



Countering clinical inertia in lipid management: Expert workshop summary

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Hyperlipidemia is prevalent

Nearly 40% of American adults have elevated cholesterol values, placing them at increased risk for cardiovascular disease and stroke.¹ In addition to lifestyle modification, a critical tool to manage cholesterol levels is the use of prescription of lipid-lowering medications. While lipid-lowering medications are widely available in the United States, there are many potential challenges with uptake and use among patients. These challenges include: making lipid-lowering medications acceptable to patients, ensuring that patients take lipid-lowering medications consistently as prescribed, and ensuring that providers have accurate and timely information about their patients' adherence behaviors. Only half of adults prescribed lipid-lowering medication take it as prescribed.¹ This lack of long-term persistence with taking lipid-lowering medications as prescribed is both a result of, and a cause for, provider inaction, otherwise known as clinical inertia.

Clinical inertia is a common, multi-faceted challenge to achieving lipid goals

Clinical inertia is defined as a lack of treatment change when a patient is not at evidence-based goals for care.²

The topic has been examined within the context of diabetes and hypertension.^{3,4} A prime example of clinical inertia is lack of treatment intensification. For example, providers may not prescribe statins or increase statin dosages as needed to practice in a manner consistent with current guidelines. There are several contributing factors to the problem of clinical inertia in the treatment of hyperlipidemia.

We assert that the Capability, Opportunity, and Motivation (COM-B) System is a useful framework^{5,6} to help explain why health care providers may fail to appropriately prescribe or intensify treatment with lipid-lowering medications. The COM-B incorporates existing behavior theories and is intended to be a comprehensive and parsimonious model.⁵ This dynamic model is made up of the interaction between three components: Capability, Opportunity and Motivation (COM) that together impact the performance of Behavior (B). Each component can influence behavior directly and, in addition, Opportunity and Capability might influence Motivation, and so affect behavior. Our depiction of the model as it relates to clinical inertia is shown in [Figure 1](#).

We describe drivers of clinical inertia within this framework. First, in the area of Capability there is a lack of harmonization of clinical practice guidelines.^{7,8} Because of this heterogeneity of guidance, healthcare providers may misinterpret current guidelines, or may continue to practice based on outdated guidelines.⁹⁻¹¹ Harmonization of guidelines may be hindered by organizations having different agendas and priorities. Subsequently, there may be informational gaps in providers' knowledge and/or understanding of cardiovascular risk assessment and intensification criteria.^{9,12} In addition to inconsistencies with guidelines, poor harmonization of guidelines may be compounded by inconsistency in patients' dose-response (eg, differences in physiological variations across individuals may be associated with different responses to the same dose of a lipid-lowering medication), thus making it more difficult to make patient-centered prescribing changes that would be necessary to attain clinical goals.¹³

The second component of the COM-B model is Opportunity, which includes structural barriers contributing to clinical inertia. Health care providers may not have the physical opportunity for treatment intensification due to

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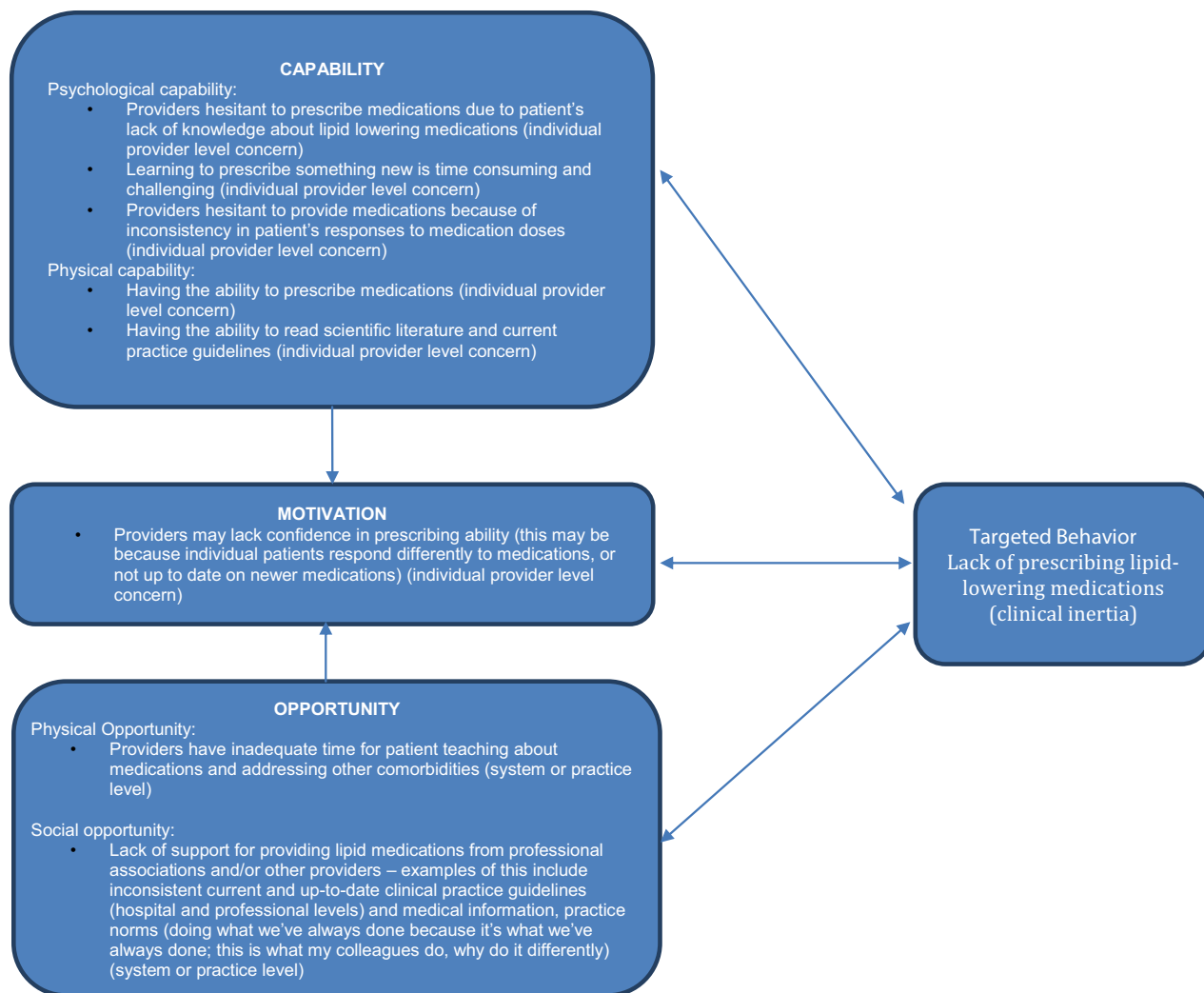
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Figure 1



COM-B framework.

inadequate time available to discuss the need for intensification with patients.¹⁴ Patients often have complex health care needs, multiple chronic conditions (eg, poorly controlled diabetes and hypertension with chronic pain and obesity), requiring management of multiple medications. As a result, there may be too many competing health priorities to address in one visit which may limit the discussion of statin dosing and adherence.¹⁵ The competing needs may be particularly difficult with limited decision support information such as delays in receiving laboratory test results, incomplete information about patients' adherence to medications, and the need to coordinate care across multiple providers.^{16,17} Overcoming these barriers may be particularly troublesome during a time-limited, traditional clinical encounter which often provides inadequate opportunity for

in-depth clinical review and discussion required to identify the optimal personalized prescribing approach. Thus, during brief clinical encounters, it may be challenging to “get the ball rolling” to overcome clinical inertia. There may also be challenges in the realm of cost, access, and requirements for prior authorization.^{18,19} These challenges may be particularly salient for some lipid-lowering therapies; there may be access restrictions and considerations related to patients' out-of-pocket costs and obtaining prior authorization.

The third component is Motivation; health care providers may not be motivated to intensify lipid-lowering medications. This lack of motivation could be in part due to negative patient perceptions about lipid-lowering medications which make it challenging to gain patients' acceptance and therefore reduce provider

motivation to prescribe.²⁰ For example, in general, many patients lack an awareness of the risk of high cholesterol as well as the benefits of cholesterol medication. In addition, among providers, there is often an underestimation of the risk/benefit and an overestimation of the rate of side effects associated with higher doses of statins for side-effects such as liver damage, risk of developing diabetes, and muscle pain.^{21,22} These misperceptions may prevail because providers lack the training and effective tools to appropriately educate patients about the potential risks and benefits of adherence to lipid-lowering medications.²⁰ Thus, it may be difficult for providers to help patients conceptualize their need for proactive, life-long medication to improve a long-term, down-stream benefit on their cardiovascular risk.²³

Provider motivation may also be hindered due to the challenges of incorporating new lipid lowering therapies into practice. For example, there are new therapies recently made available for the treatment of hyperlipidemia including PCSK9 inhibitors. PCSK9 inhibitors are monoclonal antibodies that target and inactivate a specific protein in the liver and have been found to significantly reduce LDL.²⁴⁻²⁶ However, PCSK9 are high-cost injectable medications, which add a different barrier to adherence due to refrigeration requirements. In addition, many providers report not being knowledgeable about these medications and may prefer to continue with the more traditional statin-management approach.²⁷ In general, learning to prescribe something new can be challenging and healthcare providers may not be prepared to address specific patients' concerns related to new medications.

Expert panel solutions to clinical inertia in the context of lipid management

Experts from the fields of cardiology, endocrinology, lipidology, health services and clinical research, behavioral science and pharmaceutical medical affairs gathered recently to engage in a structured process to identify solutions to address clinical inertia in chronic lipid management. These eight experts, from academia and industry, provided perspectives on drivers of clinical inertia in chronic lipid management, how to leverage behavioral science to design solutions to address health care providers' clinical inertia in chronic lipid management, and to develop recommendations on effectively implementing behavior-driven clinical inertia solutions. During the daylong in-person session, the team generated over 50 potential solutions for addressing barriers to therapy intensification in chronic lipid management. Of these potential solutions, the group engaged in a structured multi-round voting process to reach consensus and identified the most promising 18 solutions based on a Delphi process. In brief, the Delphi process is a structured approach to gather input from a panel of

experts. Experts participate in a panel, in this case solely funded by Sanofi, and provide iterative rounds of feedback. In another round of voting, these 18 solutions were further consolidated into a list of 5 action-oriented solutions that received the highest votes for their potential to significantly impact clinical inertia. These solutions were developed into descriptive prototypes and included: (1) personalized patient education and leveraging technology to enhance patient support programs; (2) prior authorization support; (3) harmonization of lipid management guidelines; (4) provider education; and (5) health care provider incentives. We describe each potential solution below.

Potential solution 1: personalized patient education and leveraging technology to enhance patient support programs

One strategy to reduce clinical inertia is to provide patients with personalized education so that they have the knowledge needed to be savvy consumers of health care and good self-managers of their health. The goal of patient education is to create informed and engaged patients who are equipped to facilitate proactive cholesterol management and treatment optimization. Ideally, patient-specific education would lead to better adherence to therapy as well as attendance at scheduled clinic visits; the latter would help enable more proactive monitoring of treatment response.

One way to provide personalized patient education is through a curated website repository with certified and up-to-date information on lipid management from evidence-based, vetted sources. Providing a respected, valid repository of information to which patients can be referred may help alleviate motivational barriers identified by providers. Personalized educational content could also be created based on specific triggers (eg, initiation the use of cholesterol medication, change in cholesterol medication, and renewal of cholesterol medication prescription). Such content could include videos, interactive games, links to peer interactions in virtual environments (eg, message boards that are moderated by clinical staff), and a guide toward preparing for discussions with clinicians. Personalized patient education could also involve patient support programs to support patients' needs by not only providing education, but also tailored support such as insurance support (eg, information about insurance benefits and copayment assistance programs), real-time medication adherence support, and adverse events management. In terms of adverse event management and personalized patient education, it may be important to address whether statin-attributed muscular side effects are a barrier to achieving long-term statin adherence and CVD reduction. A major cause of statin non-adherence are statin-attributed muscular symptoms (SAMS), which range

from rhabdomyolysis to the more common conditions of myalgia, weakness, and fatigue that may or may not be associated with laboratory abnormalities.²⁸

The COM-B system framework can be used to help address potential patient- and provider-level barriers and facilitators associated with a patient support program: capability (eg, having adequate knowledge regarding cholesterol treatment), opportunity (eg, adhering to guidelines because of quality measures requirements or peer monitoring/feedback), and motivation (eg, understanding the benefit of taking a cholesterol reducing medication outweighs the potential risk) help identify.

Support program delivery could be tailored based on a patient's preferred method of communication (eg, email, text messaging, or telephone). Patient support programs could begin automatically when a patient initiates a statin medication. At the patient's first visit, a healthcare provider could populate an order set, which includes follow-up lipid panel, topics of patient education, patient communication preferences, and further provider support needs. Approximately 1 week later the support program could trigger an outreach "appointment" using the patient's preferred contact approach (eg, text message) with emphasis on confirming that the patient initiated treatment and inquiring about any side effects or adherence challenges. These messages could be asynchronous messaging or a live person depending on the barriers/challenges an individual may be addressing. At 6 weeks, patients could be sent an automated reminder to have labs obtained. Once lab results are available, the support program could send a personalized triage with follow-up based on an individual's results. The goals would be to deliver sustained, positive reinforcement of medication adherence and facilitate focused and efficient patient/provider interactions.

Potential solution 2: prior authorization support

Prior authorization is when a health care provider must appeal to an insurance company for approval before a patient can get a specific prescription filled and may be necessary for some cholesterol-lowering medications. The prior authorization process can be time consuming and confusing thereby reducing provider willingness to prescribe medications and reduce patients' adherence to therapy. The panel recommended simplification of prior authorization rules where possible and well as changes to the process of submitting prior authorization materials. An authorization form could be developed based on the National Lipid Association's universal form.^{29,30} This form addresses different criteria required across various insurance plans and could be automated through the electronic health record. Using the electronic health record as a platform would create efficiencies in the system because some content could be auto-populated

and the form could be submitted electronically. This would also enable providers to use the form at the point of care when initiating therapy. To further ease the prior authorization process, reimbursement for health care providers' time associated with preparing and submitting a prior authorization form could be considered.

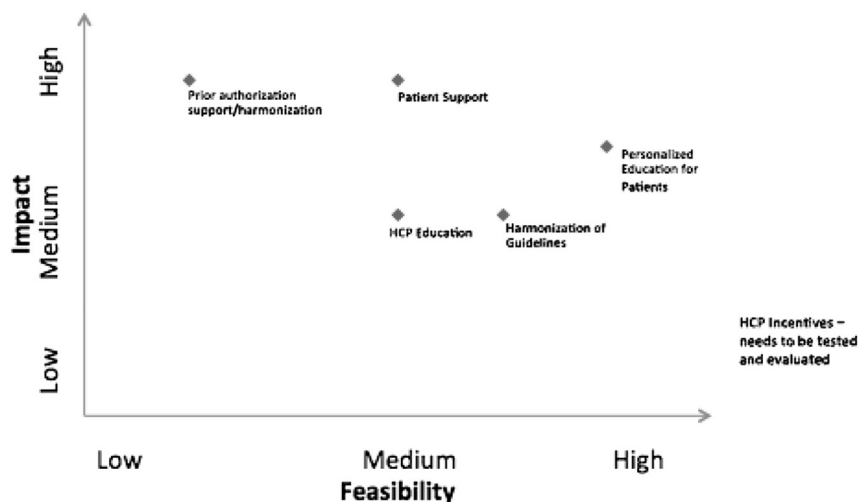
Potential solution 3: harmonization of lipid management guidelines

Currently, there are multiple guidelines for lipid management by countries and organizations. There is an ongoing effort to harmonize these guidelines being driven by expert scientific societies in cardiology, endocrinology, lipidology in the United States and internationally. Once harmonized management guidelines are published, the panel identified the need for an implementation plan. The proposed plan would feature communication and dissemination via multiple channels (eg, professional organizations' email listserv, academic publications, tip sheets). Developing clear, proactive messaging and identifying well-respected spokespersons would also be critical. The panel recommended embedding the new guidelines into electronic health record systems to automate ordering and provide easy references as well as to inform evaluation plans. While expert societies are driving the process of guideline harmonization, the communication and adoption of updated guidelines could be supported by health systems and pharmaceutical companies. These measures could address many of the barriers of provider capability including reducing barriers to knowledge of guidelines.

Potential solution 4: provider education

Provider education is an important element underlying several of the proposed potential solutions and a way of enhancing provider capability. Education could be made available in a brief, tailored, case-based and interactive format at the point of care or in the form of monthly feedback. A reminder could be generated for potential patients providing education on overall clinical practice guidelines and these guidelines could be more effectively integrated into the electronic health record. Monthly feedback could provide information about how well providers' actions align with current guidelines and could provide personalized case studies as well to make the training more accessible. Allowing continuing medical education credit for completing such training could incentivize participation. The goal would be to link education to issues that are most relevant for a specific health care provider, given his or her patient population, and to promote understanding and uptake of clinical practice guidelines to facilitate improved adherence to the guidelines.

Figure 2



Demonstration of clinical inertia reduction recommendations by impact and feasibility.

The panel reported that to maximize uptake, providers would need salary support or protected time tying educational attainment to professional advancement.

Potential Solution 5: Health Care Financial Models

Traditional health care provider incentives, such as pay-for-performance payments, are not timely and do not account for individual patient characteristics.^{24,31} To modernize health care provider incentives, the expert panel recommended a shift in this approach. Specifically, they recommended a variation of pay for performance that would involve potential payment penalties for inconsistent application of CMS statin performance measures. The panel recommended sampling a portion (5–10%) of patients from a health care provider and conducting an independent audit of a provider's performance based on a detailed case review. This audit could then generate an overall lipid management score would be used to determine performance status (high, medium, low) and a general plan of action would be created based on the performance level. For low performers, a remediation plan consisting of education and decision making tool kits could be made available. This proposed approach may have appeal over existing incentive programs because it addresses provider capability and motivation and applies principles of behavioral economics – both a lottery and loss aversion behavior science techniques to drive behavior change.³² Health care providers would be motivated to achieve a passing score, which could in turn be associated with clinical practice guidelines and appropriate statin intensification.

Conclusions

Non-communicable diseases, including hyperlipidemia, are on the rise. Clinical inertia is an important barrier limiting ideal lipid control. Sustainable solutions that take a multi-level approach (eg, patients, providers, health systems, policy) to address clinical inertia and ultimately improve lipid levels are needed. Because elevated lipids and clinical inertia are global challenges, it is important to develop tools that can be disseminated broadly and impact change at a population health level (see Figure 2). Feasible solutions with the potential for high impact on reducing clinical inertia should be prioritized.

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