# Reducing Cancer Exposure for Patients & Doctors

MAY 10, 2021

# Agenda

- Welcome & Introductions
- Video: Dr. Diethrich's Story – Invisible Impact
  - The Risk of Ionizing Radiation on Medical Personnel
- Risks and Benefits of Medical Advancements
- A Vascular Surgeon's Perspective: Effects of Radiation Exposure
- Innovations to Improve Safety for Patients, Doctors and Healthcare Workers
- How Can Government Support Innovations and Improve Safety
- Q&A

# Speakers

**Liz Powell, Esq., MPH**, former Legislative Director on the Hill; Founder of G2G that focuses on health innovation

**Matthew Eagleton, MD, FACS**, Chief, Division of Vascular and Endovascular Surgery; Co-Director, Fireman Vascular Center; Robert R. Linton Professor of Surgery, Harvard Medical School; Massachusetts General Hospital

**Madhu K . Mohan, MD, FACP,** NIH Trained Physician with Maryland Radioactive Materials License; Executive Medical Director, Doctors Community Hospital; Director, Riverside Clinical Research Center

**Vikash Goel, MS**, Inventor, Entrepreneur and Consultant, Cleveland Clinic & CTO of Centerline Biomedical, Inc.

# Pioneers in Minimally-Invasive Endovascular Procedures Risking Their Lives to Save Patients

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# VIDEO:
# Dr. Diethrich's Story
# Invisible Impact

## The Risk of Ionizing Radiation on Medical Personnel

Organization for Occupational Safety in Interventional Fluoroscopy

# Risks and Benefits of Medical Advancements

MADHU K. MOHAN, MD, FACP

# Radiation 101: Therapy vs. Medical Devices vs. Naturally Occurring

- **Radiation therapy** (also called radiotherapy) is a **cancer treatment** that uses high doses of radiation

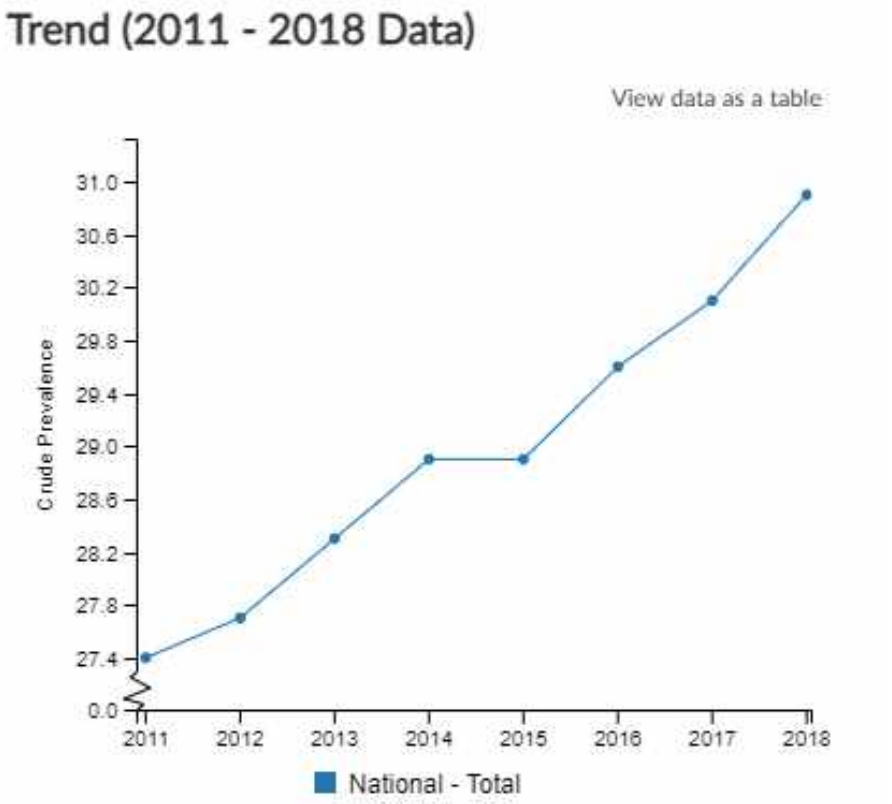
# Radiation 101: Therapy vs. Medical Devices vs. Naturally Occurring

- **General public exposed** to low doses of ionizing radiation from:
  - **Medical exposures** like computed tomography (CT) scans, X-Rays
  - **Naturally occurring radiation** (emitted from bedrock with the earth's crust, cosmic rays emitted by the sun)
  - **Occupational exposures** to ***medical***, aircrew and nuclear workers

# Significant Increase in Radiation Exposure

- **6-fold increase** in radiation exposure was experienced by healthcare workers from 1980-2014
- **74% increase** per capita in radiation exposure in the U.S. overall, during a ~30-year period – **nearly half of the exposures were related to medical imaging**

# Increased Disease and Risk Factor Rates




**% of adults age 18+ who are obese in U.S.**

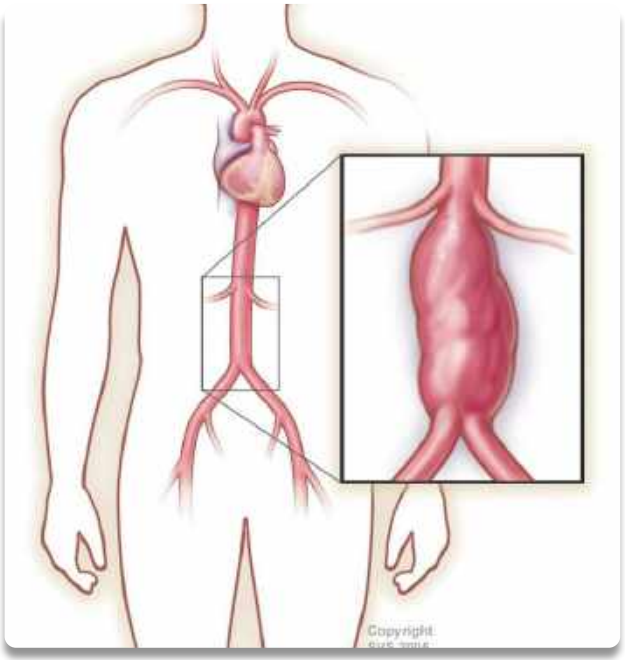
Disease Rates (1990-2019)[1]

- Cardiovascular disease (CVD) ***rates nearly doubled***
- Peripheral artery disease (PAD) rates resulting in ***2-fold increase*** (113 million cases)
- ***Steady increase*** in aortic aneurysms

Risk Factor Rates

- ***22.9% increase*** in U.S. adults with ***hypertension*** (1999-2018[2])
- ***Obesity rates*** have reached ***epidemic levels***[1] — 30.9% in 2018[3]

# Vascular Disease is Increasing Leading to Increased Procedures



- **Vascular disease** (any condition impacting the network of blood vessels) is rapidly **increasing** in prevalence, fueled by aging population and increases in obesity and diabetes
- Results in increased endovascular surgery

# A Vascular Surgeon's Perspective: Effects of Radiation Exposure

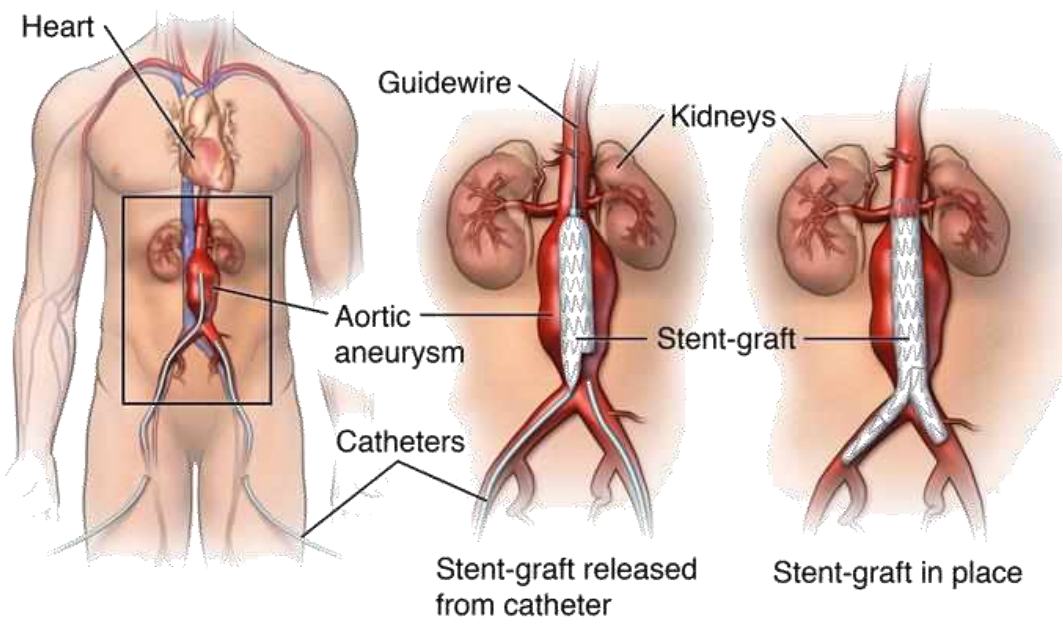
MATTHEW EAGLETON, MD, FACS

# Massachusetts General Hospital
# Division of Vascular and Endovascular Surgery

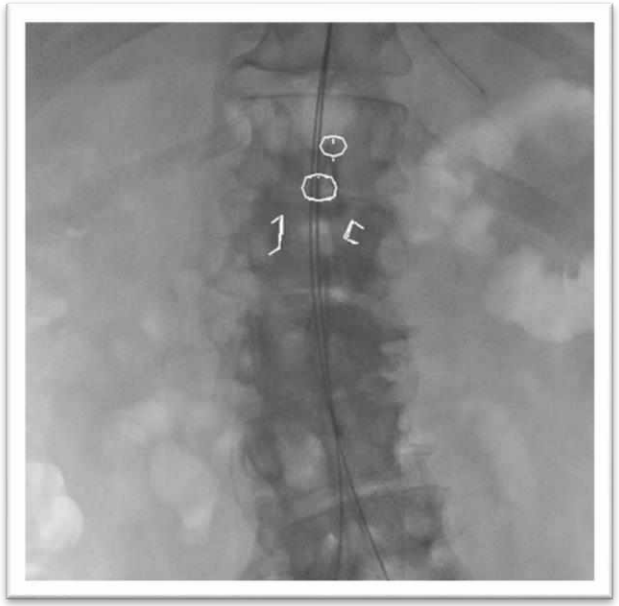

- One of **1st clinics** for evaluation and treatment of **vascular diseases** established at Mass General in 1930s
- Advancing field of vascular surgery with many **innovations** and **pioneering techniques**
- Established **1st stent graft program** for aortic aneurysms in **New England**
- The **most cumulative stent graft experience** in the region

# Endovascular Surgery

- Minimally-invasive vascular surgery with stents, balloons, wires, catheters
- Imaging is required to enable doctor to place these
- With drive towards less invasive therapies, procedures are more complicated, require increased fluoroscopy time and improved imaging
- **Standard of care must protect patients and doctors**



# The Problem: X-Ray Fluoroscopy Uses High Radiation Exposure with Limited View



- Limited 2-D visualization and navigation so use repetitive X-rays
- Ionizing radiation and nephrotoxic contrast agent must be used
- Long procedures in expensive ORs
- Limited access outside tertiary care facilities

# Occupational Health Risks Associated with Radiation Exposure

- Fluoroscopy **exposes patients and caregivers to radiation**
- A complex aortic aneurysm repair can involve the equivalent of **hundreds or thousands of X-rays**
- Many doctors are exposed on a near-daily basis, causing **cataracts, strokes, spine and orthopedic issues, and cancer**


**Changes to the eyes, which lead to cataracts**


**Spine issues from wearing heavy lead garments**


**Brain tumors closest to the radiation source**


**Miss work due to orthopedic issues**

# Protection Measures Cause Other Health Complications

- Practice ALARA – "As Low As Reasonably Achievable"
- Lead garments to "block" radiation – some procedures last several hours!
  - Lead garments must be worn for body protection
  - Additional components for head, arms, and legs
- Chronic **hip and back pain for healthcare workers**
  - **33% will miss work at some point due to orthopedic injuries due to wearing lead**

**Lead garment**

# Protecting Patients, Doctors and Healthcare Workers

**According to the FDA:**

- "Fluoroscopy can result in relatively high radiation doses, especially for complex interventional procedures (such as placing stents or other devices inside the body) which require fluoroscopy be administered for a long period of time.
  - https://www.fda.gov/radiation-emitting-products/medical-x-ray-imaging/fluoroscopy

**According to the CDC:**

- "The guiding principle of radiation safety is ALARA: As Low As Reasonably Achievable. This principle means that even if it is a small dose, if receiving that dose has no direct benefit, you should try to avoid it."
  - https://www.cdc.gov/nceh/radiation/alara.html

# ALARA: Three Basic Protective Measures Recommended in Radiation Safety

**The risk/benefit ratio must prevail in medicine** – carefully evaluate the risk of radiation exposure, for the patients, but also for the medical staff

- **Minimize time** near a radiation source to only as long as it takes to complete a procedure
- **Maximize distance** from a radioactive source as much as possible
- **Shield oneself** from a radiation source by putting something between you and the source

# Innovations to Improve Safety for Patients, Doctors and Healthcare Workers

VIKASH GOEL, MS

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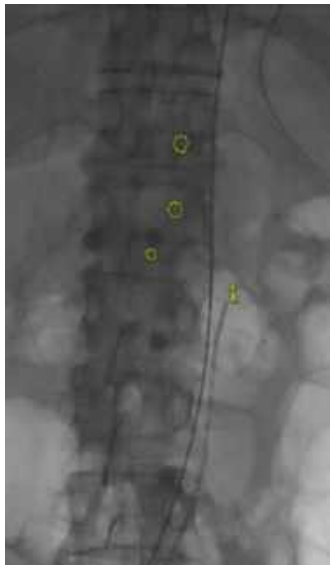
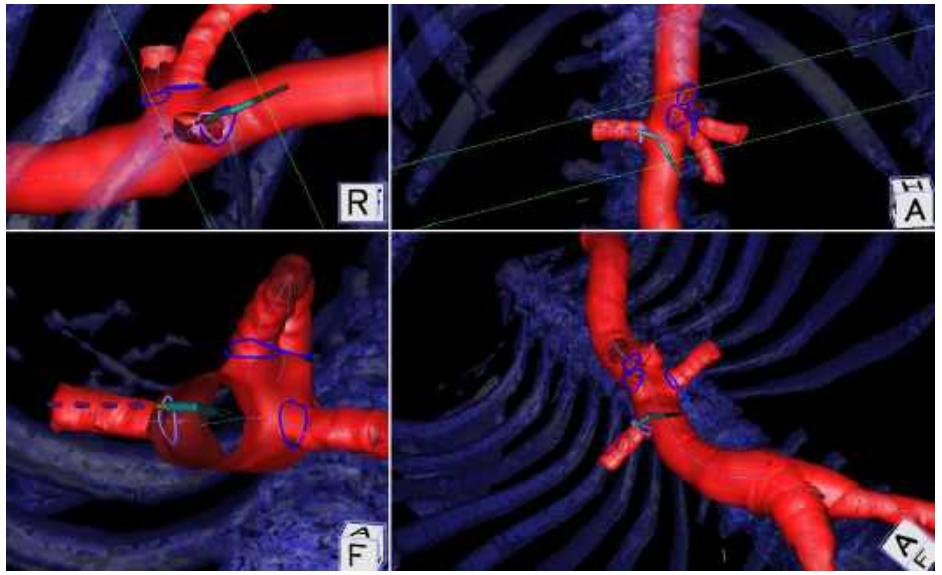
# The Solution: Innovative Technology with NO Radiation Exposure






Easy navigation with 3D and color

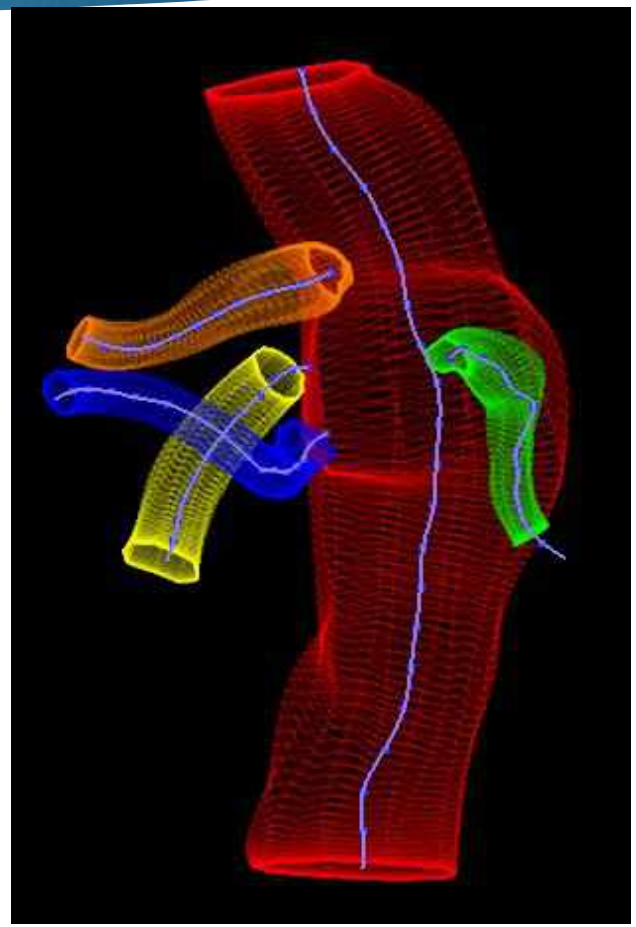
Safe electromagnetic tracking, non-ionizing-radiation based

Faster procedures, better throughput, lower costs

Broader reach of endovascular treatment

# Medical Innovation: 3D, Color Imaging with No Radiation

- New **FDA-approved** innovative technology platform to revolutionize surgical navigation and medical imaging, being introduced at sites across the country
- Platform that uses a computerized system for **modeling patient anatomy**
- Pioneering Innovative Solution out of Cleveland Clinic: **3-D, color visualization and navigation** for endovascular procedures



# Trauma Care: Civilian and Military Relevance

- Endovascular therapies are emerging as viable option for **management of acute trauma**
- Endovascular procedures rely on large, complex fluoroscopic equipment that uses radiation and can be hard for doctors to use
- Cardiovascular interventions are common in civilian and military trauma, esp. high-risk populations
- Vascular trauma is common in battlefield; blunt traumatic aortic disruption (BTAD) is the **2nd leading traumatic cause of death**

# How Can Government Support Innovations to Improve Safety

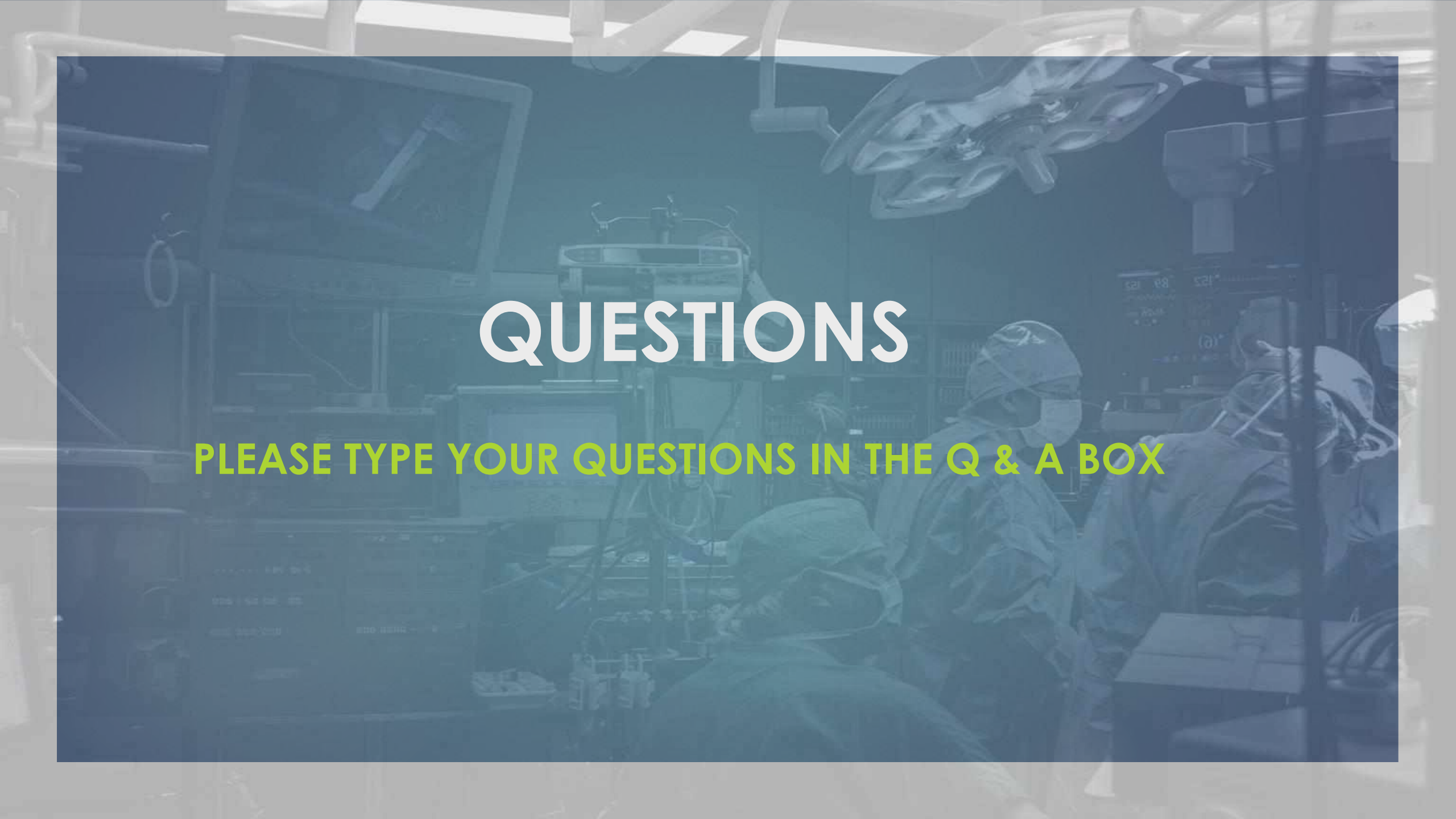
LIZ POWELL, ESQ, MPH

# Background: Safety First

- In 1994, the FDA issued a report warning patients and clinicians of the health dangers, including cancer, linked to medical procedures like fluoroscopy
- CDC issued warnings that redundant X-rays causing unnecessary risk to patients should be avoided – ALARA
- No government action to reduce radiation exposures from fluoroscopy or similar procedures

# Study the Problem and Foster Innovations

- Collect data on avoidable cumulative lifetime medical radiation exposure for healthcare professionals and require reporting by hospital systems
- Set new standard for healthcare workers on radiation exposure risks as part of a national data gathering system to inform patient safety strategies
- Private, public, military and VA health systems should use new technologies that reduce or eliminate radiation exposure
- FDA should update the 1994 report to address warnings and all technologies that can avoid radiation
- CMS should adopt MCIT rule so will reimburse once obtain FDA Breakthrough designation



# QUESTIONS

## PLEASE TYPE YOUR QUESTIONS IN THE Q & A BOX