Long COVID-19: Cardiac Sequelae

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Disclosures

None

Learning Objectives

- Understand long COVID-19 effects on the heart.
- Identify imaging related long COVID-19 cardiac/cardiovascular disease.
- Be aware of potential outcomes in long COVID related cardiac disease.

COVID-19 Infection

- 2020 WHO: SARS-CoV-2 a global pandemic

  Multi-system disease: Inflammatory & thrombogenic response to COVID-19
- Main cause of death: Respiratory
- After lung, cardiovascular injury can be significant & fatal

ACUTE COVID-19

- ACE2: COVID-19 receptor
- Causes a proinflammatory & pro-oxidative cellular state
- "*Cytokine storm*": very aggressive immune response, causing severe tissue damage.
- Response worse than the virus itself.

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- Most people recover in 12 wk, but for some symptoms may persist
- 3 in 10 w COVID can get long COVID & a higher I yr risk for heart problems
- Mild or no symptoms, pre-COVID healthy or multiple medical problems, + or – smoke or drink, renal disease, obesity

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Risk for LONG COVID*

- Female, elderly
- Obesity
- Asthma
- Poor general health
- Poor pre-pandemic mental health
- Poor socioeconomic status

*Some risk factors increased due to lockdown: stay at home, remote work, sedentary, obesity

Risk for LONG COVID

- Obesity & other cardiometabolic risk factors promote inflammation & endothelial dysfunction
- 6,907 pt (19-63 yr) obesity increased long COVID by 25%

LONG COVID Symptoms

- Fatigue, breathlessness, sudden dyspnea
- Chest pain, palpitations, low oxygen
- Headache, lightheadedness, brain fog
- Autonomic dysfunction (POTS)
- Sweating, joint pain, ankle swelling
- Nausea, diarrhea

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LONG COVID Symptoms

- Similar to post-viral syndrome w other human coronavirus infections w symptoms up to 4 yrs
  - 2002 SARS (Severe Acute Respiratory Syndrome) up to 15 yr (lung lesions)
  - 2012 MERS (Middle East Respiratory Syndrome)

LONG COVID

- Global Center for Health Security (12/27/2023)
  - Every COVID infection increased one's risk for long COVID
  - Controversial rates: 10-50%
  - Global estimates: 65 million

COVID & Reinfection

- Unclear mechanism of reinfection
- ↑ infection: ↑ risk hospital & death.
- SARS-CoV-2 rapidly mutating.
- Prior infection/vaccine immunity decreases over time.

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Potential New Tests

- Nov 2023: Cardiff Univ SOM in Cardiff, Wales
- 2 of 3 patients with long COVID: anxiety and depression
- ↑ 4 complement proteins* predicted long COVID with 78.5% accuracy

* Ba, iC3b, C5a, TCC

ATTENDANCE VERIFICATION CODE

5681

COVID-19 Heart

COVID-19: Heart

- Viral infections that cause endothelial dysfunction = worse prognosis
- Several hypotheses on injury by COVID-19 infection
- Exact mechanism: Unknown

COVID-19: Heart

- Proposed mechanisms:
  - direct viral invasion by ACE II receptor & autoimmune dysregulation w cardiotoxicity
  - dysregulation of the angio-tension-aldosterone sys
  - endotheliitis and thrombo-inflammation

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COVID-19: Heart

- Mechanism of COVID-related heart disease: Unclear
- True prevalence: Uncertain, but likely high
- 2020 Wuhan, China: 27.6% of hospitalized COVID-19 pt had heart damage with or w/o prior heart disease.

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Other Studies

- 52% female,109 d post-COVID, 73% CV (exertional dyspnea, CP, palpitations), > symp = > inflammation/injury than asymp;
- At 329 days, 57% symptoms persisted & more likely w diffuse myocardial edema

Other Studies

- 534 pt with long COVID, 58% CMR abnormalities at 12 months
- Low baseline LVEF predicted abnormal CMR at 12 months
- Cardiac biomarkers* not identify abnormal CMR in long COVID

* Troponin, β natriuretic peptide

COVID-19: Heart

- Symptoms/conditions:

  - MI, myocarditis, pericarditis, stress cardiomyopathy, arrhythmias, multisystem inflammatory syndrome in adults (MIS-A) and children (MIS-C), CVA, macrothrombotic disease, microthrombotic disease, bleeding diasthesis

COVID-19: Heart

- Hypoxia from COVID-19 lung disease can effect/damage the myocardium (indirect)
- Direct myocardial damage can occur up to 1 year after a + COVID-19 test (symptomatic & asymptomatic)

Myocardial damage

- Not differentiate between normal healthy vs comorbid factors
- Brookings Institute: racial/ethnic minorities more likely to get long COVID & health problems*

* Indigenous, AA, Latino: higher infection rates, exposure and prior health problems that may prolong symptoms, unequal healthcare access

COVID-19: Heart*

- Myocarditis/pericarditis (rare)
- Stress cardiomyopathy
- Myocardial infarction (1.3-4.9%)
- Arrhythmia** (most freq: A fib)
- Acute coronary syndr, ↑ troponin
- Heart failure, hypertension
- RV dysfx, pulm HTN (14-33%, 12%)

* Tobler DL, et al. Long-Term CV Effects of COVID-19: Emerging Data Relevant to the CV Clinician. Current Atherosclerotic Reports (2022)24:563-570. (A review)

** 10.4% w moderate –severe COVID

COVID-Heart (most freq)

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COVID-Arrhythmias

- Bradyarrhythmias (i.e., high grade AV block)
- Tachyarrhythmias (atrial fib, atrial flutter, ventricular tachycardia, ventricular fibrillation
- > risk w worse disease (i.e., ICU)
- No symp – mod COVID: 1/3 new ECG changes & arrhythmias

COVID-Cardiac MR

- No symptoms – severe acute COVID
- 37-71 days post-COVID, 78% had abnormal CMR:
  - 73% ↑ T1
  - 60% ↑ T2
  - 32-45% myocarditis-like LGE
- MRI did not correlate with cardiac biomarkers (i.e. troponin)

COVID-Cardiac MR

- 74 pt 6 months post-COVID, 4% LGE, but overall function not clinically significant c/w healthy controls or in cardiac biomarkers

COVID-19: Vascular

- Coagulopathy
- Autonomic nervous system inflammation → POTS (Postural orthostatic tachycardia syndrome); 5:1 female; estimated 1-3 million US, 2-14% post-COVID, 5 X ↑ post-COVID* than post-vaccine

* Many develop 6-8 months post-COVID; also ↑ risk: severe illness/viral - mononucleosis, pregnancy, trauma, surgery, autoimmune disease (SLE, Sjogren's, celiac disease)

VA COVID Study* (2022)

- + COVID: 153,760 (3/1/20 -1/15/21)
- No COVID: 5,637,647 (2019)
- No COVID: 5,859,411 (2017 pre-COVID historical cohort)
- Mainly older (61 yr) white (71%) males (89%); 12 mo post-COVID**

- * Large study on link between long COVID & heart dis. *Xie Y, et al. Long-term cardiovascular outcomes of COVID-19.* Nature Medicine Mar 2022(28)p 583-590.
- ** Survived 1st 30 days of COVID infection & F/U for 12 months post COVID

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VA COVID: Per 1000*

- 45.29 Cardiovascular (CV)
- 23.48 Major CV (MI, CVA, death)
- 19.86 Dysrhythmia (10.74 atrial fib)
- 12.72 Other CV (11.61 HF, 3.56 nonischemic cardiomyopathy)
- 9.88 Thromboembolic (5.47 PE, 4.16 DVT)

* Compared to controls

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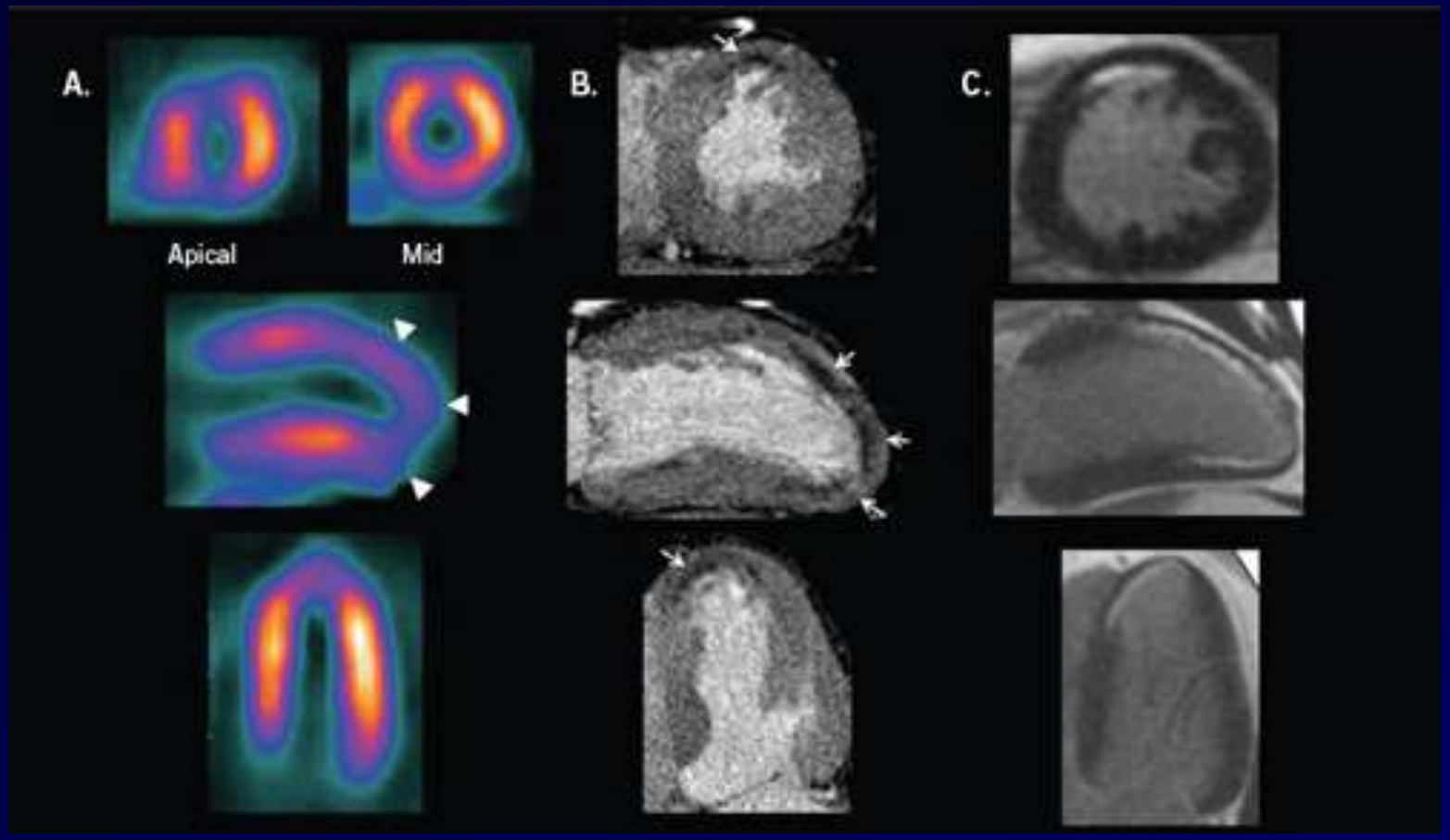
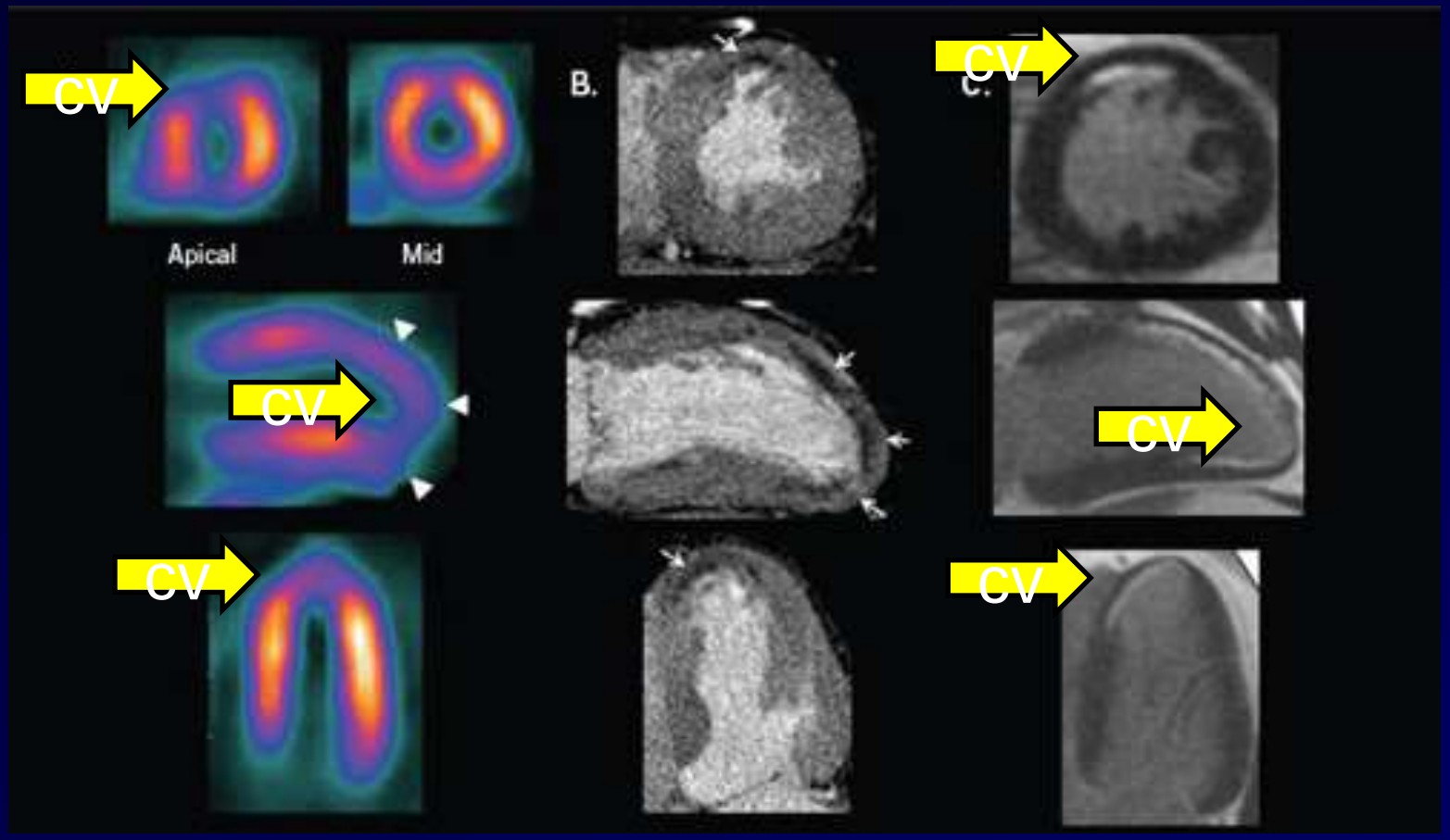


Anterior apical inferior infarction*

- Nicol ED, et al “Multimodality Imaging of Myocardial Infarction” Br J Cardiol 2009:16:43.



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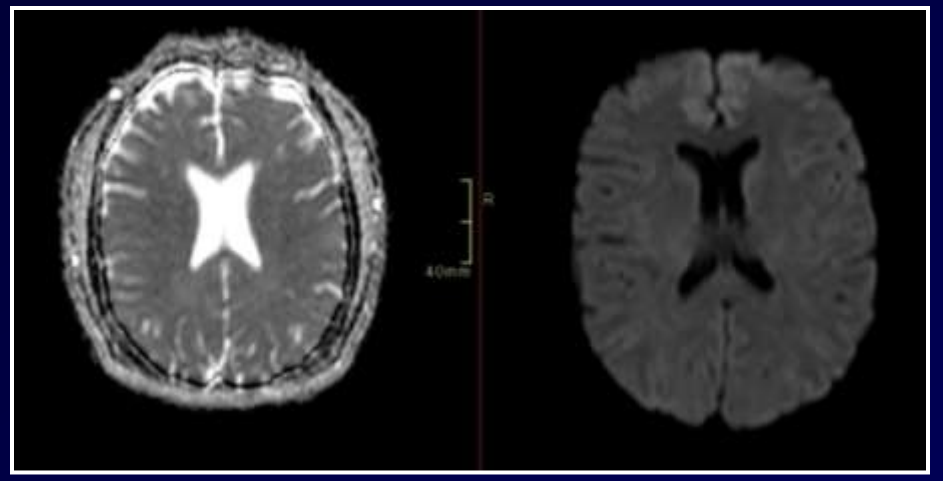

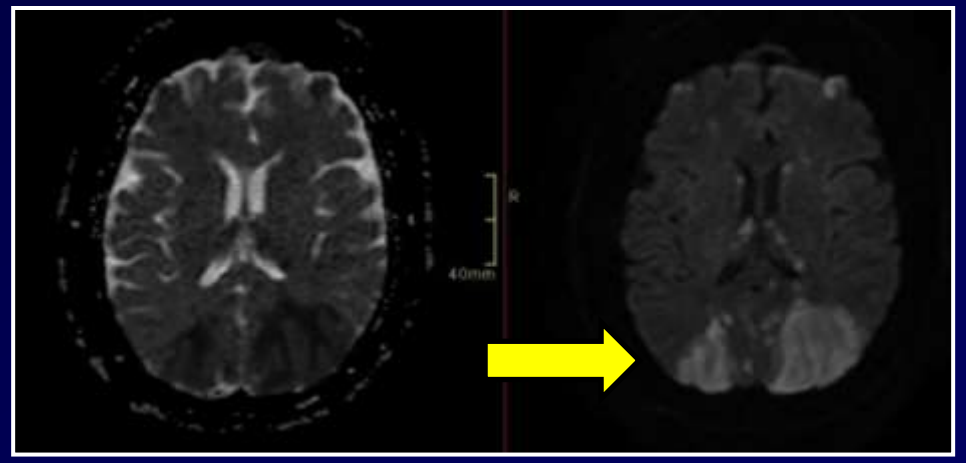

DWI

Normal

Bilateral likely embolic CVA

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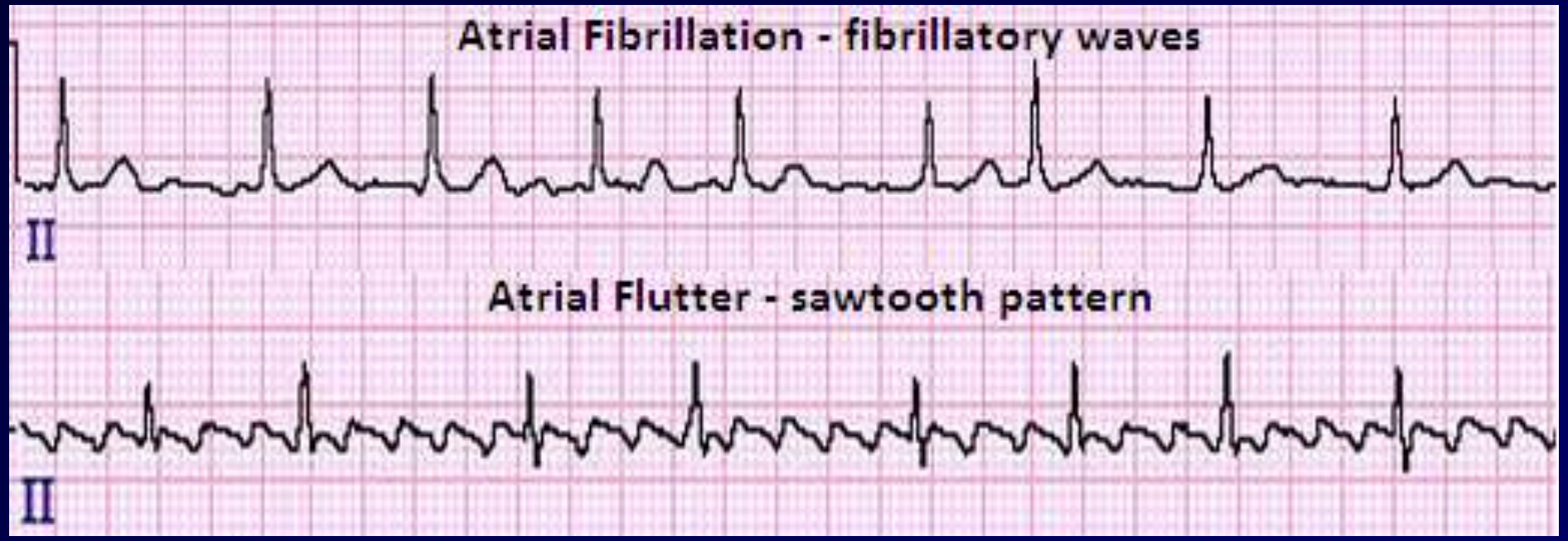

https://www.healio.com/cardiology/learn-the-heart/cardiology-review/topic-reviews/atrial-fibrillation/atrialfibrillation-quickfactsheet

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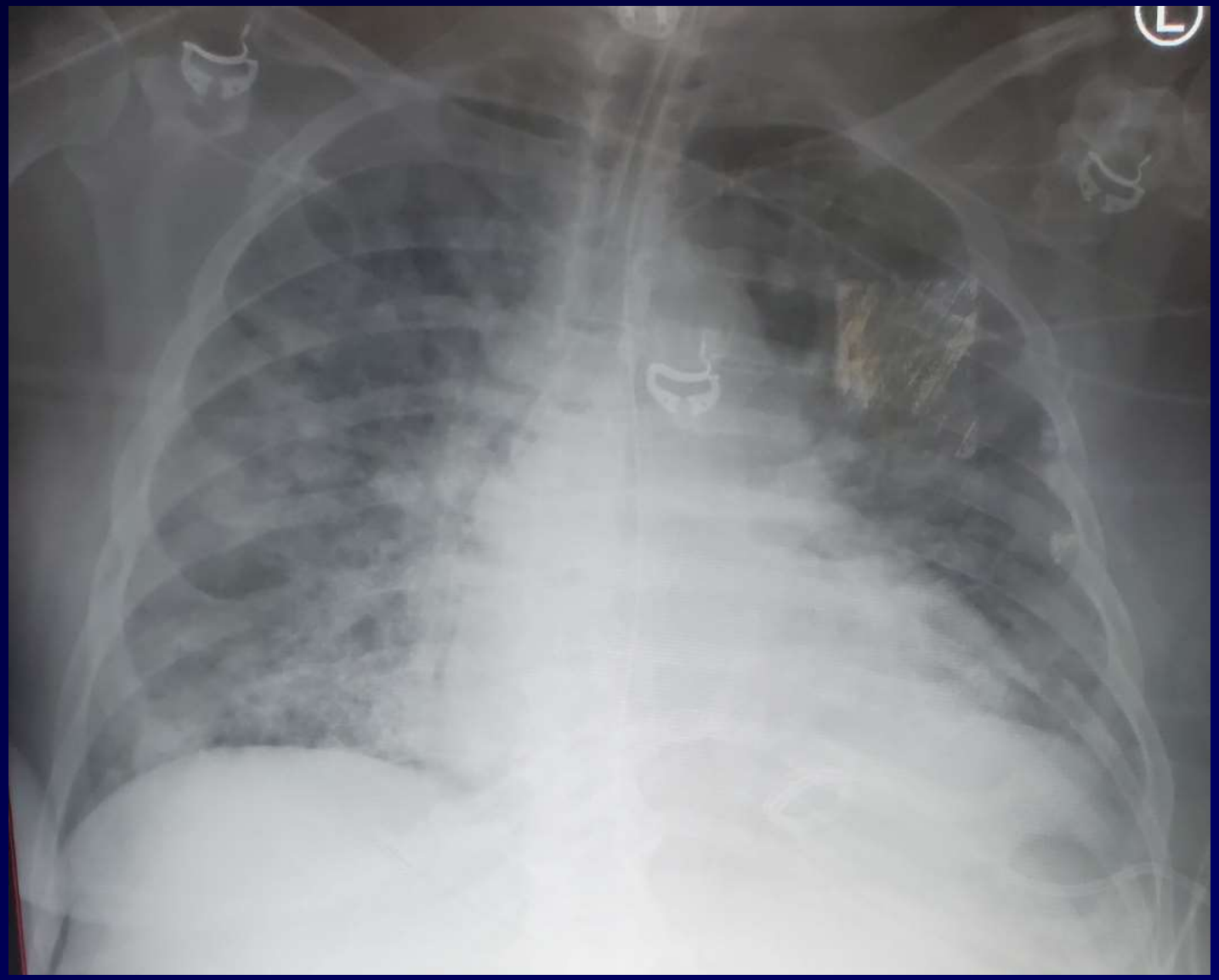

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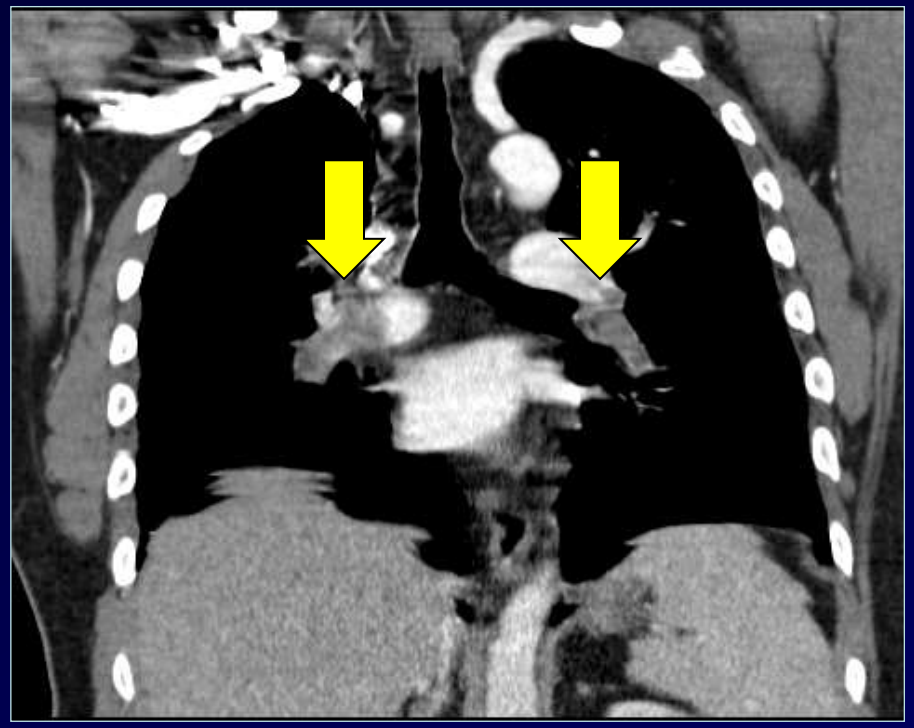
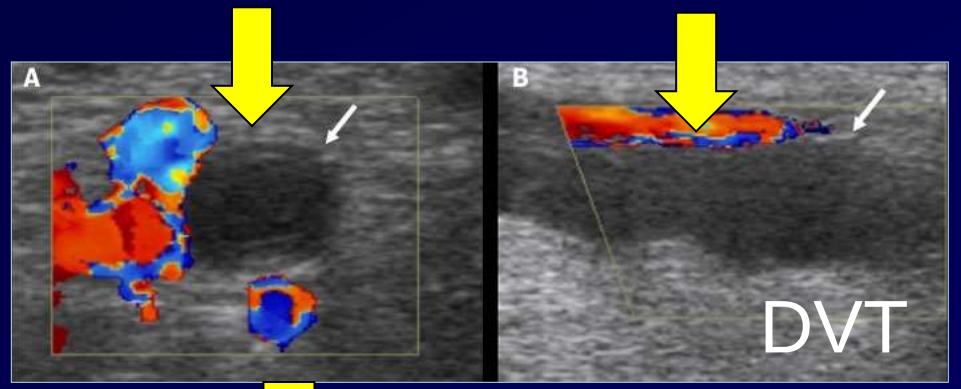
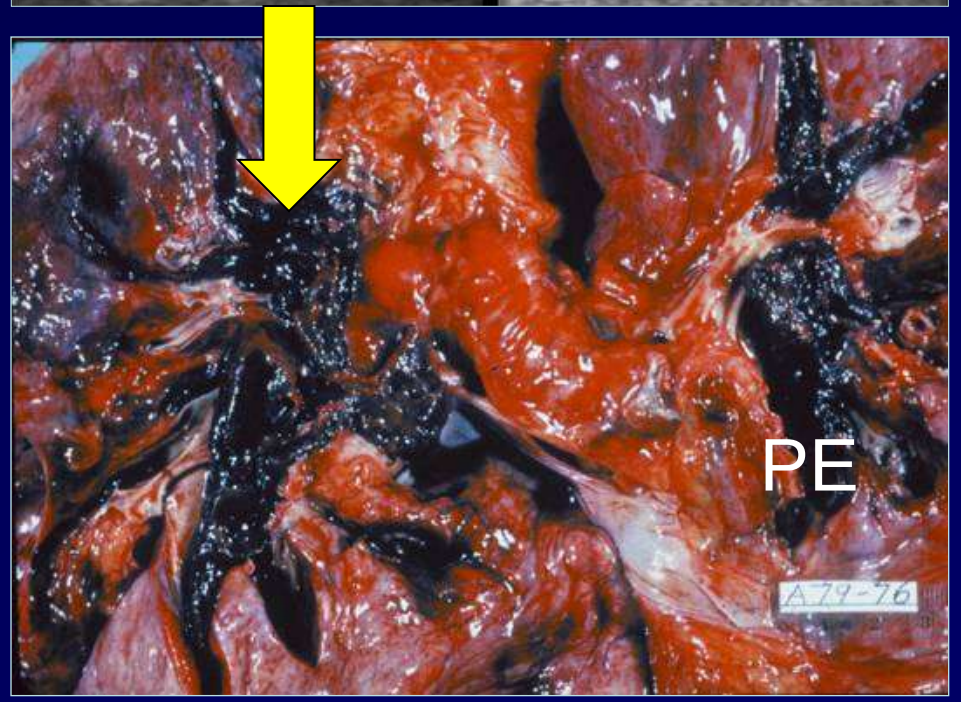
Venous Thromboembolism (DVT or PE)



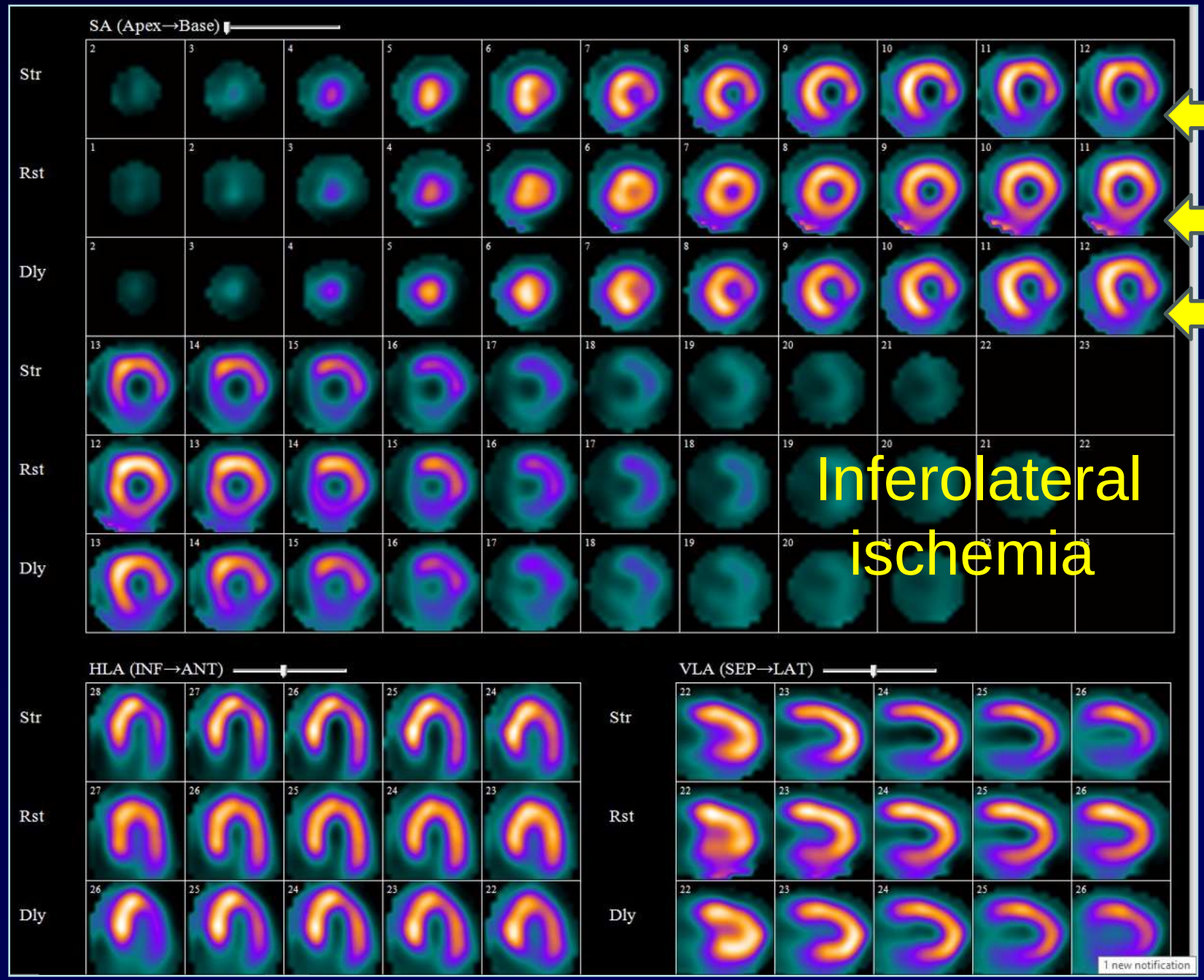
PE





VA COVID: Per 1000

- 7.28 Ischemic heart disease (5.35 acute coronary syndrome, 2.91 MI, 2.5 angina)
- 5.48 CV disorders (4.03 CVA)
- 1.23 Heart inflammation (0.98 pericarditis, 0.31 myocarditis)


SA (Apex→Base)
Str
Rst
Dly
Str
Rst
Dly
Inferolateral ischemia
HLA (INF→ANT)
Str
Rst
Dly
VLA (SEP→LAT)
Str
Rst
Dly
1 new notification

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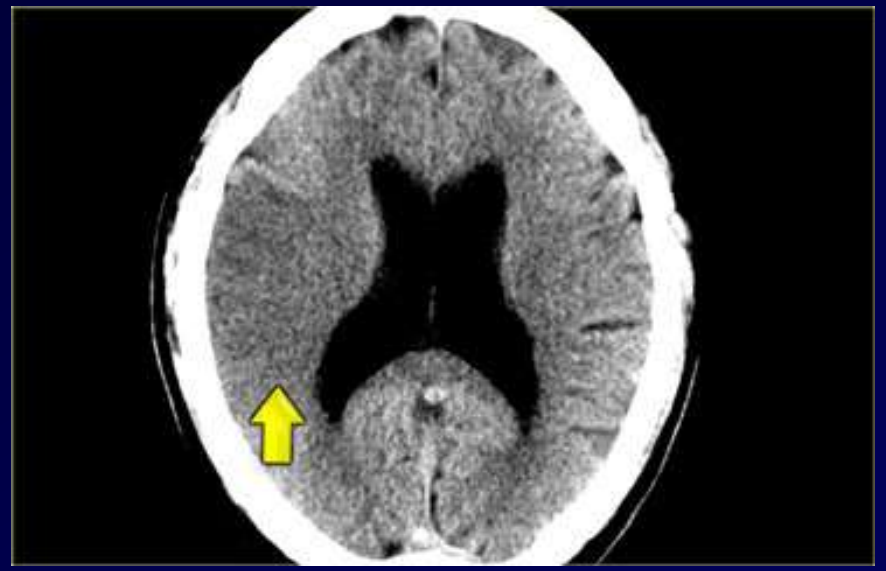

Acute Stroke

https://radiologyassistant.nl/neuroradiology/brain-ischemia/imaging-in-acute-stroke

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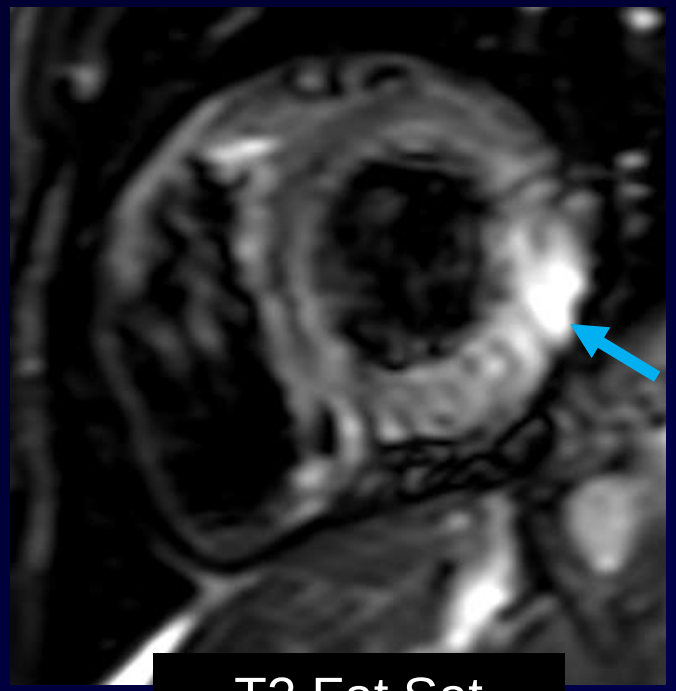
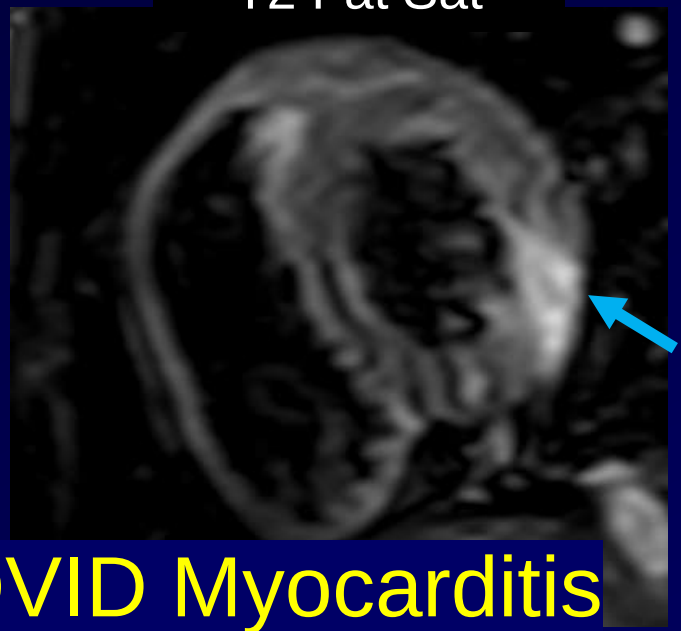
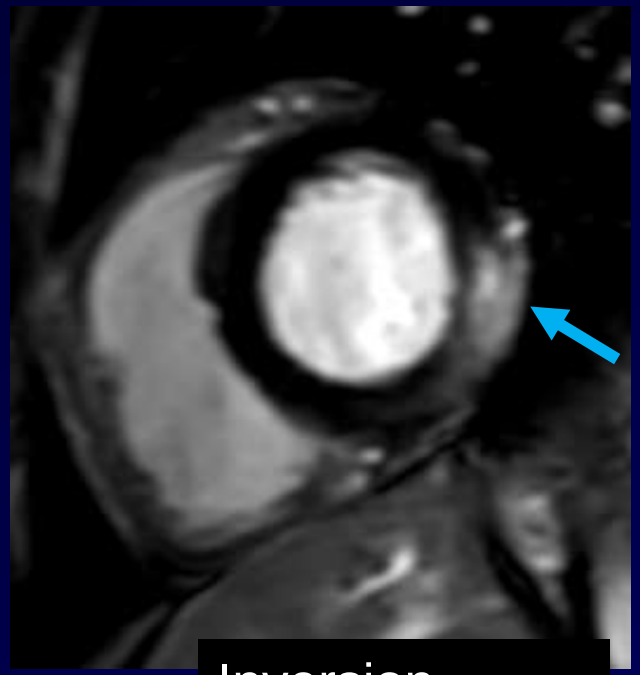
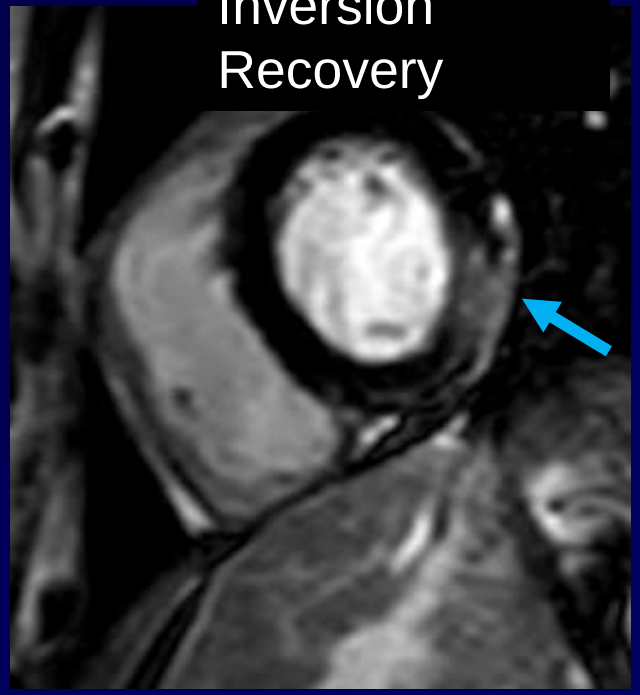


T2 Fat Sat

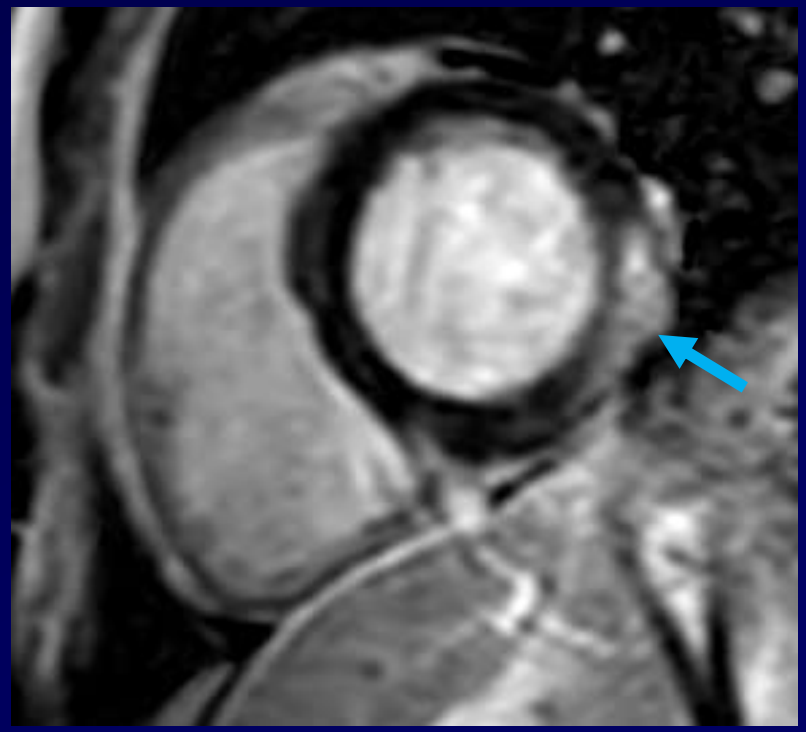




Inversion Recovery



29 yo M acute chest pain, NSTEMI, ICU. No prior or FH CAD. Normal CTA. Troponin 1900



PSIR

COVID Myocarditis

Courtesy of CS Restrepo MD

VA COVID: Per 1000

- Atrial fibrillation & heart failure: greatest CV burden
- 10 more individuals/1000 compared with control

VA COVID: Per 1000

- Patient with more severe disease, had higher CV risks (i.e., ETT, ICU)
- CV risks still exists whether pt hospitalized or not
- ↑ risk regardless of age, race, sex, obesity, smoking, ↑ BP, DM, CVD, chronic kid disease, ↑ lipid

VA COVID (2020-21)

- Predated micron/omicron & wide vaccine use
- 73,435 post-COVID-19 infection
- 11 million control: ½ preCOVID, ½ in same time frame as infected & non-hospitalized
- 99% not vaccinated

VA COVID (2020-21)

- ↑ blood clots, CVA, heart failure, mental issues, multi-organ
- > likelihood than non-COVID:
  - 72% CAD
  - 63% MI
  - 52% CVA

VA COVID (2020-21)

- 1 yr post-infection, higher risk: arrhythmias, myocarditis, heart failure, thrombosis-related heart disease (de novo cardiac dis?)
- 72% more likely heart failure, 63% MI, 52% stroke than those who never had COVID

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Other Studies

- 100 discharged COVID pt, 78% cardiac abn & 60% myocarditis
- 26 college athletes with asymptomatic SARS-CoV-2

  46% with myocarditis
- 3 mo post hosp, ventricular remodeling in 29% of 79

  COVID-19 survivors

Other Studies

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Other Studies

- CP, palpitations & tachycardia often seen 6 mo post-COVID-19
- > 40,000 discharged COVID-19 pt had ↑ risk new respiratory,

  DM & CV disease at 140 days compared with controls
- Ongoing cardiac sxs: 54% myocardial edema, 38% LGE*

* septum, anterior, anterolateral, inferior LV wall

2022 VA COVID Reinfection Study

- 1 COVID: 443,588
- 2 or more COVID: 40,947
- No COVID: 5,334,729
- Regardless of vaccine status, reinfection ↑ death, hospital, multi-organ acute & chronic sequelae

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- Reinfection ↑ cardiovascular incidents (HR 3.02) only 2nd to pulmonary (HR 3.54)
- Risks ↑ with ↑ infection
- No relationship between vaccination status & reinfection
- Consider history of COVID as a cardiovascular disease risk

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Other studies

- Vaccinated less likely to get long COVID than unvaccinated COVID pt
- 3 months post COVID, 32% survivors w heart damage; 89% long COVID pt w cardiac symptoms: 53% CP, 68% palpitations, 31% new POTS

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Other studies: Post-COVID

- 1 yr follow up, 2% new hypertension (disruption renin-angiotensin, ACE2 ↑ Na + water), new heart failure needing hospitalization, 2.7% new R heart failure w/o L heart failure or hypertension
- New diabetes, major adverse cardiac events (MACE)

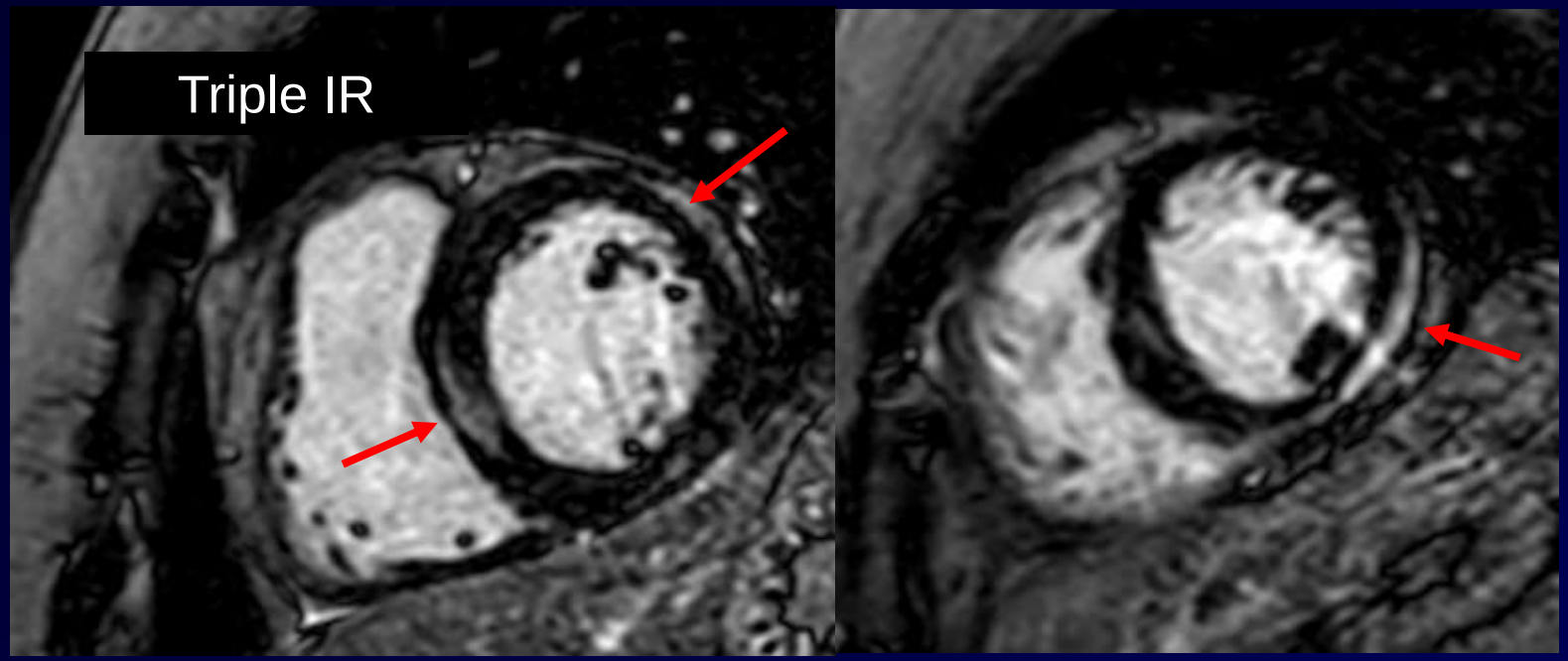
Myocarditis

- Recovering COVID, ↑ myocarditis & arrhythmia than those w/o COVID
- Myocardial inflammation in 20-35% of SARS-CoV-2 hospitalized pt
- 16 x ↑ COVID-19 than COVID-19 neg
- Myocarditis is low but > than vaccine related myocarditis

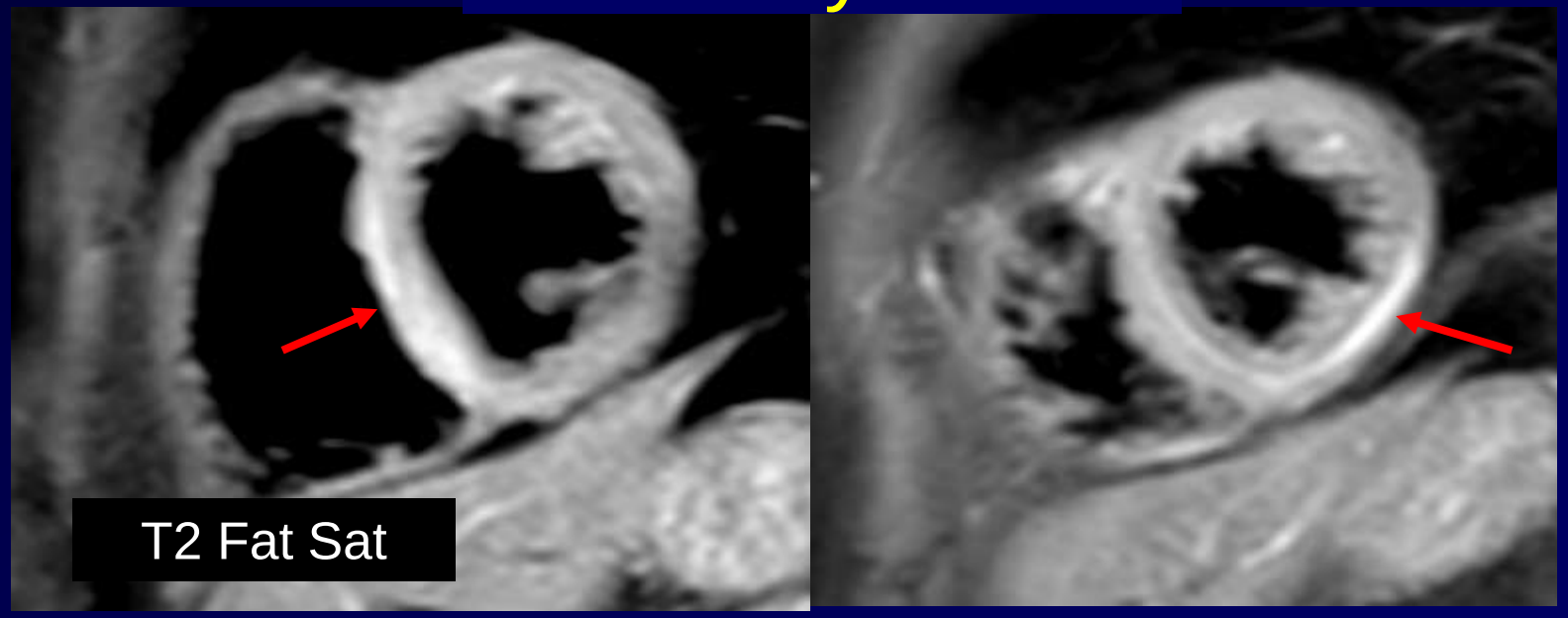
29 yo M Acute chest pain.
Elevated troponin: 63,543 (Normal: < 15 ng/L)
Normal catheter angiogram
COVID-19+

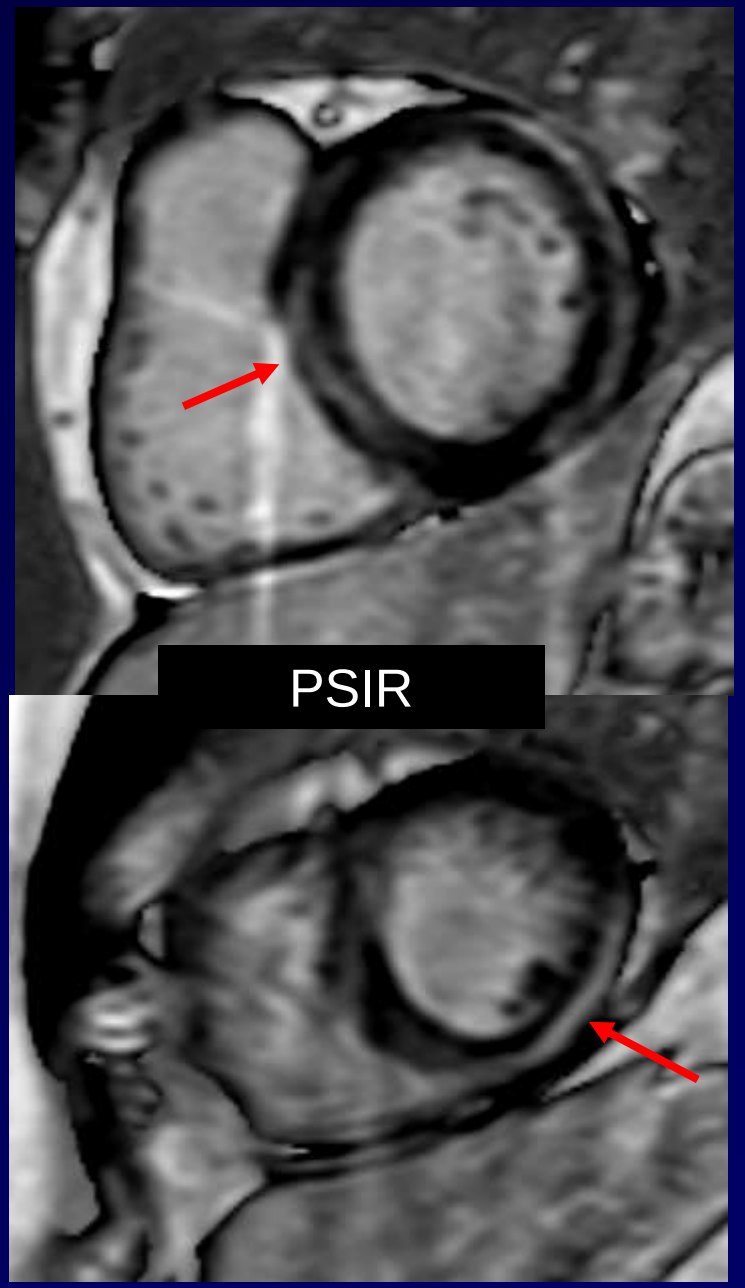
CMR: + LGE COVID myocarditis

Courtesy of CS Restrepo MD



COVID Myocarditis





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Vaccine-associated Myocarditis- Rare

- Association between COVID-19 myocarditis & arrhythmia in young males; men at greater risk
- British Health Services: ↑ myocarditis 28 d post-vaccine 2nd dose mRNA in 10/million vs 40/million, esp males 18-29 yrs

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- British Health Services: ↑ myocarditis 28 d post-vaccine 2nd dose mRNA in 10/million vs 40/million, esp males 18-29 yrs

Medicines & Healthcare Products Regulatory Agency (21 June 23)

- Pfizer/BioNTech vaccine per million
  - 10 myocarditis; 6 pericarditis
- Moderna monovalent vaccine per million
  - 14 myocarditis; 8 pericarditis

Vaccine-associated Myocarditis

- Israel: relative risk 3.24
- Excess risk post-vac 2.7/100,000 vs 11/100,000 post SARS-CoV-2 infection
- Estimates that vaccines prevented > 10 hosp & 3-4 ICU due to COVID-19 if not vaccinated

Summary: COVID-19 timeline Cardiovascular Complications

- ACUTE: Acute coronary syndrome, myocardial injury, myocarditis, pericarditis, pulmonary hypertension
- OVERLAP: Arrythmia, R & L heart failure, thrombotic (PE, DVT), CVA, ↑ R ventricular longitudinal strain

Summary: COVID-19 timeline Cardiovascular Complications

- CHRONIC: ↑ **risk**: arrhythmias, heart failure, acute coronary syndrome, RV dysfunction, myocardial fibrosis, new diabetes, new hypertension, cardiac ischemia in healthy pt or w/o prior CAD, hypoxia, local/systemic inflammatory immune activation, POTS

Learning Objectives

- Understand long COVID-19 effects on the heart.

Learning Objectives

- Understand long COVID-19 effects on the heart.
    - Highly heterogeneous sequelae in COVID survivors of all disease severity & of all ages occurring > 3 months & lasting for at least 2 months

Learning Objectives

- Identify imaging related long COVID cardiac/cardiovascular disease.

Learning Objectives

- Identify imaging related long COVID cardiac/cardiovascular disease.
  - Chest: PE
  - Cardiac: Myocarditis, pericarditis
  - Myocardial perfusion: Ischemia, infarction/fibrosis
  - Ultrasound: DVT

Learning Objectives

- Be aware of potential outcomes in long COVID related cardiac disease.

Conclusion

- COVID-19 infection affects many organs to include the heart.
- The mechanism of COVID-19 cardiac injury remains unclear.
- Long COVID can result in significant long term cardiac disease.

2024 NRC Basics

Darlene Metter MD, FACNM, FSNMMI

SCHOOL OF MEDICINE
UT HEALTH SCIENCE CENTER™
DEPARTMENT OF RADIOLOGY

Disclosure

- Recent NRC Advisory Committee on the Medical Uses of Isotopes (ACMUI) Chair.

Learning Objective

- Understand the role of the NRC in medicine.
- Be able to apply basic NRC regulatory rules in Nuclear Medicine.

Pre-Test

Question # 1

Which of the following board(s) has/have 2024 NRC recognition or “deemed status” for specific AUs?

a. ABR
b. AOBR
c. ABNM
d. ABRO

Question # 2

After obtaining the required training & experience, which of the following providers may pursue an AU status for their practice?

a. Associate RSO
b. Physician assistant
c. Podiatrist
d. Dentist
e. Veterinarian

Question # 3a

What does 10 CFR Part 35 regulate?

a. Radiation protection
b. Radiation safety
c. Medical use of byproduct material
d. Medical use of radioisotopes

Question # 3b

Which Authorized User regulation is for training & experience for imaging and localization?

a. 10 CFR 35.290
b. 10 CFR 35.390
c. 10 CFR 35.392
d. 10 CFR 35.394

Question # 3c

Which Authorized User supervises imaging, localization and the therapeutic administration of unsealed byproduct material requiring a written directive?

a. 10 CFR 35.290
b. 10 CFR 35.390
c. 10 CFR 35.490
d. 10 CFR 35.590

Question # 3d

An AU under 35.290 relinquishes their AU status to work in a non-clinical area. 8 years later relocates to a site needing an AU under 35.290? What can be done to re-establish this AU status?

Question # 4

Which of the following requires a written directive?

a. I^{131} 50 µCi
b. Tc^{99m} 40 mCi
c. In^{111} 6 mCi
d. Tl^{201} 20 mCi

Question # 5

If a patient's life is in danger, how long can a written directive be delayed after an oral directive?

a. 12 hours
b. 24 hours
c. 2 days
d. 3 days

Question # 6a

How long must a licensee keep a copy of a written directive?

a. 3 years
b. 5 years
c. 10 years
d. Indefinite

Question # 6b

How long must a licensee keep a copy of a medical event?

a. 3 years
b. 5 years
c. 10 years
d. Indefinite

Question # 7a

What is the NRC public exposure limit?

a. 100 mrem
b. 200 mrem
c. 300 mrem
d. 400 mrem
e. 500 mrem

Question # 7b

Is breast feeding regulated?

a. Yes
b. No

Question # 7c

A nursing mother administered unsealed byproduct material, can be released by the licensee if the total EDE to any individual does not exceed which of the following?

a. 100 mrem
b. 200 mrem
c. 300 mrem
d. 400 mrem
e. 500 mrem

Question # 7d

A pt is administered 2 mCi I-131 NaI in 01/2022, for an order dated 12/2016 and in 2022 is under a different & not the 2016 ordering AU provider in the same institution. Is this a medical event?

a. Yes
b. No

Question # 7e

A pt is administered 25 mCi I-131 NaI. The written directive prescribed activity is 20 mCi of I-131 NaI. Is this a medical event?

a. Yes
b. No

Question # 7f

A pt is administered 25 mCi I-131 NaI. The written directive prescribed activity is 20 mCi of I-131 NaI. If this is a medical event, what should the AU do?

a. Notify the RSO.
b. Notify the regulatory agency.
c. Rewrite the written directive.
d. Rewrite the patient consent.

Question # 8

After discovery of a medical event, when must the licensee notify the NRC/regulatory agency?

a. 1 day
b. 3 days
c. 7 days
d. 14 days

Question # 9

For a nursing mother who receives a radiopharmaceutical, which of the following infant doses if exceeded must the licensee give guidance to D/C nursing and the consequences if nursing continues?

a. 50 mrem
b. 100 mrem
c. 300 mrem
d. 500 mrem

Question # 10

Are there more NRC or Agreement States? How many of each?

Are military medical centers under the NRC or have a special status?

In an Agreement state, what state entity makes the agreement with the NRC?

Question # 11

To whom is the NRC accountable to?

How many potential NRC commissioners are there?

Nuclear Regulatory Commission

1974: Congress created the NRC as an independent agency to ensure the safe use of radioactive materials for beneficial civilian purposes while protecting people & the environment.

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Nuclear Regulatory Commission

Regulates commercial nuclear power plants & other uses of nuclear material (i.e., NM) through licensing, inspection & enforcement of its requirements.

Note: NRC regulates. Not the practice of medicine.

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Nuclear Regulatory Commission

5 Commissioners appointed by the President & confirmed by the Senate for 5 year terms. The President designates the Chairman who is the official spokesperson of the Commission & accountable to Congress.

- Chairman Christopher Hanson

2024 NRC Commissioners

NRC Advisory Committees

1. Reactor Safeguards
2. Medical Uses of Isotopes
3. Ad hoc Licensing Support Network Advisory Panel

NRC Advisory Committees

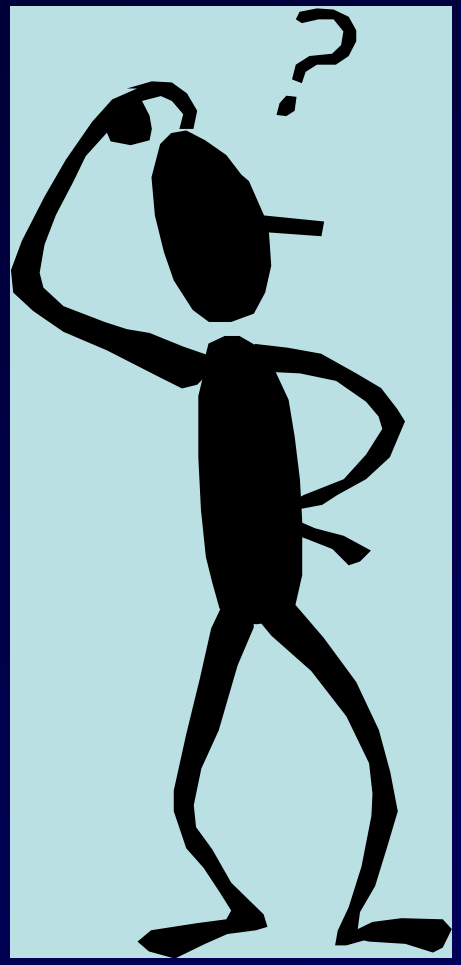
1. Reactor Safeguards
2. Medical Uses of Isotopes
3. Ad hoc Licensing Support Network Advisory Panel

Advisory Committee on the Medical Uses of Isotopes (ACMUI)

- Advises the NRC on policy & technical issues that arise in the regulation of the medical uses of radioactive material in diagnosis & therapy.
- 13 members

Advisory Committee on the Medical Uses of Isotopes (ACMUI)

What is an authorized user (AU)? Why should I care ?



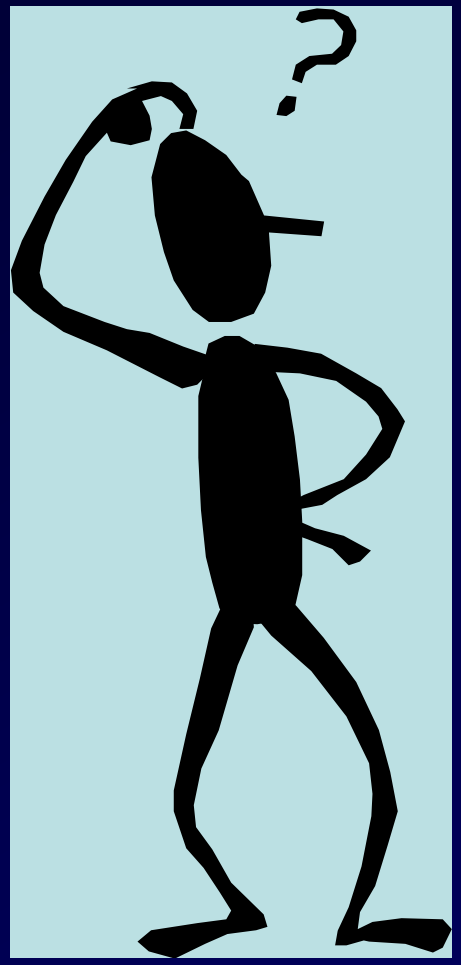
A licensed physician, dentist or podiatrist identified on the license or permit meeting specific requirements.

Other physicians may work with radioactive material, but only under the AU.*

Courtesy of F Mettler

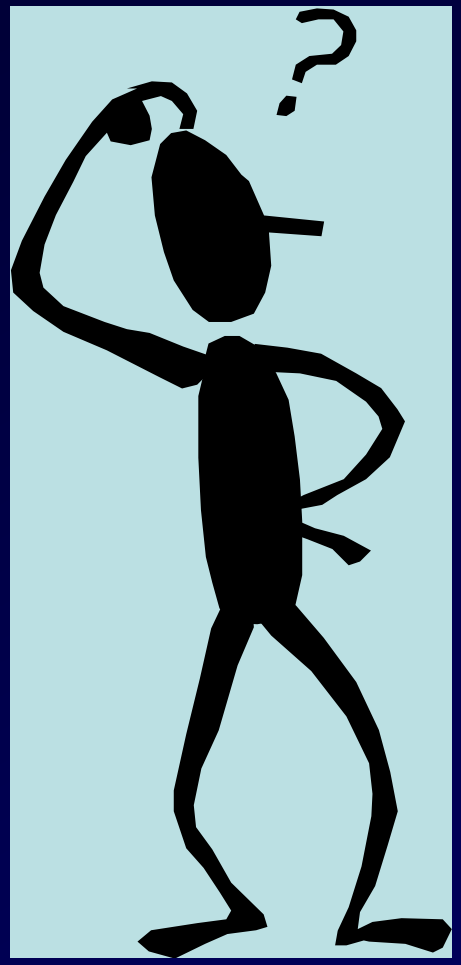
*10CFR35.390.

Veterinary Authorized User



A licensed veterinarian AU is under 10 CFR Part 30 “Rules of general applicability to domestic licensing of byproduct material.”

Veterinary Authorized User

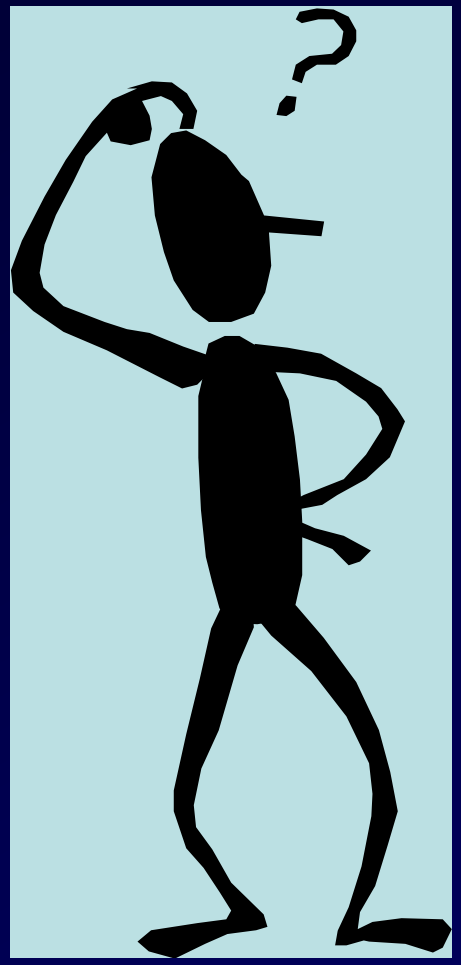


"Veterinary Uses of Nuclear Material" is for general use: diagnostic, therapeutic & research in domestic pets* and non-food animals.

Not approved for animals intended for the human food supply.

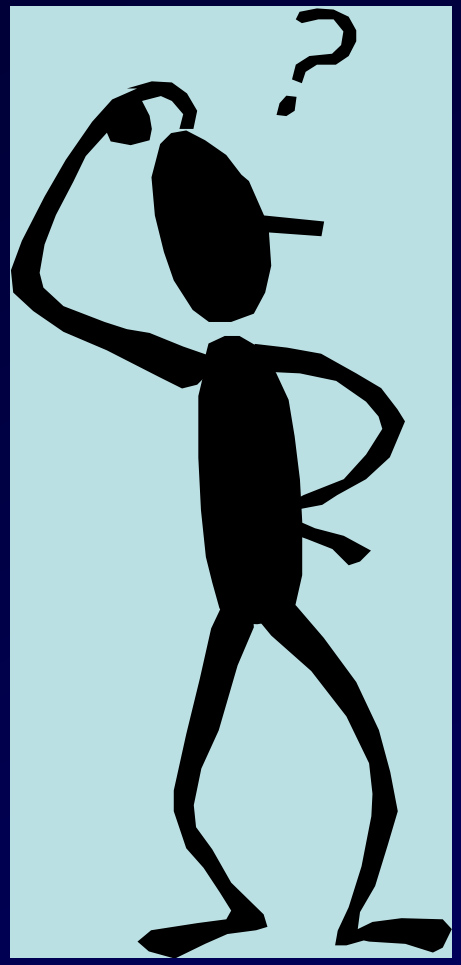
*Hyperthyroid cats Rx with I-131

NRC “Deemed Status”



A status conferred by the NRC in formal recognition that the NRC’s review, continued-stay review & evaluation of programs meet certain T&E criteria for specific categories of Authorized Users.

Prior ABR AU*



10 CFR 35.290: Imaging & localization

10 CFR 35.392: NaI-I131 < = 33 mCi

10 CFR 35.394: NaI-I131 > 33 mCi

*NRC Deemed Status ABR until 12/31/2023

ABR AU: DR, RO, MP, RSO*

Ending 12/31/2023:

1. Outside the ABR mission
2. Availability of the Alternate Pathway (NRC: T&E status quo); Form 313a
3. Diverts resources away from basic ABR objectives (exams, service)

*ABR ED: B Wagner 3/29/2022

ABR 2021-2022 Data for AU-E Certificates

- Diagnostic radiology (DR): 67%
- DR/Interventional radiology: 79%
- Radiation oncology: 97%
- Medical physicist: nearly 100%
- Radiation safety officer: nearly 100%

ABR 2021-2022 Data for AU-E Certificates

- Diagnostic radiology (DR): 67%
- DR/Interventional radiology: 79%
- Radiation oncology: 97%
- Medical physicist: nearly 100%
- Radiation safety officer: nearly 100%

ABR AU: DR, RO, MP, RSO*

- Jan 2024 no ABR AU eligible
- Same ABR exam to include Core
- RISE (will rename it)
- No separate scoring. Exam graded as a whole

*ABR ED: B Wagner 3/29/2022

2024 Radiology AU

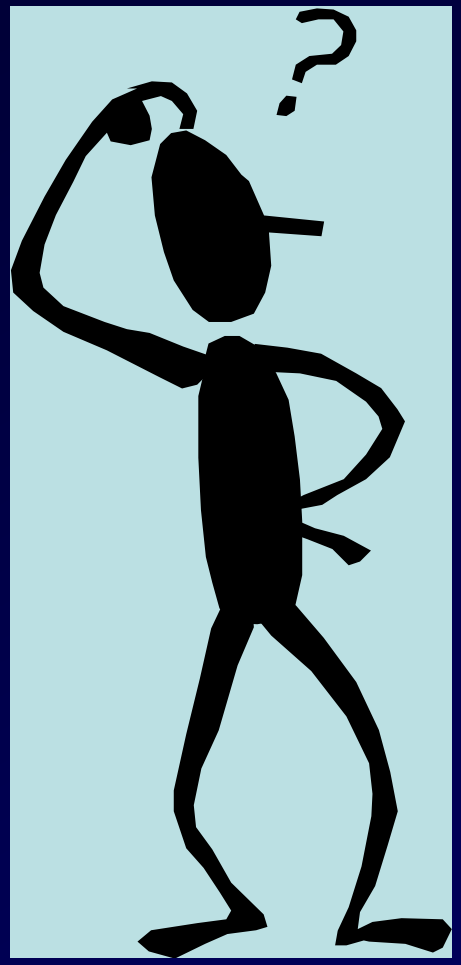
- NRC & some Agreement states
- Utilize Form 313(AUD) – 35.100, 35.200, 35.500 (10 CFR 35.39 35.190, 35.290, 35.590)
  - 35.39: Recentness of T&E
  - 35.190: Uptake, dilution, excretion
  - 35.290: Imaging & localization
  - 35.590: Diag sealed sources/devices


AUTHORIZED USER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION

2024 Radiology AU

- Utilize Form 313(AUT) – 35.300 (10 CFR 35.59, 35.390, 35.392. 35.394, 35.396)
  - 35.390: Unsealed byproduct material requiring a written directive
  - 35.392 & 35.394: <= & > 33 mCi I-131
  - 35.396: Parenteral administration of unsealed by product material requiring a written directive

ABNM* Diplomat AU



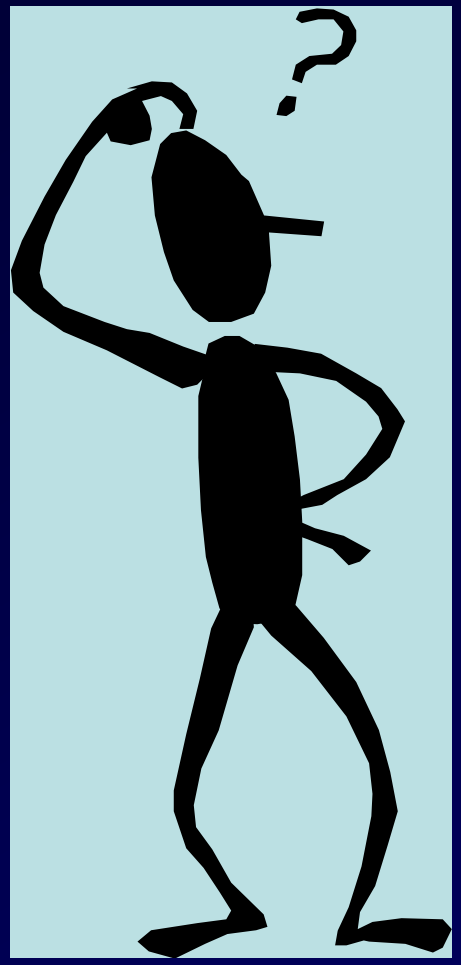
*NRC Deemed Status

10 CFR 35.390: Training for the use of unsealed byproduct material for which a written directive is required.

Incorporates activities of 35.190* and 35.290.

- 35.190 Training for Uptake, Dilution & Excretion

ABR Nuclear Radiology AU



10 CFR 35.390: Training for the use of unsealed byproduct material for which a written directive is required.

- Alternate pathway
- No “deemed status”

Question # 1

Which of the following board(s) has/have 2024 NRC recognition or “deemed status” for specific AUs?

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b. AOBR
c. ABNM
d. ABRO

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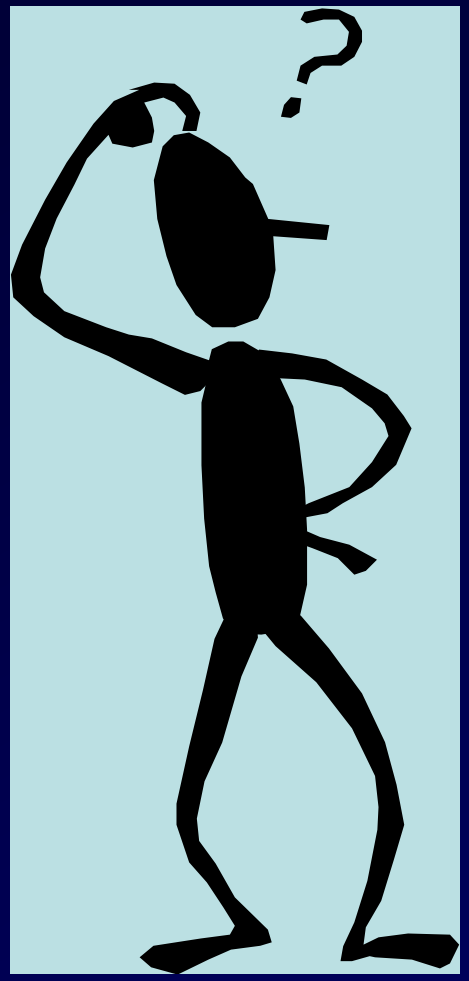
nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html

ABNM
Am B of Science in NM
Am B of Health Physics
Am B of Medical Physics

Diagnostic Radiology Residents after 1/1/2024 (10 CFR 35.390)

- ACGME accredited NM fellowship
- Otherwise, will not qualify for the ABNM certification exam
- Thus, to get on a license as an AU, pursue the Alternate Pathway

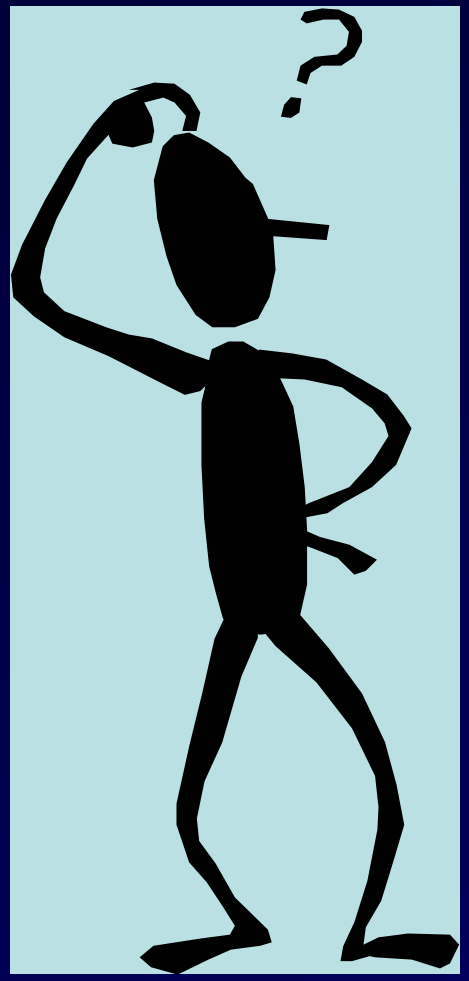
What is an authorized user (AU)? Why should I care ?



You do NOT need to be an Authorized User to read nuclear medicine or PET studies.

Courtesy of F Mettler

What is an authorized user (AU)? Why should I care ?

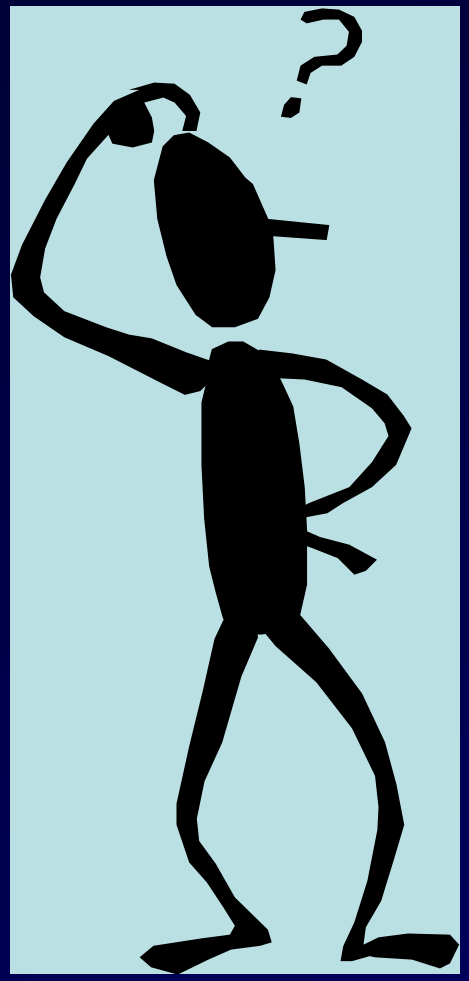


Only an authorize user can sign a written directive (e.g. any therapy or any I-131 > 30 uCi)*

*10CFR35.390

Courtesy of F Mettler

What is an authorized user (AU)? Why should I care ?



Every NM operation must have an AU for the specific activity being performed.

Courtesy of F Mettler

Recentness of Training

- 10 CFR 35.59
- T & E must have been obtained within 7 years preceding the date of application or the individual must have had related continuing education & experience since the required T&E was completed.

Question # 2

After obtaining the required training & experience, which of the following providers may pursue an AU status for their practice?

a. Associate RSO
b. Physician assistant
c. Podiatrist
d. Dentist
e. Veterinarian

Question # 2

After obtaining the required training & experience, which of the following providers may pursue an AU status for their practice?

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d. Dentist
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Question # 3a

What does 10 CFR Part 35 regulate?

a. Radiation protection
b. Radiation safety
c. Medical use of byproduct material
d. Medical use of radioisotopes

Question # 3a

What does 10 CFR Part 35 regulate?

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b. Radiation safety
c. Medical use of byproduct material
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Question # 3b

Which Authorized User regulation is for training & experience for imaging and localization?

a. 10 CFR 35.290
b. 10 CFR 35.390
c. 10 CFR 35.392
d. 10 CFR 35.394

Question # 3b

Which Authorized User regulation is for training & experience for imaging and localization?

a. 10 CFR 35.290
b. 10 CFR 35.390
c. 10 CFR 35.392
d. 10 CFR 35.394

Question # 3c

Which Authorized User supervises imaging, localization and the therapeutic administration of unsealed byproduct material requiring a written directive?

a. 10 CFR 35.290
b. 10 CFR 35.390
c. 10 CFR 35.490
d. 10 CFR 35.590

Question # 3c

Which Authorized User supervises imaging, localization and the therapeutic administration of unsealed byproduct material requiring a written directive?

a. 10 CFR 35.290
b. 10 CFR 35.390
c. 10 CFR 35.490
d. 10 CFR 35.590

Question # 3c

Which Authorized User supervises imaging, localization and the therapeutic administration of unsealed byproduct material requiring a written directive?

a. 10 CFR 35.290
b. 10 CFR 35.390
c. 10 CFR 35.490 - Brachytherapy
d. 10 CFR 35.590 – Sealed Sources

Question # 3d

An AU under 35.290 relinquishes their AU status to work in a non-clinical area. 8 years later relocates to a site needing an AU under 35.290? What can be done to re-establish this AU status?

Question # 3d

According to the NRC, the physician needs to provide evidence of CME, per 10 CFR 35.59 *Recentness of Training* in order to be approved for the same use. Provide their AU eligible ABR certificate & the additional CME they have received since completing the required T&E.

1. What is the difference between a medication order and a written directive?

2. What are the 6 components of a written directive?

3. What agents require a written directive?

Medication Orders vs. Written Directives

- Medication order: all drug orders (radioactive or not)
- Written directive: All therapeutic agents & any Na I-131 > 1.11 MBq (> 30 µCi)

What is in a written directive?

Written Directive (6)

- Consist of patient name, RP, dosage, route of administration, date, & AU signature*
- If pt life in danger, can be delayed by 48 hr
- Copies must be kept for 3 year

* For unsealed byproduct material. Other WDs for radiation oncology.

Written Directive (Y90)

- Consist of patient name, RP, dosage, route of administration, treatment site (i.e., segment), date, & AU signature

Written Directive Agents

- ^{131}I – NaI (thyroid), MIBG (neuroblastoma), Iobenguane/Azedra (pheochromocytoma, paraganglioma)
- Bone pain: ^{89}SrCl, ^{153}Sm-Lexidronam, ^{32}P-Sodium Phosphate (polycythemia vera)
- ^{90}Y-Zevalin (lymphoma)
- ^{32}P- Chromic Phosphate (malignant effusions & ascites)
- ^{90}Y- Microspheres (hepatic malignancies)

Written Directive Agents

- ^{223}Ra Dichloride (prostate bone met w/o visceral metastasis)
- ^{177}Lu - Dotatate (neuroendocrine)
  Vipivotide tetraxetan/Pluvicto (PSMA-prostate CA)

How long is a written directive effective?

a. 3 years
b. 5 years
c. 7 years
d. No time limit

How long is a written directive effective?

a. 3 years
b. 5 years
c. 7 years
d. No time limit

Written Directive (WD)

- Per NRC, a WD is an internal document of the licensee, and thus will not have an expiration date like a medical prescription.

- A medical prescription is valid for a certain time period (usu 12 months, occ 6 months and up to 24 months, varies between states).

Written Directive (WD)

- WD is used to verify the correct pt, radiopharmaceutical, dosage, route of administration, AU, date of the WD.

Question # 4

Which of the following requires a written directive?

a. I^{131} 50 µCi
b. Tc^{99m} 40 mCi
c. In^{111} 6 mCi
d. Tl^{201} 20 mCi

Question # 4

Which of the following requires a written directive?

a. I^{131} 50 µCi
b. Tc^{99m} 40 mCi
c. In^{111} 6 mCi
d. Tl^{201} 20 mCi

Question # 5

If a patient's life is in danger, how long can a written directive be delayed after an oral directive?

a. 12 hours
b. 24 hours
c. 2 days
d. 5 days

Question # 5

If a patient's life is in danger, how long can a written directive be delayed after an oral directive?

a. 12 hours
b. 24 hours
c. 2 days
d. 5 days

Question # 6a

How long must a licensee keep a copy of a written directive?

a. 3 years
b. 5 years
c. 10 years
d. Indefinite

Question # 6a

How long must a licensee keep a copy of a written directive?

a. 3 years
b. 5 years
c. 10 years
d. Indefinite

10 CFR 35.40

Written Directive (WD)

- WD is used to verify the correct pt, radiopharmaceutical, dosage, route of administration, AU, date of the WD.

- WD can only be administered under the license where the physician is an AU.

1. What is a medical event?

2. When does the NRC or state operations center need to be notified?

Medical Event

- Dose > 5 rem EDE

Or

- 50 rem to an organ, tissue or shallow dose equivalent to the skin

AND

- dose > +/- 20% of prescribed dose

Medical Event

- Dose > 5 rem EDE

Or

- 50 rem to an organ, tissue or shallow dose equivalent to the skin

AND

- wrong radioactive drug;
- wrong route;
- wrong individual;
- wrong mode;
- or leaking source.

Medical Event

ALSO:

Any administration of by-product material or radiation from such that results in an unintended permanent functional damage to an organ or system as determined by a physician.

Question # 6b

How long must a licensee keep a copy of a medical event?

a. 3 years
b. 5 years
c. 10 years
d. Indefinite

Question # 6b

How long must a licensee keep a copy of a medical event?

a. 3 years
b. 5 years
c. 10 years
d. Indefinite

Question # 7a

What is the NRC public exposure limit?

a. 100 mrem
b. 200 mrem
c. 300 mrem
d. 400 mrem
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What is the NRC public exposure limit?

a. 100 mrem
b. 200 mrem
c. 300 mrem
d. 400 mrem
e. 500 mrem

Question # 7b

Is breast feeding regulated?

a. Yes
b. No

Question # 7b

Is breast feeding regulated?

a. Yes
b. No

Question # 7c

A nursing mother administered unsealed byproduct material, can be released by the licensee if the total EDE to any individual does not exceed which of the following?

a. 100 mrem
b. 200 mrem
c. 300 mrem
d. 400 mrem
e. 500 mrem

Question # 7c

A nursing mother administered unsealed byproduct material, can be released by the licensee if the total EDE to any individual does not exceed which of the following?

a. 100 mrem
b. 200 mrem
c. 300 mrem
d. 400 mrem
e. 500 mrem

Question # 7d

A pt is administered 2 mCi I-131 NaI in 01/2022, for an order dated 12/2016 and in 2022 is under a different & not the 2016 ordering AU provider in the same institution. Is this a medical event?

a. Yes
b. No

Question # 7d

A pt is administered 2 mCi I-131 NaI in 01/2022, for an order dated 12/2016 and in 2022 is under a different & not the 2016 ordering AU provider in the same institution. Is this a medical event?

a. Yes
b. No

Written Directive (WD)

- WD is used to verify the correct pt, radiopharmaceutical, dosage, route of administration, AU, date of the WD.

- WD can only be administered under the license where the physician is an AU.

Written Directive

- 10 CFR 35.40
- A written directive (WD) must be dated and signed by the AU before administration of I-131 NaI > 30 uCi or any therapeutic dosage of unsealed byproduct material or any therapeutic dose of radiation from byproduct material under that license.
- A WD must be prepared within 48 hours of an oral directive.

Y-90 Microspheres (06/2012)

- Written directive (WD): administered activity as written or “delivered at stasis”
- Emergent conditions: WD altered, the AU must be notified & amend the WD w/in 48 hr after the administration (reason, date, AU signature)

Question # 7e

A pt is administered 25 mCi I-131 NaI. The written directive prescribed activity is 20 mCi of I-131 NaI. Is this a medical event?

a. Yes
b. No

Question # 7e

A pt is administered 25 mCi I-131 NaI. The written directive prescribed activity is 20 mCi of I-131 NaI. Is this a medical event?

a. Yes
b. No

Medical Event Reporting

1. Medical event reporting is required except when an event results from patient intervention.
2. After discovery of the medical event, telephone NRC/state regulatory agency w/in 1 calendar day.

10 CFR 35.3045

Medical Event Reporting

3. Written NRC or regional office notice w/in 15 calendar days of discovery.
    - de-identified patient

10 CFR 35.3045

Medical Event Reporting

1. ME reporting is not punitive.
2. The NRC was created to assure public health & safety in the use of radioactive material (Regulators).
3. ME reporting assesses trends in patient safety issues to affect change to improve health and safety for the public.
    - i.e, Recall on a Y90 catheter

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2. The NRC was created to assure public health & safety in the use of radioactive material (Regulators).
3. ME reporting assesses trends in patient safety issues to affect change to improve health and safety for the public.
   - i.e, Recall on a Y90 catheter

Licensee Reporting

1. A licensee is not required to notify the patient w/o first consulting the referring physician.

10 CFR 35.3045

Licensee Reporting

2. Referring physician & pt/relative also need to be notified w/in 24 hrs after discovery. If pt not notified, why not.

3. If the referring physician or pt cannot be reached w/in 24 hr, the licensee shall notify them ASAP.

10 CFR 35.3045

Licensee Reporting

4. Copy of NRC/regulatory report provided to the referring physician w/in 15 days with pt name.

10 CFR 35.3045

Question # 7f

A pt is administered 25 mCi I-131 NaI. The written directive prescribed activity is 20 mCi of I-131 NaI. If this is a medical event, what should the AU do?

a. Notify the RSO.
b. Notify the regulatory agency.
c. Rewrite the written directive.
d. Rewrite the patient consent.

Question # 7f

A pt is administered 25 mCi I-131 NaI. The written directive prescribed activity is 20 mCi of I-131 NaI. If this is a medical event, what should the AU do?

a. Notify the RSO.
b. Notify the regulatory agency.
c. Rewrite the written directive.
d. Rewrite the patient consent.

Question # 8

After discovery of a medical event, when must the licensee notify the NRC/regulatory agency?

a. 1 day
b. 3 days
c. 7 days
d. 14 days

Question # 8

After discovery of a medical event, when must the licensee notify the NRC/regulatory agency?

a. 1 day
b. 3 days
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Dose Administration

- All administered doses need to be within 20% of the prescribed dose.*
- 10% rule **
- +/- > 20% for medical event & dose to patient

** So do not get to 20%

* 10 CFR 35.63

Does the +/- 20% apply to ranges, therapeutic and diagnostic procedures?

- “A dosage that is outside the prescribed range can be used for medical purposes if the AU so directs.” This needs to be modified BEFORE the dosage is to be administered.
- Yes. The 20% rule applies to both therapeutic and diagnostic procedures.

10 CFR 35.63

ATTENDANCE VERIFICATION CODE

5697

Occupational Worker: Pregnancy

- After a written declaration of pregnancy & given the estimated date of conception, the dose limit is < 5 mSv /0.5 rem during the entire preg.
- Dose limit is absorbed dose to the fetus (not the mother or the badge)

Courtesy of F Mettler

Pregnancy

- There is no requirement for employee to declare her pregnancy to employer.
- If > 0.45 rem has been reached before declaration of the pregnancy, only an additional fetal dose of 0.05 rem is permitted.

Courtesy of F Mettler

Pregnancy

- If pregnancy is NOT declared, there is NO fetal dose limit.
- A pregnancy can also be undeclared (in writing).

What do you tell the breastfeeding patient?

10CFR35.75:* If the dose to the infant > 100 mrem, the licensee must give

1) guidance on interruption or D/C breastfeeding

2) information on consequences if continues to breastfeed

- ^{131}I: stop, 6 wk prior
- ^{99m}Tc: 24hr
- ^{67}Ga: 4 wk; ^{111}In: 4 d
- ^{18}FDG: 4 hr*

Infant exposure: 4-12 hr

Nursing Mothers & Radiopharmaceuticals

• Stop	^{131}I-NaI, ^{124}I-NaI, all alpha, ^{177}Lu dotatate diagnostic or therapeutic
None	^{15}O, ^{82}Rb, ^{68}Ga
1 hour	^{11}C, ^{13}N

Nursing Mothers & Radiopharmaceuticals

• 4 hours	^{18}F
• 24 hours	^{99m}Tc
• 3 days	^{123}I-NaI
• 4 days	^{201}Tl-chloride
• 6 days	^{111}In WBC,-pentetreotide

Nursing Mothers & Radiopharmaceuticals

- 28 days
- None

^{67}Ga, ^{89}Zr

^{90}Y Microspheres

For breast & SNL sources as long as the sources are not in the breast

Question # 9

For a nursing mother who receives a radiopharmaceutical, which of the following infant doses if exceeded must the licensee give guidance to D/C nursing and the consequences if nursing continues?

a. 50 mrem
b. 100 mrem
c. 300 mrem
d. 500 mrem

Question # 9

For a nursing mother who receives a radiopharmaceutical, which of the following infant doses if exceeded must the licensee give guidance to D/C nursing and the consequences if nursing continues?

a. 50 mrem
b. 100 mrem
c. 300 mrem
d. 500 mrem

Question # 10

Are there more NRC or Agreement States? How many of each?

Are military medical centers under the NRC or have a special status?

In an Agreement state, what state entity makes the agreement with the NRC?

Are there more NRC or Agreement states?

Are there more NRC or Agreement states?

Agreement states

Agreement vs NRC States

NRC: 10 states/regional compacts
- Equal to NRC regulations

Agreement: 39 (pursuing agreement state status: Connecticut)
- Equal to or stricter than NRC
- Agreement between the NRC and the state's governor

Agreement vs NRC States

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Agreement vs NRC States

What are military medical centers under?

Agreement vs NRC States

What are military medical centers under?

NRC

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Agreement vs NRC States

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Agreement vs NRC States

In an Agreement state, what state entity makes the agreement with the NRC?

Governor.

Question # 11

To whom is the NRC accountable to?

How many potential NRC commissioners are there?

Question # 11

To whom is the NRC accountable to?

Question # 11

To whom is the NRC accountable to?

Congress

Question # 11

How many potential NRC commissioners are there?

Question # 11

How many potential NRC commissioners are there?

Five

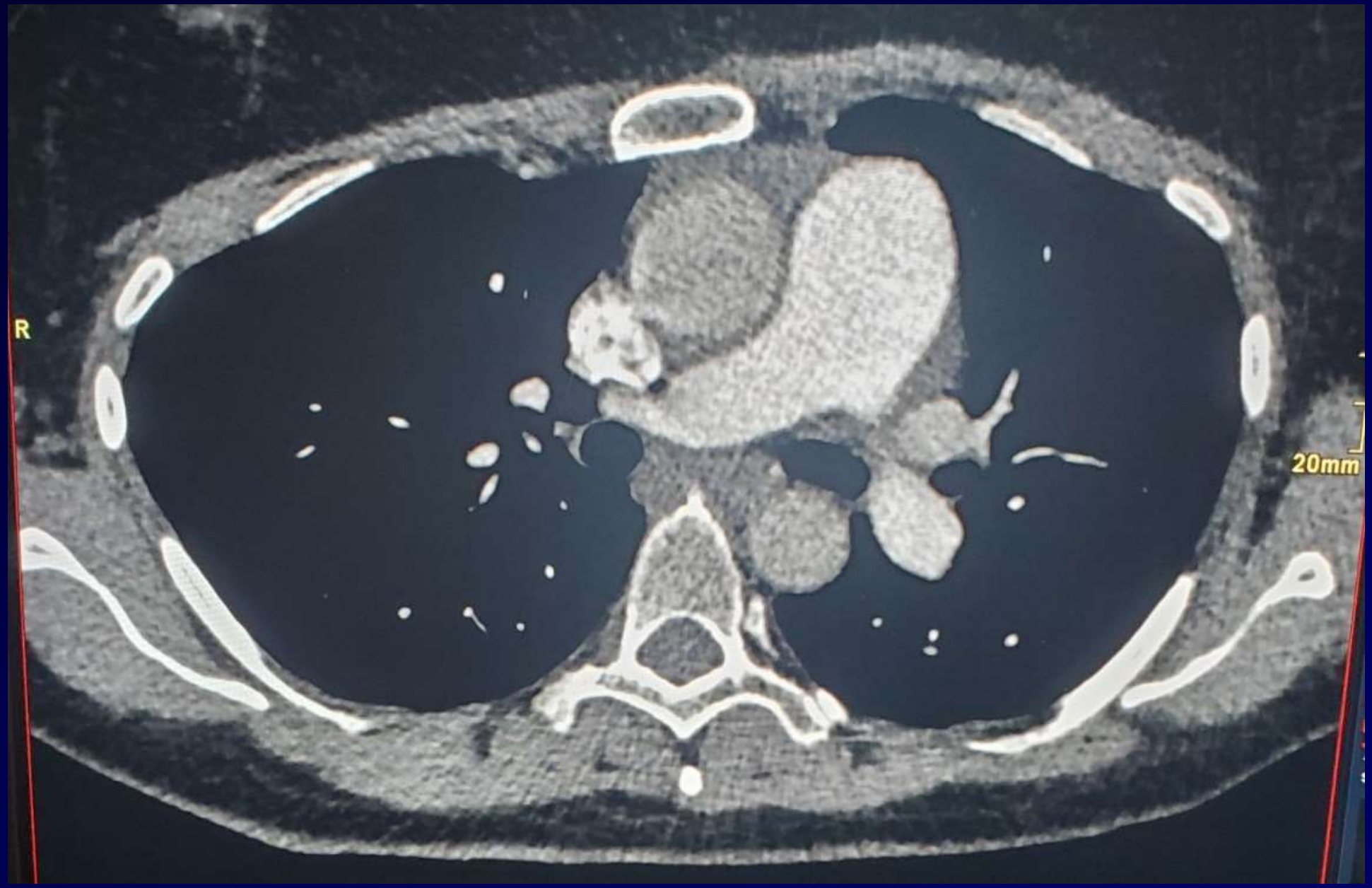
Summary

- Nuclear Regulatory Commission
- NRC vs Agreement states
- 2024 NRC recognized boards for AU eligibility
- Written directive

Summary

- Medical event and reporting
- Pregnancy & nursing mothers administered byproduct material

“Thank you”
for your
attention.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