

IMPLEMENTATION CONSIDERATIONS

Using simplified clinical criteria to screen more patients for ATTR-CM

Early detection of transthyretin amyloid cardiomyopathy (ATTR-CM) is critical for timely disease management. But detecting ATTR-CM can be challenging because it affects multiple systems in the body and clinical criteria are complex. To increase early detection of ATTR-CM without overburdening healthcare systems, simplifying the clinical criteria and integrating them into care workflows are essential.

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Audience

- Hospitals and health systems
- Physicians and medical groups

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Challenge

Although ATTR-CM is primarily characterized by its impact on the cardiovascular system, it may also affect other systems, such as the nervous and gastrointestinal systems. While different specialists may see a single piece of the puzzle, they may not have the information necessary to form a comprehensive diagnosis—especially given the rarity of ATTR-CM.¹ Providers who mostly see patients with common causes of heart disease may not always remember the extensive list of clinical criteria for ATTR-CM and are thus unlikely to catch those cases. Broader screening can help find cases of ATTR-CM, but screening strategies need to be efficient to support adoption.²



Approach

Integrate simplified clinical criteria into existing care pathways to screen the right patient population at the right time. For this strategy, find a population with an existing gap in ATTR-CM detection, determine whether simplified clinical criteria are compatible, and integrate that simplified criteria into the patient care pathway and staff workflow. When patients in the care pathway meet the criteria, route them to amyloidosis screening.²

The four key steps to developing simplified clinical criteria

01 Identify a gap in ATTR-CM detection with an opportunity for efficient screening.

02 Based on patient population and workflow, decide which simplified criteria to use.

03 Create a path to the next testing steps for patients flagged by the criteria.

04 Educate staff on the simplified clinical criteria screening process.

01 Identify a gap in ATTR-CM detection with an opportunity for efficient screening

The specific patient population being screened for ATTR-CM affects how simplified clinical criteria are developed and implemented, so the first step is choosing the right patient population to screen.²

First, look at patient populations that are at high risk for ATTR-CM. If the rate of those patients being diagnosed with ATTR-CM is lower than the rate reflected in current research, more screening may be needed to detect cardiac amyloidosis. For example, a physician at Duke Department of Medicine recommends broadly screening heart failure with preserved ejection fraction (HFpEF) patients for the presence of amyloid, as HFpEF is associated with cardiac amyloidosis.^{3,4}

Second, look for points along each patient care pathway where amyloidosis screening can be integrated using existing processes, technologies, and staff activities. For example, if patient data is already being reviewed centrally as part of a quality initiative, adding an ATTR-CM screening checklist to that review may require few additional resources but lead to high impacts on patient outcomes and increased efficiency.

Finally, develop a screening process that doesn't add extra steps for patients. For example, incorporating amyloidosis screening into preexisting patient visits or post-op procedures will reduce the need for patients to make additional appointments.



The reality is that we see a lot of different phenotypes. We have to screen a lot more people with the proper tools. Start by looking broadly for specific risk factors.

– **Marat Fudim, MD**

Cardiologist

Duke University Health System

02 Based on patient population and workflow, decide which simplified criteria to use

Healthcare organizations can use existing simplified clinical criteria as-is, modify existing criteria, or create their own criteria.² Which simplified checklist, scorecard, or criteria to use for ATTR-CM screening will depend on the patient population’s clinical nuances and on its impact on provider and staff workflow. Consider the four questions below when choosing simplified clinical criteria.

Which patient touchpoints on the care pathway can reveal the clinical clues for ATTR-CM?

Organizations should develop simplified clinical criteria based on the information available at each patient touchpoint on the care pathway. For example, simplified clinical criteria embedded within the echocardiogram imaging department may be different than clinical criteria used by primary care providers (PCPs). Clinical clues available via echo might include imaging abnormalities or other visual indicators of disease, whereas the information available to PCPs might involve patient reports of symptoms or findings from an examination at a patient visit.

What are the clinical nuances of the screened population?

The clinical nuances of each patient population will determine how simplified clinical criteria are developed and implemented. For example, Prisma Health reviewed patients receiving treatment for ATTR-CM at their hospital to determine the commonalities among them. The resulting simplified clinical criteria thus were targeted to the unique traits of their own patient population with ATTR-CM. For example, Prisma’s patient population has a higher rate of diabetes than the national average, which means diabetic neuropathy is also common. For its simplified clinical criteria, Prisma had to distinguish neuropathy without diabetes—which raises suspicion of ATTR-CM—from diabetic neuropathy.² Neuropathy without diabetes became one of the simplified clinical criteria of ATTR-CM. Prisma also noticed that their patients with ATTR-CM were more likely to have the genetic version of ATTR-CM than average, which led them to put more emphasis on genetic testing during the diagnostic process.

“Cardiac amyloidosis is a rare disease, so we have a limited patient population. It’s helpful to have the tools available to catch patients that don’t fit the guideline model and be more specific to what our typical patient may look like.

– Marina Matthews-Carter, PharmD, BCACP

Clinical Pharmacist
Prisma Health

What method of adding ATTR-CM screening to patient touchpoints will impact provider workflow the least?

The way that simplified clinical criteria is implemented can determine how much provider workflows are impacted. For example, paper checklists or decision trees that need to be evaluated manually are ideally easy for providers to memorize, reference, and apply. Clinical criteria that has been integrated into a centralized quality improvement process may have more room for complexity. Automating criteria in the electronic health record (EHR) or another system that can easily calculate results may create minimal impact on workflow, even as scoring complexity rises.

How many patients will the criteria flag?

Clinical criteria that flag too many patients can create system backlogs and clinical burden—but criteria that flag too few patients will miss cases of ATTR-CM. The right percentage of patients being diagnosed will depend on the specific patient population chosen for screening and should reflect current clinical literature.

Engaging providers early in the development of ATTR-CM clinical criteria will increase the likelihood of the process working from a clinical and workflow perspective. And involving providers early will also foster buy-in from key providers and staff. Consider involving:

- Heart failure specialists, who have insight into the best options for clinical criteria.
- Primary care doctors and general cardiologists, who are the front line of care for patients and are often involved in patients’ entry into screening.
- The clinical care team—such as nurse navigators, clinical coordinators, clinical pharmacists, genetic counselors, echo sonographers, radiologists, the cardiac MRI team, and the structural heart team—who can be ideal partners in implementing a new process and moving patients through the process, since these staff members often have multiple patient touchpoints along the patient journey.
- Other specialists, including oncology, hematology, neurology, and orthopedics, who can be a source of referrals and/or a place to send patients.
- Quality improvement champions, service line leaders, and administrators, who can help get system buy-in and resources.

03 Create a path to the next testing steps for patients flagged by the criteria

Thoughtfully designing how patients are notified and referred for further work-up can increase the chances that flagged patients follow up on the next steps, particularly if the screening process is automated or centralized.² Consider the three best practices listed below:

Entrust a familiar provider to talk to the patient about ATTR-CM.

Patients may be more responsive if their own PCP or cardiologist talks to them about ATTR-CM, partly because getting this information from someone who is not their provider can make some patients worry about privacy. If the patient's provider isn't familiar with ATTR-CM, equip them with resources and education.

Make sure patients understand next steps and why they are important.

For example, patient care navigators and similar roles may be well-positioned to talk to patients about the urgency of completing the recommended follow-up testing. Take-home patient education materials can also help patients to retain information.

Make it easy for providers to refer to the right specialists or tests.

For example, using prepopulated order sets in the EHR can ensure that once patients are flagged by the simplified clinical criteria, providers can easily and intuitively order the next steps. If prepopulated order sets are not an option, creating easy-to-reference one-pagers or assigning a patient care navigator to review order sets can help keep orders consistent across referring providers.

“ No one likes to receive the call about being at higher risk for a rare disease. It's always nicer—and the patient is more responsive—if the primary care doctor or general cardiologist approaches them about ATTR-CM. And afterward, the patient is more likely to adhere to treatment.

– **Menhel Kinno, MD**

Cardiologist

Loyola University Medical Center

04 Educate staff on the simplified clinical criteria screening process

Provider education about clinical criteria doesn't necessarily need to include every sign and symptom of ATTR-CM.² Instead, educate providers and staff about how to apply the simplified clinical criteria and the next steps in the process, which are easier to retain than an in-depth understanding of the disease. Be sure to include everyone who might initiate the simplified clinical criteria screening process, move patients through the process, or receive results of the process.

To optimize the impact of provider education, educational strategies should be:

- **Simple.** Distill new information into need-to-know criteria and next steps to avoid overwhelming providers and staff. For example, one health system teaches providers when and how to refer patients for imaging, rather than how to recognize a specific disease in the clinic.
- **Convenient.** Use preexisting training days or create protected time to make it convenient for providers and staff.
- **Repeated.** Deliver trainings several times and through different mediums so providers and staff have multiple opportunities to learn. Providers and staff will be more likely to retain information if they receive both an in-person training and an easy-to-read one-pager to refer to later.
- **Supported by providers:** Emphasize that simplified clinical criteria for ATTR-CM screening only supports provider expertise, rather than replaces it. If providers understand that clinical criteria make their workflow easier, they may be more likely to buy in.

Results

How to know it's working

One way to measure the success of a screening program is to look at the ratio of patients screened to patients diagnosed in the selected patient population.² If the ratio of patients being diagnosed with ATTR-CM is lower than the rate described by clinical literature for that population, some patients may still be falling through the cracks. That said, because simplified clinical criteria are designed to use few resources, new processes are likely worth continuing even if the rate is initially lower than expected—as long as the clinical criteria aren't creating provider backlogs or administrative burdens elsewhere.

Other qualitative and quantitative measures that may be useful to determine the impact of simplified clinical criteria:

- Care and clinical quality measures
- Time to diagnosis or treatment
- Percentage of patients referred who received complete, appropriate screening
- System capacity, such as wait times to see a specialist or undergo imaging
- Patient satisfaction scores
- Provider satisfaction and workload considerations

Share the results of data collection broadly, including an analysis of what worked and what didn't. These efforts can help other departments decide whether and how to implement simplified clinical criteria for other conditions.



I want to see that only one out of 10 patients we test is positive because we're screening so much. I don't want to miss patients, so that's why we're consistently screening broader patient pools.

– **Kulpreet Barn, MD**

Cardiologist

Deborah Heart & Lung Center

Case in Brief: Duke University Hospital

The challenge

Because echocardiogram reports weren't flagging indications of cardiac amyloidosis, providers missed some patients who could have been diagnosed earlier in the disease progression. Often, sonographers did not recognize the visual patterns in the echo image that indicated amyloidosis. In some cases, this dynamic led to re-imaging, which comes at a cost for both health systems and patients.⁵

The organization

Duke University Hospital is nationally ranked in cardiology and heart surgery by *U.S. News and World Report* for 2023-2024. Their hospital-based lab has more than 50 sonographers.

The approach

Duke built simplified clinical criteria for ATTR-CM into the echo screening process: A workflow diagram and pathology checklist printed on cards are attached to every scanner. When a sonographer sees clues from the pathology checklist in an echo image, they add strain for complete imaging—a process that only takes a few extra minutes. Duke also created standardized documentation and order sets to communicate echo results to providers and clarify next steps.

How it works

To create simplified clinical criteria for ATTR-CM detection in echo images, Duke investigated imaging patterns in 30 years of digital documentation for patients eventually diagnosed with ATTR-CM. After identifying clinical patterns in past echos, Duke created several simplified criteria for sonographers, consulting cardiac experts, and clinical researchers to assess their validity.

Duke also created standardized language to regulate how suspicion of amyloidosis in echo findings are communicated. Right now, sonographers use semi-standard language to create reports (such as, "suspicion of amyloid—please investigate clinically"). In the future, Duke is planning a drop-down within reporting software, so that sonographers can select the same language for amyloid suspicion every time—making it easier for echo readers and providers to interpret.

Once a patient is suspected of amyloidosis, providers use an order set integrated into the EHR to easily initiate follow-up, including ordering bloodwork or referring to a specialist. Because the next steps are standardized, providers can more easily give effective, consistent follow-up care without relying on a heart failure specialist for amyloidosis expertise.

Finally, Duke implemented a system of colleague feedback for ongoing quality improvement. In addition to the ongoing trainings offered, an echo advisor is assigned to each shift to assist other sonographers in reading tricky images. This “buddy system” ensures that all sonographers have immediate feedback—leading to improved imaging data and less re-imaging.

The results

Duke's simplified clinical criteria process has increased identification of suspected amyloidosis, diagnosis rates, and earlier diagnosis. Sonographers feel more confident in their results and recommendations, and they are more likely to collaborate with providers and comply with protocols. Implementing the echo advisor program raised the rate of sonographer compliance with protocols from 85% to 98%.

Sonographers are also more satisfied with their work, because their work impacts long-term patient care—and can positively change the course of a patient's life.

“ We used to flag amyloid maybe once a year. Now, we recognize patients throughout the week that fit the criteria.

– **Ashlee Davis**
Chief Technologist
Duke University Health System



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Endnotes

1. Kittleson MM, Maurer MS, Ambardekar AV, et al. Cardiac Amyloidosis: Evolving Diagnosis and Management: A Scientific Statement From the American Heart Association. *Circulation*. June 2020.
2. Note: Unless otherwise specified, all information in this case study came from Advisory Board interviews with officials from Deborah Heart & Lung Center, Duke University Health System, Loyola University Medical Center, and Prisma Health.
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4. Davies DR, Redfield MM, Scott CG, et al. A Simple Score to Identify Increased Risk of Transthyretin Amyloid Cardiomyopathy in Heart Failure With Preserved Ejection Fraction. *JAMA Cardiology*. September 7, 2022.
5. Note: Unless otherwise specified, all information for the Case in Brief came from Advisory Board interviews with officials from Duke University Health System.

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