

# Implementation of a Protocol for Non-Conditional Cardiac Implantable Electronic Devices

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# Introduction

- Increasing needs of MR for CIEDs that do not carry FDA labeling as MR conditional
  - MR conditional generators that have been combined with nonconditional leads or MR conditional systems implanted in patients that do not meet all specified conditions of use
- Multiple pilot studies were reviewed that demonstrated safety of CIEDs that are appropriately screened and programmed into a prespecified protocol
- Evaluation of patient is performed by EP cardiology after it is determined MR is the best imaging modality and no alternative is available

# Qualifiers

- Device has been implanted at least 6 weeks
- Patient needs to be alert and responsive
- Patient be scanned on 1.5T scanner and monitored by ACLS trained staff
- Risk-benefits discussion with the patient should be performed and patient education given

### MRI with Non-Conditional Pacemaker

You have a pacemaker or implantable cardioverter defibrillator (ICD) that is not FDA approved to go through an MRI scan. This is also called a non-conditional pacemaker/ICD. It could be because the pacemaker or the wires are not approved for MRI. It may also be because the wires and pacemaker MRI safe, but are from different companies, so the combination has not been tested before.

#### Deciding to have the MRI

Your doctor has ordered an MRI as part of your workup. If you choose to do the MRI, you will see a heart doctor to make sure doing an MRI is safe with your pacemaker.

Studies show that MRIs with non-conditional pacemakers are generally safe. When they are screened and set into an MRI safe mode, studies show there were no pacemaker or wire failures reported. MRIs with non-conditional pacemakers or ICDs can safely be performed with very little risk.

After talking to the heart doctor, you know there are still low risks that may happen if you have the MRI.

These risks are:

- Pacemaker failure
- Irregular heartbeat or arrhythmia
- Pacemaker reset
- Changes in setting
- Shock
- Heat injury to the heart
- Death



#### During the MRI

During the MRI scan, a nurse will be checking your vital signs and heart rhythm with special equipment. You will be able to speak to the staff while in the MRI machine the whole scan. Tell staff right away if you feel pain or discomfort from the pacemaker.

Symptoms to report are:

- Heating of the pacemaker
- Fast heartbeat
- Dizziness
- Pain

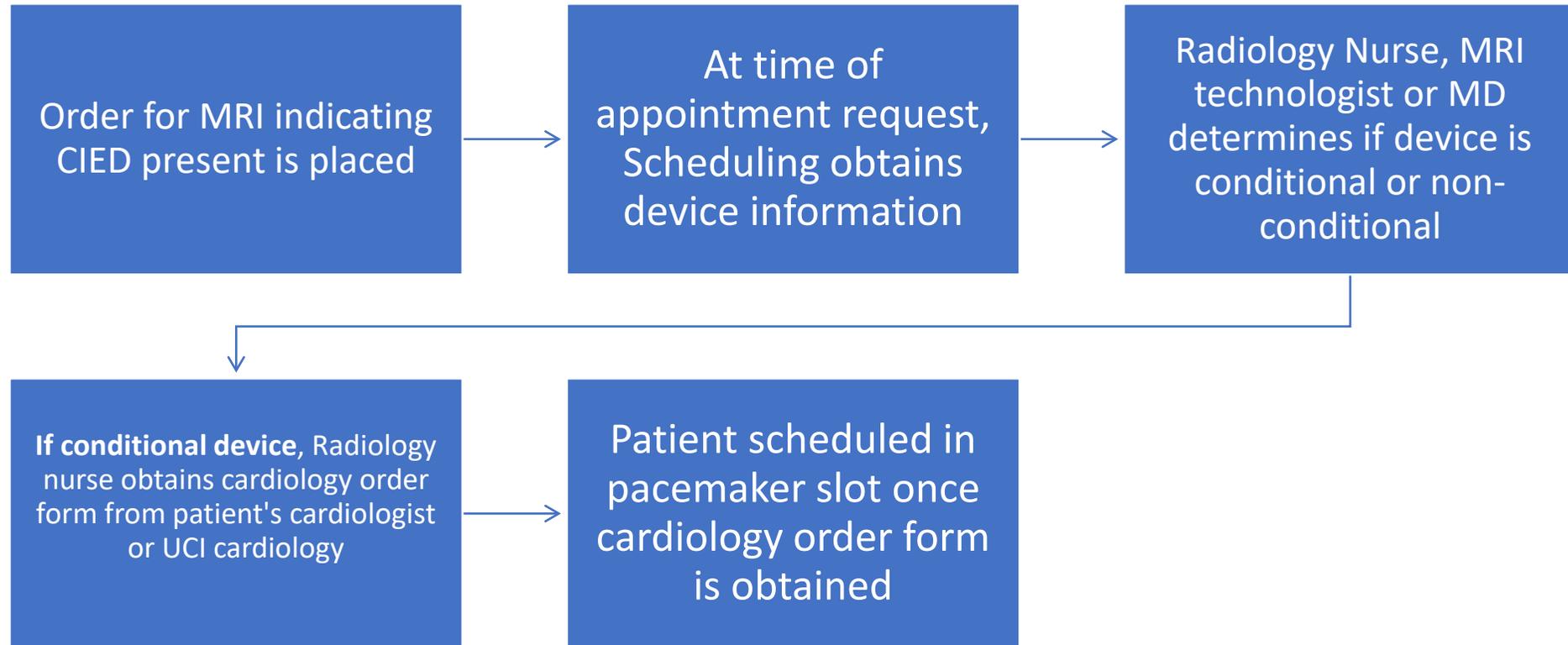
#### After the MRI

Right after the MRI, your pacemaker will be changed back to the original settings. You may be asked to see to your heart doctor if there are any unexpected symptoms or changes to the pacemaker settings.

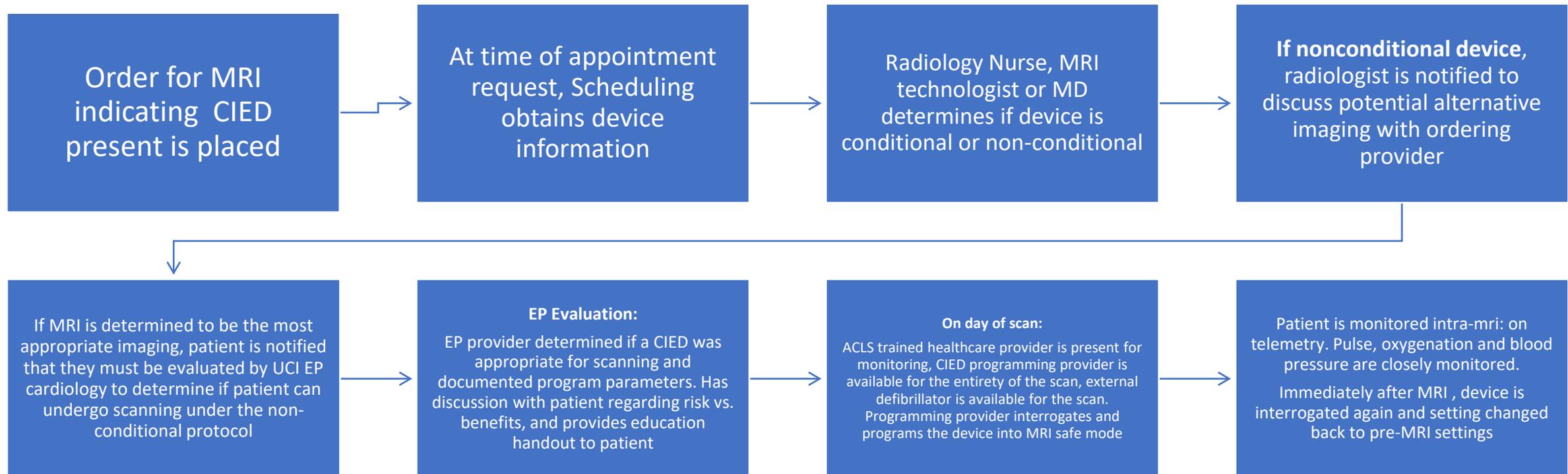
# Limitations

- Excluded permanent epicardial, abandoned or fractured leads.
- Device must not be near end of life
- Limited to the scans protocolled on the specific machines
  - Unable to perform breast or cardiac MRIs

# Conditional CIED Workflow

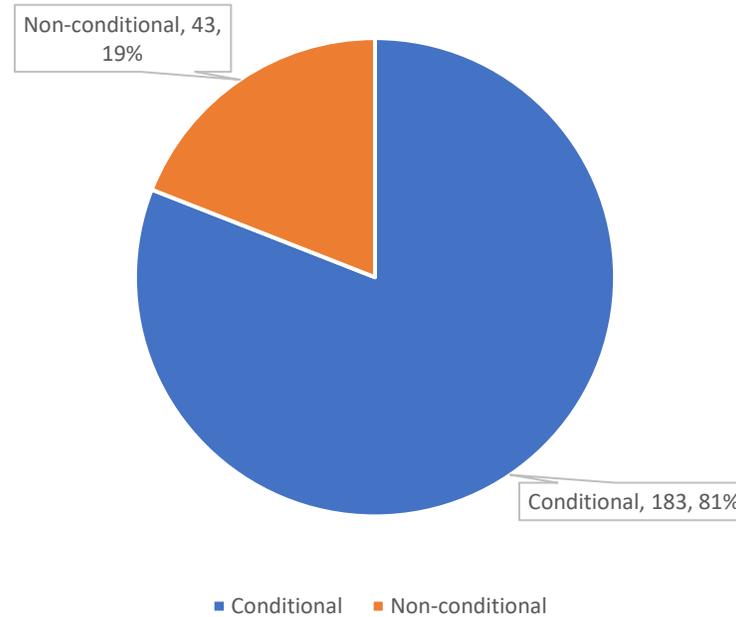


# Non-conditional CIED Workflow

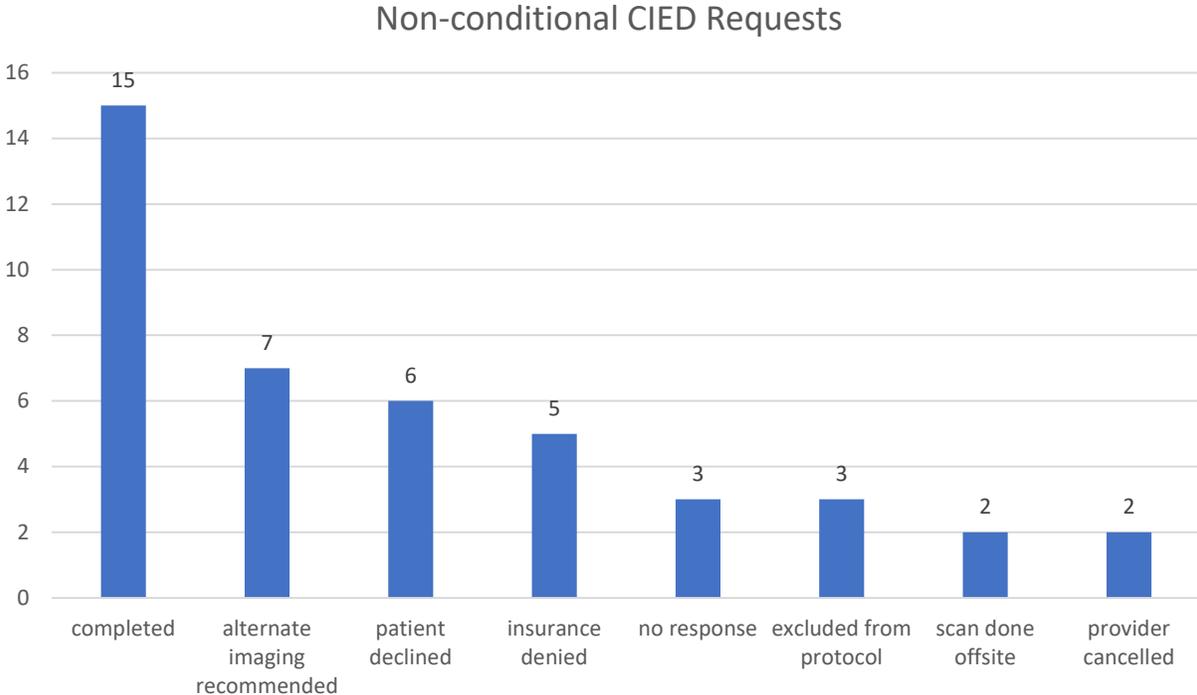


# Scheduling Requests for MRI with CIED

CIED requests, April 2021 - April 2022



# Outcome of Non-conditional CIED Requests



# Summary

- Expanded MRI capability to 6.64% of the sample population who initially did not qualify for MRI
- All patients were scanned with out any adverse clinical incident and no parameter changes, resets or limitations in programming were noted in any CIEDs scanned

## References

- 1 *2017 HRS Expert Consensus Statement on Magnetic Resonance Imaging and Radiation Exposure in Patients with Cardiovascular Implantable Electronic Devices*, <<https://www.hrsonline.org/guidance/clinical-resources/2017-hrs-expert-consensus-statement-magnetic-resonance-imaging-and-radiation-exposure-patients>> (2017).
- 2 Russo, R. J. *et al.* Assessing the Risks Associated with MRI in Patients with a Pacemaker or Defibrillator. *New England Journal of Medicine* **376**, 755-764, doi:10.1056/NEJMoa1603265 (2017).