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TRANSFORM: ACS BEST PRACTICES FOR LDL-C MANAGEMENT

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CV BUSINESS WHITE PAPER

With Support From:

AMGEN

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INTRODUCTION

Lipid-lowering therapy with statins is a cornerstone in the secondary prevention of cardiovascular events after an acute coronary syndrome (ACS) event.¹ This CV Business White Paper explores the rationale and best practices for improving lipid management post-ACS as framed by the TRANSFORM-ACS initiative.

TRANSFORM: Accelerating Lipid Lowering Post ACS (TRANSFORM: ACS) is part of the multi-project TRANSFORM series developed by the American College of Cardiology (ACC) to turn ACC clinical algorithms and standards into actionable results for patients while lowering administrative barriers for clinicians and patients.² The goal of TRANSFORM: ACS is to improve secondary prevention for post-ACS patients through the intensification of relevant lipid therapies. The project hypothesizes that rapid cholesterol testing after an event (within the hospital and within 75 days after discharge) will drive subsequent initiation of lipid-lowering treatment within the first year post-ACS.² A secondary hypothesis is that testing after an event would increase adherence more effectively than current practice. This quality improvement project focuses on approaches to address early lipid testing after an ACS event that may drive low-density lipoprotein cholesterol

(LDL-C) management to goal within the first-year post-ACS.² Highlighted best practices are gleaned from sites participating in the initiative, published literature and the MedAxiom knowledge base.

This document provides a solution-focused resource to support the clinical team in achieving early lipid measurement and initiation of guideline-directed lipid-lowering therapies during ACS hospitalization, ensuring follow-up lipid testing in the ambulatory setting to facilitate rapid achievement of LDL-C targets in the secondary prevention of atherosclerotic cardiovascular disease (ASCVD). Issues are addressed through an understanding of:

- [Initiation of appropriate lipid-lowering therapy](#)
- [Escalation of therapy](#)
- [Team-based care delivery](#)
- [Patient engagement and adherence](#)
- [Managing quality, performance and change](#)

INITIATION OF APPROPRIATE LIPID-LOWERING THERAPY

Early Initiation: The Cornerstone of Secondary Prevention of Cardiovascular Events After ACS

To effectively achieve desired LDL-C levels and monitor responses to statin therapy, lipid panels should be routinely analyzed post-acute myocardial infarction (AMI).³ While guidelines recommend in-hospital initiation of high-intensity statin therapy in patients with ACS, desired LDL-C levels are frequently not attained following discharge.⁴⁻⁶ Acute changes in the lipid profile immediately following infarction have been reported.³ This concern has led some to defer lipid measurement and thus drug therapy initiation until weeks or months after an ACS event.

Ensuring early attention to lipid management post-ACS requires debunking the long-held notion that clinically significant alterations in lipids occur after an ACS event, precluding meaningful interpretation until well beyond hospital discharge.⁷ The Limiting Undertreatment of lipids in ACS with Rosuvastatin (LUNAR) study assessed lipid changes one to four days after onset of ACS, before initiation of study treatment. Mean lipid levels had relatively little variation in the four days after ACS, thus allowing lipid measurement early in the patient's hospitalization to guide the selection of lipid-lowering medication.⁷

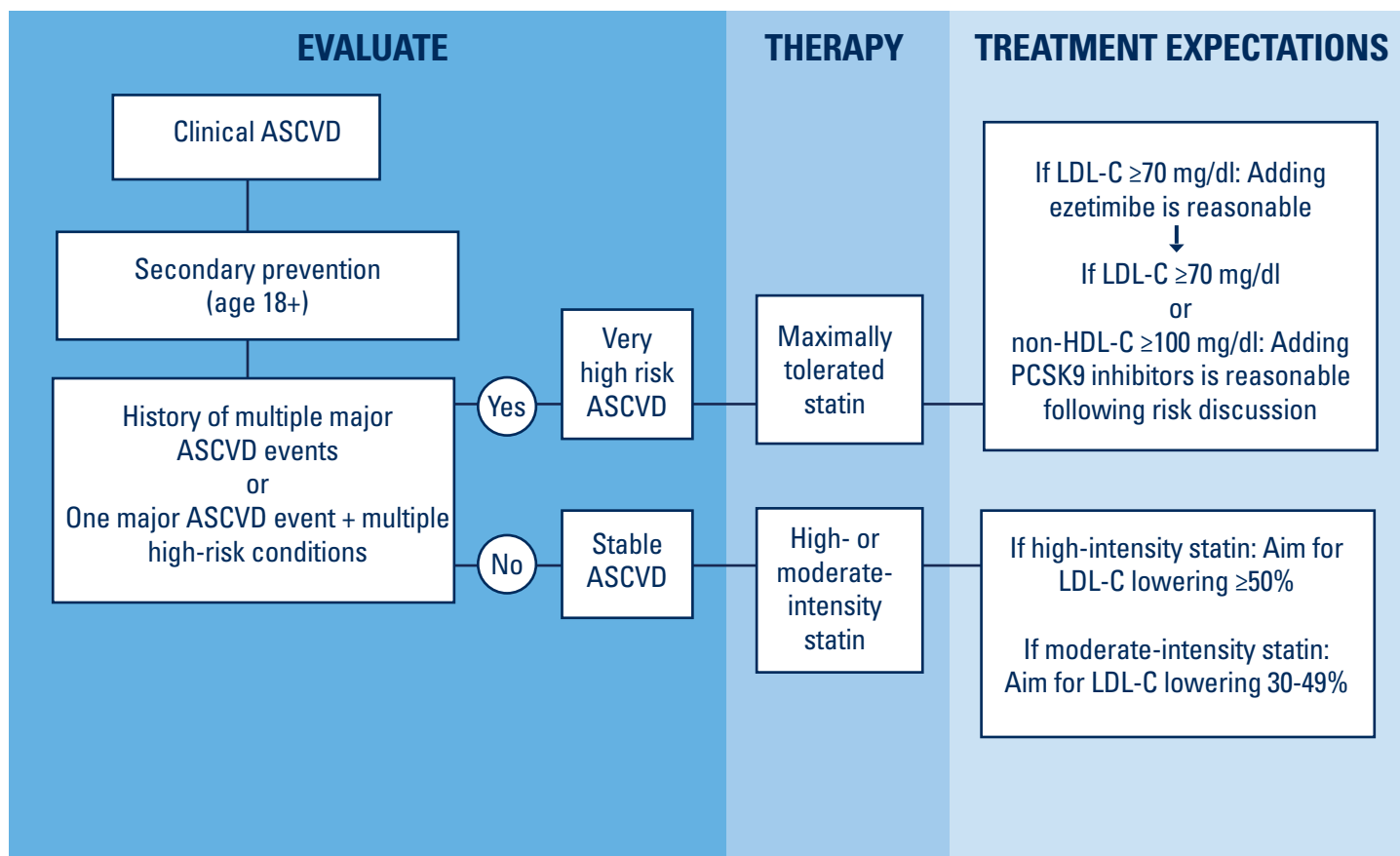
With this understanding, LDL-C levels obtained within 48 hours of hospitalization are reliable for making treatment recommendations. From a practical standpoint, these observations have implications for clinicians caring for patients hospitalized post-ACS. All patients presenting with ACS deserve an evaluation of lipids while in the hospital. Accurate knowledge of baseline lipid levels may affect the initiation of lipid-lowering therapy, the selection of a specific statin and its dosage, and the potential need for adjunctive lipid therapy and may influence the patient's willingness to adhere to a recommendation for long-term lipid-lowering therapy.⁸

Promoting Guideline Adherence

System-level interventions can facilitate the achievement of guideline-recommended LDL-C levels and decrease the lag time between guideline publication and clinical implementation.⁹ Ideally, clinicians should obtain lipid panels within the first 24 hours of an ACS event.^{4,5} Systematic evaluation of the efficacy of lipid-lowering therapy initiated

post-ACS should be performed early, with a >50% reduction target for LDL-C from baseline.⁹ There are multiple reasons that lead to undertreatment, including adverse effects and perceived risks of statins; disparities in race, sex, and geographical location; variations in protocols and practices across health systems; perceived prohibitive costs; and clinical inertia in cases of preexisting lipid-lowering medications.⁹ Best practices that support guideline adherence should aim to limit practice variation, overcome clinical inertia, recognize and address side effects, ease patient financial burden, encourage medication adherence and recognize patient-specific disparities.

Treatment algorithms provide support for planning lipid-lowering treatment. Implementing treatment algorithms can streamline decision-making toward achieving optimal LDL-C levels.^{4,5,9} Decision trees that translate lipid guidelines into clinical practice can be valuable for directing appropriate therapy to achieve desired LDL-C levels and decrease cardiovascular disease (CVD) risk in post-ACS patients.¹⁰



Familial hypercholesterolemia (FH) confers a high or very high cardiovascular risk and occurrence of premature CVD in comparison to the general population.¹¹ As such, emphasis on FH screening in ACS patients is an important consideration.¹¹ A specific pathway for the correct diagnosis and appropriate pharmacological approach is necessary for persons with a known or suspected family history of FH.¹¹ Leveraging in-hospital pathways to refer treatment-naïve patients with LDL-C >190mg/dL to a lipid specialist can facilitate diagnosis of FH.¹⁰

Clinical Decision Support to Allow Cognitive Offloading

We've learned from other evidence-based therapies for hyperlipidemia that efficacy and safety in cardiovascular outcome trials and strong guideline recommendations are still insufficient in ensuring successful implementation in clinical practice.¹² While individual patient conditions may create barriers to the adoption of therapies, there is increasing evidence that clinical inertia toward medication initiation and titration remains a significant factor in the widespread uptake of guideline-directed medical therapy (GDMT) in secondary prevention of ASCVD. The underappreciation of patient risk likely feeds the lack of attention to monitoring the effectiveness of and titrating lipid-lowering agents. Despite clinical trials that support rates of adverse events similar to or lower than placebo, patients' concerns for side effects may result in hesitation to initiate new therapies.¹³ The risk of omission with GDMT is often downplayed or ignored, and LDL-C levels lazily hang above the recommended threshold.

One way in which adherence to published guidelines can be encouraged during a patient's hospitalization is the use of clinical decision support tools to promote cognitive offloading in a busy hospital environment. An example is the use of logic-driven order sets directing the initial care of ACS patients that include lipid measurement and high-intensity statins. Using logic, electronic health record (EHR) alerts fire only when therapies have not been ordered. Including pre-checked orders can further ensure that diagnostics and therapies are placed in a timely fashion in an "opt out" versus an "opt in" approach.¹⁴ EHR alerts have historically shown mixed efficacy in changing clinician behavior.¹⁵ However, as demonstrated in the PROMPT-HF trial, the use of real-time, targeted, and tailored EHR-based alerts can lead to improved treatment rates in an outpatient setting.¹⁵ Furthermore, this study found that 79% of alerted providers agreed the alerts encouraged improved prescribing of medical therapies.¹⁵

BEST PRACTICES – INPATIENT CARE CONSIDERATIONS

- Use order sets with pre-checked orders (at hospital admission and discharge) for high-intensity statins, lipid panel and cardiac rehabilitation.
- Employ clinician input to develop real-time, targeted, logic-based reminders/alerts that fire only when conditions have not been met.
- Use a defined care pathway with medication escalation and lab testing to direct patient management.
- Maintain an awareness of cultural sensitivities and the potential for treatment bias.
- Begin discharge planning early in the hospital stay.



Promoting automatic referrals for hospital-based interventions has a significant positive impact on patient enrollment into specialty programs. Flexible systems that provide access to supporting services and adapting care to meet the changing needs of the patient are essential to managing the patient through the care continuum.¹⁶ Evidence supports that restructuring the patient discharge process to include activities such as discharge medication reconciliation and counseling, along with post-discharge follow-up and monitoring can potentially decrease the incidence of adverse outcomes post-discharge.¹⁷ ACS patients should be discharged with a lipid-lowering therapy prescription according to an algorithm and a letter mentioning the patient's LDL-C goals.¹⁰







KEY POINTS IN THE DISCHARGE PROCESS¹¹

1. Follow-up plan
2. Identifying LDL-C level the patient should achieve
3. Discharge communication to primary cardiologist and/or primary care physician, including:¹¹
 - Desired LDL-C level
 - Time to next LDL-C evaluation
 - Pharmacological approach to reach goal
 - Timing for follow-up
4. Information provided to patient:
 - Patient risk and consequent LDL-C management¹¹
 - Follow-up visit plan (include lipid profile monitoring)
 - Lifestyle interventions

BEST PRACTICES – HOSPITAL DISCHARGE

- Use a discharge checklist to help ensure attention to GDMT.
- Schedule timely follow-up appointments at the time of discharge.
- Include lifestyle management instructions and resources for diet and weight management, exercise and smoking cessation.
- Collaborate with care team members including pharmacy, exercise physiology, nutrition, etc.
- Provide clear communication and patient hand-off including accessible documentation and a transparent management plan and goals.

Factors Impacting LDL-C Lowering to Achieve Recommended Levels

Variations in treatment protocols across health systems	Clinical inertia	Side effects
		
Costs	Poor medication adherence	Racial, gender, and geographical disparities
		

Modified from Claessen BE, Guedeney P, Gibson CM, et al. Lipid management in patients presenting with Acute coronary syndromes: A review. *J Am Heart Assoc.* 2020;9:e018897.

ESCALATION OF THERAPY

Escalation of Therapy in the Hospital Setting

To address significant treatment gaps in achieving recommended LDL-C levels, care should target aggressive lipid-lowering therapy and provide patients with a clear follow-up strategy to optimize LDL-C management to a desired goal. Clinicians have an opportunity to reassess LDL-C management in patients hospitalized for ACS who are already taking statins. Treatment algorithms that guide the evaluation of current lipid-lowering therapy and the addition of secondary therapies can take advantage of an opportune time to adjust therapy to help prevent future cardiac events. ACS patients already receiving a maximally-tolerated statin whose LDL-C remains above target levels should be evaluated for the addition of nonstatin therapies.

Escalation of Therapy in the Ambulatory Setting

Current ACS guidelines outline the use of high-intensity statins to be initiated as early as possible after patient presentation.⁵ This includes the patient being discharged on high-dose statin. Although prescription of high-dose statins is common after presentation with ACS, the intensity of therapy and proportion of patients achieving recommended LDL-C levels are often not in line with recommendations. Contributing factors include providers' lack of compliance with the guidelines, failure to adjust dose or frequency of lipid-lowering therapies, and poor tolerance or compliance with treatment by patients.⁹ Effective strategies to ensure appropriate patient therapies during the ACS transition period need to target all of these areas. Key best practices have emerged that focus on patient care during post-ACS transitions and may improve medication adherence. These best practices will be outlined in each of the targeted areas.

Provider Guideline Compliance

Post-ACS patients are at high risk for recurrent events and thus require a targeted pharmacological approach for optimal management of underlying risk factors. One potential gap is the lack of common tools defining specific key steps for the management of patients with an ACS during hospitalization, discharge and follow-up. Attention should be drawn to the continuous evaluation of the lipid profile, and the prescription of lipid-lowering therapies at all stages – acute phase, discharge and follow-up.¹¹ The EuroPath tool is an example of a simple self-assessment tool to help bridge the gap between guidelines and practice. It may be used as a surrogate for a clinical decision tool or practice reminder.¹¹

A systematic evaluation of the efficacy of the lipid-lowering therapy initiated post-ACS should be performed early, four to six weeks after the index event. Reassessment of lipid levels is warranted by the significant individual variability in the lipid response to both dietary measures and lipid-lowering medications.⁹ It also provides the opportunity to monitor the therapeutic adherence and any potential clinical or biological adverse effects.⁹



TEAM-BASED CARE DELIVERY

Nurse- and Pharmacist-Facilitated Medication Adherence

Best practices have been identified using various team members to improve patient engagement for medication adherence.^{16,17} Multidimensional interventions delivered by pharmacists include medication reconciliation at admission and/or discharge, patient-specific counseling and education, motivational interviewing, developing individualized care plans and medication lists, and collaboration with the patient care team during medical rounds.¹⁷ Patient education can be delivered via different strategies, including distribution of medication boxes, literacy aids, sending reminders and offering feedback, motivational interviewing, and reinforcing the importance of medication adherence according to the Health Belief Model (HBM).^{16,17}

Nurse-coordinated care has been demonstrated to improve the achievement of LDL-C targets after an ACS event.¹⁹ Merely starting the guideline-recommended dose is insufficient to reach the guideline-recommended LDL-C target level.²⁰ Nurse-coordinated care, combined with guideline-based titration recommendations, improves ACS patient outcomes.¹⁹ Nurses can take a more active role in coordinating care between healthcare settings.¹⁶ Knowledge sharing and interdisciplinary collaboration across boundaries are essential to the continuity of care and should be part of a nurse's role and competence.¹⁶

Medication adherence can be transferred to the pharmacist to ensure continuity of care.²¹ "Teach and Treat" describes the use of clinical pharmacists as an extension of the multidisciplinary cardiovascular care team for secondary prevention medication management post-AMI in patients with left ventricular dysfunction. This program used a multidisciplinary model of care, supported by senior medical leadership, and is an accepted practice model.²² These programs require a clearly defined and robust clinical governance structure, which generates widespread trust and confidence in all staff members. The "Teach and Treat" pharmacist education program included experiential learning, taught lectures, online webinars, access to guidelines and physical exam training. These pharmacy-led clinics were developed to support patient care in between primary care and cardiology clinic visits post-discharge. Medications (ACEIs [or ARBs] and beta-blockers) were dosed appropriately 66% of the time for patients cared for in these clinics compared to 25% in the traditional care model.²¹

Patients perceive pharmacists as a useful source of medication-related information.¹⁷ Pharmacists' involvement in the care of ACS patients include, but are not limited to, medication reconciliation, promoting proper medication use, discharge patient counseling, supporting self-care and post-discharge follow-up.¹⁷ In addition, use of pharmacists to support ACS care has been shown to improve medication optimization, support transitional care, cardiac rehab participation, and medication adherence.²³ A pharmacist-supported care transition has been shown to help further reduce the risk of recurrent cardiovascular events and achieve optimal patient outcomes.²³

BEST PRACTICES – AMBULATORY CARE

- Develop workflows to promote awareness and documentation of patients' progress toward an LDL-C <70 mg/dl.
- Create clinic workflows that support prior authorization and financial counseling as needed for non-statin therapies.
- Develop standard work around the frequency of lipid reassessment.
- Promote the use of cardiac rehabilitation to support and reinforce strategies to achieve LDL-C level.
- Incorporation of nurse-coordinated care programs.

PATIENT ENGAGEMENT AND ADHERENCE

Patients experience difficulty adhering to medication regimens for multiple reasons, including socioeconomic factors, cost, insurance issues, concomitant illness, adverse effects and frequent dose adjustments.⁹ One reason for statin discontinuation or nonadherence is concern for adverse effects. Strategies to promote statin rechallenge in patients should include a multidisciplinary approach to increase knowledge, improve patient engagement, alleviate health disparities, and optimize provider-patient communication.⁹ It is imperative to provide a positive patient experience and communicate clearly as patients progress through the system. The use of multidisciplinary team members can facilitate care delivery, education and communication to increase adherence and improve outcomes in this population.¹² Medication adherence is defined as a process by which patients take their medication as prescribed by their healthcare professionals. Adherence to a combination of long-term cardiovascular medications is key to managing morbidity in this patient population. Only 60% of coronary artery disease patients have appropriate long-term medication adherence.^{24,25} Studies suggest that delivery of interventions such as patient education, counseling, intensified care, medication aids, reminders, financial incentives, and collaborative care methods significantly improve adherence.^{24,25} Findings of a meta-analysis indicated adherence rates as high as 70% could be achieved.²⁵ Most of the studies were comprised of more than one intervention. In conclusion, intervention is better than no intervention.²⁵

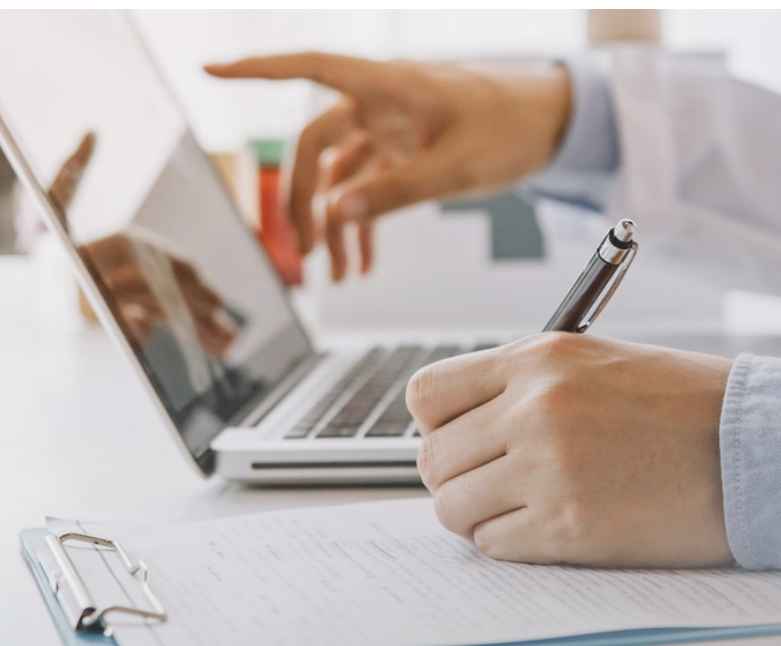
Patient engagement strategies including text messages have gained traction with multiple studies showing this as a low-cost opportunity to improve patient compliance.²⁵ A review of 16 studies that included text-based interventions to improve patient compliance showed that these interventions approximately doubled the likelihood of adherence to a medication regimen in patients with chronic disease.²⁶

Medication nonadherence may be intentional or unintentional. Intentional medication nonadherence is deliberate and associated with patient motivation. Unintentional nonadherence is related to lack of capacity or resources to take medications. Unintentional nonadherence to medication appears to be the major form suggesting that interventions delivered early in the post-discharge period may prevent the relatively high nonadherence following ACS.²⁷ A recent literature review by Molloy and colleagues found that behavioral techniques that focus on establishing a routine or habit associated with taking the medication may reduce medication nonadherence in post-ACS patients.²⁷

Cardiology care in the inpatient setting and during the transition period to outpatient care is associated with better patient outcomes. Follow-up care was defined as having been seen in a cardiology clinic within 60 days after discharge from ACS event. These patients were more likely to be on evidence-based medications including a statin and to have had a primary care visit.²⁸

BEST PRACTICES – THERAPEUTIC ADHERENCE

- Employ shared decision-making tools and techniques.
- Assign designated care team members for patient education.
- Ensure patient instruction is documented in the EHR.
- Utilize strategies to promote adherence and understanding of treatment recommendations (e.g., teach back, motivational interviewing, personalized patient reminders).
- Assess barriers to medication adherence.
- Ensure medications are available/prescriptions filled at discharge (e.g., “meds to beds”).
- Provide counseling regarding side effects and their management.
- Discuss progress toward LDL-C management goals with the patient.
- Maintain awareness of cultural and social issues impacting adherence.



MANAGING QUALITY, PERFORMANCE AND CHANGE

Monitoring care delivery performance and adherence to clinical guidelines requires a multifaceted approach. Involving local stakeholders to develop multidimensional interventions based on an assessment of current practices is essential to evaluate clinical knowledge, underlying skepticism, or beliefs that may hinder the success of interventional strategies. Further, involving those closest to the work can uncover otherwise unappreciated challenges and create ownership of the final product. This can begin by having the care team map workflows, incorporating evidence-based guidelines and highlighting obstacles to completing the work.

Once the workflow is agreed upon and the structure is in place to implement it, socializing the change, monitoring compliance and providing performance feedback is critical. An ACC/American Heart Association report on clinical guideline implementation strategies found that the two strategies that were most effective in improving both process of care and clinical outcomes were: 1) performing audits with feedback, and 2) providing educational information directed at changing practice.²⁹

Effective change management is a lever for increased engagement and performance. When developing or modifying existing clinical treatment pathways, the effective use of change management strategies will increase the likelihood of success. Ninety-four percent of projects meet or exceed their goals when change is managed effectively.³⁰

Managing change begins with raising awareness of the “what” and the “why” of the change in practice, followed by highlighting the benefits of making the change. Providing clinical team members with the knowledge needed to enact a change in practice along with the tools and technology to streamline workflows will make change efforts easier to institute. Using a visual management system (e.g., communication boards, newsletters) to share data, success stories, and communicate improvement opportunities helps keep all team members aware of progress. Verbal updates in staff huddles and department meetings allow time for questions and team member input. Finally, providing an opportunity for feedback on what is working well and what challenges remain facilitates the identification of remaining barriers and the opportunity to celebrate success.

BEST PRACTICES – PERFORMANCE AND CHANGE MANAGEMENT

- Ensure an engaged dyad leadership structure with clear delineation of performance expectations.
- Use a visual management system to communicate status of quality and process improvement efforts.
- Employ purposeful change management strategies to support quality and process improvement efforts.
- Participate in the ACC NCDR® Chest Pain – MI Registry™ and leverage reports to monitor the rate of ACS patients discharged on high-intensity statin.
- Develop EHR reports to evaluate rates of LDL-C >70 mg/dl in patients with a history of AMI. Set annual achievement goals and share findings on a regular basis.



RESOURCES

- [2022 ACC Expert Consensus Decision Pathway for Integrating ASCVD and Multimorbidity Treatment](#)
- [ACC ASCVD Risk Estimator Plus](#)
- [ACC Dyslipidemia Clinical Topic Collection](#)
- [ACC Non-statin Therapies Pocket Guide](#)
- [ACC Statin Intolerance App](#)
- [American Society for Preventive Cardiology – Non-statin/PCSK9i Access Tools](#)
- [Dutch Criteria for Familial Hypercholesterolemia](#)
- [SMART Risk Score – Secondary Prevention ASCVD](#)
- [Statin Myths Patient Information](#)
- [ACC NCDR Chest Pain – MI Registry](#)

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