote Safe Device Use

- Partner with CMS to enhance facility quality assurance practices
  - Refine accreditation criteria, interpretive guidelines and conditions of participation
  - Incorporate dose optimization and justification
- Promote efforts to develop diagnostic reference levels locally and nationally
Support Clinical Decision Making

- Establish recordkeeping requirements for CT and fluoroscopic devices
  - Linking dose information with patient records
  - Transmission of imaging data to local or national database
  - Incorporation of exam ordering systems

- Promote efforts to develop appropriate referral criteria
Increase Patient Awareness

- Provide patients with tools to track their personal medical imaging history

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**X-RAY RECORD CARD**

Name: ____________________________

Health Ins. Co.: ____________________________

Policy No.: ____________________________

For additional cards, write to FDA, HFZ-220, 1350 Piccard Dr.,
Rockville, MD 20850

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**HELP REDUCE X-RAY RISKS & COSTS**

- Feel free to ask your doctor how an x-ray will help with the diagnosis and treatment.
- Don’t refuse an x-ray if there’s a clear need for it. Remember, the risk is small.
- Ask if a gonad shield can be used for yourself and for your children during x-rays of the abdomen.
- Tell the doctor or x-ray personnel if you are, or might be pregnant, before having an x-ray of the abdomen.
- Don’t insist on an x-ray if the doctor explains there is no need for it.

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<tr>
<th>DATE</th>
<th>TYPE OF EXAM</th>
<th>REFERRING PHYSICIAN</th>
<th>ADDRESS WHERE X-RAYS ARE KEPT</th>
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Future State

- A new medical center is built in California
- Radiology clinic purchases a new CT system
- Gains accreditation to perform CT and other medical imaging exams
Facility QA

- Staff are trained to properly use equipment and its dose reduction features.
- The facility routinely reviews data and assesses dose protocols, taking action to ensure exams are justified and that dose is optimized.
Patient awareness

- Patients and their caregivers come for exams with a medical imaging history card in hand.
- Staff are trained to discuss risks and benefits of medical imaging procedures and answer patient questions.
A hospital exam ordering system evaluates appropriateness of the exam before it begins
- Based on referral criteria established by facility, medical professional organizations

Imaging protocols and settings are reviewed in advance
- System requires verification of settings, controls access to changes and tracks modifications made by staff
Equipment features

- The system automatically retrieves information from hospital data systems and/or other dose registry.
  - Verifies that settings and dose are within expected range.
  - Alerts users when outside the range or if the patient recently had another medical imaging exam.
During each exam, the system automatically collects imaging settings and dose data.

- Transmits data to hospital PACS system, the patient’s electronic health record and a National Dose Registry.
Questions

More information at: