

Evaluation of a Multidisciplinary Lipid Clinic to Improve the Care of Individuals With Severe Lipid Conditions: a RE-AIM Framework Analysis

Laney K Jones (✉ ljones14@geisinger.edu)

Geisinger <https://orcid.org/0000-0002-6182-5634>

Megan McMinn

Geisinger Health

David Kann

Geisinger Health

Michael Lesko

Geisinger Health

Amy C. Sturm

Geisinger Health

Nicole Walters

Geisinger Health

Nan Chen

Geisinger Health

Kerrienne Fry

Geisinger Health

Ross C. Brownson

Washington University in Saint Louis

Samuel S. Gidding

Geisinger Health

Marc S. Williams

Geisinger Health

Alanna Kulchak Rahm

Geisinger Health

Research

Keywords: RE-AIM, hyperlipidemia, cardiology, implementation science

Posted Date: August 2nd, 2020

DOI: <https://doi.org/10.21203/rs.3.rs-51142/v1>

License:  This work is licensed under a Creative Commons Attribution 4.0 International License.

[Read Full License](#)

Version of Record: A version of this preprint was published on March 19th, 2021. See the published version at <https://doi.org/10.1186/s43058-021-00135-8>.

Abstract

Background. Individuals with complex dyslipidemia, or those with medication intolerance, are often difficult to manage in primary care. They require the additional attention, expertise, and compliance counseling that occurs in multidisciplinary lipid clinics (MDLCs). We conducted a program evaluation of the first year of a newly implemented MDLC utilizing the RE-AIM (reach, effectiveness, adoption, implementation, and maintenance) framework to provide empirical data not only on program effectiveness, but also on components important to local sustainability and future generalizability.

Methods. The purpose of the MDLC is to increase uptake of guideline-based care for lipid conditions. Established in 2019, the MDLC provides care via a centralized clinic location within the healthcare system. Primary care providers and cardiologists were invited to refer individuals with lipid conditions. Using a pre/post study design, we evaluated implementation outcomes from the MDLC using the RE-AIM framework.

Results. In 2019, 420 referrals were received, and 83 patients were seen in the MDLC (reach). In the lipid subgroups, we found improved diagnosis of condition, increase in prescribing of more aggressive lipid-lowering therapies, high rates of medication prior authorization approvals, and significant reductions in lipid levels (effectiveness). Of the 796 active primary care and cardiology providers in 2019, only 18% (146/796) referred patients to the MDLC (adoption). At the patient-level, 50% (41/82) of patients had at least one follow-up visit with the MDLC, with 12% (10/82) having two or more follow-up visits in 2019 (implementation). At the provider-level, an average of 35 patient referrals per month were made from primary care providers or cardiologists (SD 12) (implementation). During monthly meetings of the operational team, the decision to transition from in-person follow-up to telehealth appointments was implemented to increase capacity and sustain the clinic (maintenance).

Conclusions. We found improved diagnosis and risk stratification, increase in guideline-recommended treatments prescribed and clinically significant lowering of lipid levels. Attention to factors including multiple points of contact, duration of visits, extraneous comorbidities and social support could aid in better understanding the success of patient outcomes.

Contribution To The Literature

(3-5 bullet points of no more than 100 words)

- Research has shown that use of implementation science for program evaluation can lead to more sustainable programs, but multidisciplinary lipid clinics (MDLCs) have not been evaluated using such frameworks.
- This paper applies the RE-AIM framework to evaluate MDLC implementation and demonstrates how such clinics close an important gap in care management for individuals with lipid conditions.
- The RE-AIM framework is widely used for program evaluation; this paper applies it to the evaluation of a

new MDLC initiated within a healthcare system to improve management and treatment uptake in individuals with lipid conditions.

Background

The reduction of lipid levels has been shown to prevent cardiovascular disease (CVD) at individual and population levels (1). Cholesterol levels are typically managed in primary care settings. While this works for most people, some individuals have medication side effects or underlying severe lipid conditions that make management difficult. These individuals require specialized care in order to achieve lower cholesterol and triglyceride levels and the corresponding CVD risk reduction benefit. Primary care providers (PCPs) often refer these individuals to lipid specialists who have the expertise to more effectively manage medication options and diagnose underlying causes of dyslipidemia. The providers of the multidisciplinary lipid clinic (MDLC) focus their effort on reducing CVD risk for individuals with hyperlipidemia conditions that are not well controlled. While MDLCs may vary in staffing, typical clinical staff includes physicians, advanced practitioners, pharmacists, dietitians, and genetic counselors working in concert (2-8). Such MDLCs have been shown to increase the number of individuals achieving target low-density lipoprotein cholesterol (LDL-C) goals and improve lipid-lowering medication adherence, effectively lowering CVD risk of patients seen by the MDLC (2, 6).

Despite their demonstrated effectiveness, MDLCs have not been widely implemented outside of academic medical centers (9). Applying an implementation science framework can help understand the role of contextual barriers and facilitators necessary for MDLC program implementation; thus, improving sustainability within healthcare settings and generalizability to new settings. Additionally, when there is an implementation gap, implementation science can help to understand the causes of the gap. Reach, Effectiveness, Adoption, Implementation and Maintenance (RE-AIM) is one framework that has been used for over 20 years in the planning and evaluation of interventions (10, 11). MDLCs have not previously been evaluated using an implementation science framework and this represents a novel contribution to the field.

For this study, we conducted a program evaluation of the first year of a newly implemented MDLC utilizing the RE-AIM framework to provide empirical data not only on program effectiveness, but also on components important to local sustainability and future generalizability and replication.

Methods

Setting

Geisinger is an integrated healthcare system consisting of multiple hospitals, outpatient facilities, and a health plan located in 45 counties in central and northeast Pennsylvania. The system provides care for approximately 1.5 million patients annually. Clinical decisions and guidance for procedures and treatments are made by designated clinical teams and are implemented by every healthcare provider in

the system. This method not only ensures consistency and high-quality care, but also promotes evidence-based care by reducing unexplained clinical variation. Additionally, coverage by the health plan is synchronized with clinical decisions made within the healthcare system to ensure high-quality care is affordable and accessible to all health plan members (about a third of Geisinger patients). Geisinger serves a rural, medically underserved, and low-income population. In Geisinger's coverage area 32 of the 45 counties are designated as rural and the average household income is 15.3% lower than the US average. Geisinger's mission and vision is to be a model for other developing healthcare systems through continued learning via clinical research (12).

In January 2019, Geisinger implemented an MDLC to facilitate the translation of evidence-based guidelines(13) to the management of high-risk lipid conditions. Patients referred are currently unable to meet cholesterol and triglyceride treatment goals in primary care or cardiology clinics. The Geisinger MDLC is staffed with a cardiologist boarded in lipidology, genetic counselor, and a pharmacist all with specialized training in lipid conditions. This clinic meets bi-monthly at one clinic location within the healthcare system.

Population

Any individual within the Geisinger system diagnosed with or suspected to have a lipid condition can be referred to and seen by the MDLC. A variety of lipid conditions are evaluated and treated in this clinic, including, but not limited to, familial hypercholesterolemia (FH), hypertriglyceridemia, various rare familial dyslipidemias, and other unnamed or undiagnosed dyslipidemias (Table 1) (13).

Clinical Implementation

The purpose of the Geisinger MDLC is to increase uptake of guideline-recommended treatment for all lipid conditions (13). Prior to implementation of this clinic, individuals with these conditions had to receive specialty multidisciplinary lipid care outside the Geisinger system at locations that required significant travel to urban sites in Pennsylvania for specialized management. Preventive cardiology leadership within the Heart Institute initiated the MDLC and sent out an email to the entire Heart Institute, and Community and Family Medicine providers inviting them to refer patients. The invitation introduced the MDLC, purpose, details on which providers were part of this clinic and how to refer. Table 2 details the MDLC implementation strategy using Proctor's guidelines for defining and specifying implementation strategies (14) and the template for intervention description and republication checklist.

Data Collection and Outcomes Measured

This study evaluates the MDLC using the RE-AIM framework. Using a pre/post study design, clinical outcomes were assessed for all patients one year after implementation of the MDLC.

Reach is measured at the individual-level and defined in three ways: 1) the number of patients in the healthcare system, 2) the number of patients who were referred to the MDLC, and 3) the number of patients seen by the MDLC who had a documented lipid condition on their problem list and had been

active patients within the healthcare system (i.e., had a primary care or cardiology visit in 2019) (15). Patients could be referred to the MDLC by any provider using a general cardiology outpatient referral and note the MDLC in a comment section. A specific outpatient referral for the MDLC was not created within our system, though dependent upon the success and volume of this clinic, one can be created in the future.

Effectiveness is the measure of the implementation strategy's impact on patient outcomes (15). Because treatment approaches differ by condition, the patient population was stratified by diagnosis to create three clinical patient subgroups: FH, hypertriglyceridemia, and dyslipidemia. Effectiveness measures chosen for this study were change in lipid levels, medication use, and genetic testing. Change in lipid levels were assessed using a baseline lipid value either from the initial MDLC visit, or the most recent visit prior to the initial MDLC visit compared with the value from the most recent MDLC visit. Lipid-lowering medications and outcomes were reported for each condition based on guideline recommendations (13). The number of genetic tests ordered and completed results were reported.

Adoption, when measured at the provider level, is defined as the number and percent of providers that participate in the implementation strategy;(15) that is, the number of patients who had a diagnosis of a lipid condition versus how many were actually referred by a PCP or cardiologist. Any PCP or cardiologist who saw a patient with a lipid condition documented on their problem list diagnoses in 2019 was included in the analyses.

Implementation can be measured at the patient-, provider- and system-level and describes the extent to which the elements of the program are implemented (15). Patient-level implementation is a measure of how many referred patients had follow-up visits to the MDLC versus only the initial visit. At the provider-level, this is the percentage of eligible patients referred per eligible provider.

Maintenance is the measure of sustainability of the program over time (16). For this study, qualitative evidence indicating strategies to improve the sustainability are presented that were discussed in monthly lipid clinic meetings between MDLC providers and Heart Institute leadership.

Statistical Analysis

Descriptive statistics were used for the demographics of both the study cohort and three subgroups. Continuous variables were analyzed using the Kruskal-Wallis test, and categorical variables were analyzed using a Fisher exact test. We reported Mean \pm SD and Median (range) of lipid levels for all subgroups and used the Wilcoxon signed rank test to detect any differences in lipid levels before and after for each subgroup.

Results

Reach. Of the 452,748 unique patients who had a visit at the healthcare system in 2019, 32% (143,154/452,748) had a diagnosis of a lipid condition on their problem list. There were 420 referrals

received for the MDLC in 2019. Of those 420 referrals, 3 referenced the 'MDLC' specifically and 92 referenced the 'lipid clinic.' There were 83 patients scheduled and seen by the MDLC in 2019. Of those 83 patients, 1 patient was self-referred, and 4 patients did not have a primary care or cardiology visit in 2019 or lipid condition diagnosis code.

Effectiveness. Of the 83 patients seen in the MDLC in 2019, 82 were alive at the time of analysis and are presented in the results. Of those 82 patients, 29% (24/82) had a clinical or genetic diagnosis of (FH), 20% (16/82) had hypertriglyceridemia, and 51% (42/82) had uncharacterized dyslipidemia. Demographics of these populations are described in Table 3.

Familial hypercholesterolemia. Six of the 24 individuals with FH had prior positive genetic testing for the condition. Those who did not have a prior genetic testing result had testing ordered at the clinic. Genetic testing ordered through the MDLC (n=18) yielded: 5 positive results, 2 variants of unknown significance, and 5 negative results. Six genetic tests are still pending (e.g., order not signed, order expired, active order but sample has not yet been drawn). Of the 24 patients in the FH subgroup, 23 (96%) had intensification of their medication regimens including starting a medication or addition of a new medication. The one untreated patient was pregnant which impacts use of lipid-lowering therapy. At the initial MDLC visit, 17 (71%) patients were prescribed at least one medication. After a visit at the MDLC, 16 patients had medications added to their regimen (11 added ezetimibe, 7 added a statin, and 12 added a PCSK9 inhibitor) and the six (86%) of the 7 patients who were not taking any lipid-lowering medication at the time of their initial MDLC visit were prescribed medication by the MDLC. Fourteen of the 24 individuals with FH were prescribed medications for which their insurance required a prior authorization. A total of 16 prior authorizations were submitted (3 individuals had prior authorizations submitted for both PCSK9 inhibitors and icosapent ethyl, or for two PCSK9 inhibitors). Of the 16 medication prior authorizations, 88% (14/16) were approved (12 were for PCSK9 inhibitors and 2 for icosapent ethyl) and 13% (2/16) were denied for PCSK9 inhibitors. Lipid levels were available for comparison before and after MDLC visits in a subset of patients (n=12) showed a 79 mg/dL reduction in average LDL-C ($p<0.001$) and reduction in other lipid values (Table 4). Of the 12 patients with pre and post values, only 17% (2/12) had an LDL-C less than 100 mg/dL prior to a visit with the MDLC, however, 75% (9/12) met this goal after seeing the MDLC.

Hypertriglyceridemia. None of the 16 individuals attending MDLC diagnosed with hypertriglyceridemia had prior genetic testing. Genetic testing was ordered on 14 of the 16 individuals (81%) and identified 1 positive result for a variant associated with familial lipoprotein lipase deficiency, 2 variants of unknown significance, and 6 negative results; 3 tests are pending and 2 were not completed. Of the 16 patients in the hypertriglyceridemia subgroup, 13 (81%) patients' medication regimens were intensified. At the initial MDLC visit, 14 (88%) patients were prescribed at least one of medication to treat their hypertriglyceridemia. While being seen at the MDLC, 13 patients had medication changes (2 dose changes, 1 switched medications within the same medication class, 8 added medications (6 patients started icosapent ethyl, 2 started atorvastatin, and 1 started a fibrate)), and 1 patient who was not taking any triglyceride-lowering medications was prescribed a medication. One drug-drug interaction was

reconciled by the clinic to prevent harm to the patient. At the time of analysis, 16 (100%) of the 16 patients in the hypertriglyceridemia subgroup after being seen by the MDLC were prescribed a medication for the treatment of hypertriglyceridemia. Three of the 15 individuals with hypertriglyceridemia were prescribed medications for which their insurance required a prior authorization, resulting in a total of 3 prior authorizations submitted. All were approved (2 were for PCSK9 inhibitors and 1 for icosapent ethyl). Lipid levels were available for comparison before and after MDLC visits for all but one patient (n=4) and showed a 467 mg/dL reduction in average triglycerides (Table 4). Of the 4 patients with pre and post values, only a quarter (1/4) had a triglyceride level less than 150 mg/dL prior to a visit with the MDLC, however, 75% (3/4) met this goal after seeing the MDLC.

Uncharacterized dyslipidemia. None of the 42 individuals with dyslipidemia had prior genetic testing for the condition. Genetic testing found no positive result, 24 negative results, 6 tests are pending and 1 was cancelled by patient due to cost. Genetic testing was not performed for 11 individuals (genetic testing on 33/42; 71%). At the initial MDLC visit, 32 (76%) patients were prescribed at least one medication to treat their dyslipidemia. Of the 42 patients in the dyslipidemia subgroup, 35 (83%) had intensifications to their medication regimens. While being seen at the MDLC, 25 patients added a medication to their current regimen (5 ezetimibe, 6 statin, 17 PCSK9 inhibitor, 2 niacin, 7 icosapent ethyl, and 1 omega-3) and 5 of the 10 patients who were not taking any medication for their dyslipidemia was prescribed a medication by the MDLC. At the time of analysis, 36 (86%) of the 42 patients in the dyslipidemia subgroup were prescribed a medication to treat their dyslipidemia. Eighteen of the 42 individuals with dyslipidemia were prescribed medications for which their insurance required prior authorization. A total of 18 prior authorizations were submitted. Of the 18 medication prior authorizations, 16 were approved (16 were for PCSK9 inhibitors), 1 was denied for icosapent ethyl, and 1 had an unknown status for a PCSK9 inhibitor. Lipid levels were available for comparison before and after MDLC visits in a subset of patients (n=21) showed a 48 mg/dL reduction in average LDL-C (<0.001) and reduction in other lipid values (Table 4). Of the 21 patients, 38% (8/21) had an LDL-C less than 100 mg/dL prior to a visit with the MDLC, however, 71% (15/21) met this goal after seeing the MDLC.

Adoption. Of the 796 active PCP or cardiologists in 2019, only 19% (148/796) referred patients to the MDLC. The average percent of eligible patient referrals from eligible providers was 0.25% (SD 3.75%). Referrals to MDLC were also received from another 48 providers outside of the targeted cardiologists and PCPs (genetic counselors, pharmacists, critical care providers) or from providers whose patient did not have a diagnosed lipid condition on their problem list.

Implementation. At the patient-level, 50% (41/82) of patients who attended the MDLC had at least one follow-up visit with the MDLC, with 12% (10/82) having two or more follow-up visits in 2019. The 50% (41/82) of patients who only had one visit were more likely to have been seen later in 2019 (October through December). At the provider-level, there was an average of 35 patient referrals per month (SD 12) to the MDLC.

Maintenance. In monthly meetings with the MDLC clinic providers and Heart Institute leadership and administration, we discussed the transition from traditional in-person follow-up visits to telehealth appointments. The rationale for this transition was to improve capacity due to limited number of available appointments per clinic day and would increase access as individuals would have the opportunity to be seen virtually, either at home or a clinic site near their home. Additionally, we discussed the platform needed for telehealth visits, training of schedulers to know where and when to book these appointments, where and how the MDLC providers would join the telehealth visit and obtain access for all providers and discuss methods for documenting on these types of visits. Additionally, a recent pandemic, COVID-19, necessitated the use of telemedicine throughout Geisinger, but this merely accelerated the transition that was already planned for the MDLC.

Discussion

It is widely accepted in implementation science that simply rolling out a new professional guideline or making a new model of care available is insufficient to lead to practice change that will impact patient or population health outcomes (17). Often, sufficient details are lacking to replicate the implementation strategies utilized for the evidence-based intervention or new care model (14). Therefore, evaluation of multi-level outcomes related to process and context as well as patient outcomes is necessary when implementing interventions in the real-world (15).

In our evaluation of the first year after implementing a new care model, we found there are many individuals within our system with lipid conditions, but only a small number have been referred to the MDLC (0.25%); indicating substantial additional implementation strategies may be needed to improve reach of the MDLC. At present, in the total population of patients with lipid disorders we do not know how many would be eligible for referral based on medication intolerance or failure to achieve lipid treatment goal. Only by evaluating this can the true care gap be evaluated and used to develop strategies to expand referrals.

The MDLC itself was effective in improving guideline-recommended care for the individuals in our one-year post-implementation evaluation who were referred and seen by the MDLC. We found their improved prognosis based on risk stratification, increase in guideline-recommended treatments prescribed and clinically significant lowering of targeted lipid levels to improve the prevention of future CVD events. By identifying genetic risk of individuals with FH and other familial dyslipidemias, clinicians are able to understand CV risk and more aggressively treat this condition. The team-based approach had high rates of approval for prior authorizations submitted which allowed for more expensive treatment to be used by patients meeting appropriate criteria for use. A reduction of 40 mg/dL of LDL-C for individuals with cholesterol conditions is thought to reduce CV events by 20% which is clinically significant and is an accepted intermediate outcome per guidelines (18). In patients with FH seen through the MDLC, the mean reduction in LDL-C was 79 mg/dL which is predicted to reduce CV events by 40%. In addition, the number of patients achieving a target of LDL-C below 100 mg/dl increased from 15% to 69%, a more than 4-fold increase.

We were able to reach additional clinicians, other than those originally targeted by early communications about the MDLC. Based on the referral volume after one year of MDLC implementation with referrals from only PCPs and cardiologists, we have shown: 1) a need for the MDLC in the Geisinger system, 2) a significant clinical impact on those patients managed by the MDLC, 3) an enormous care gap with only 0.25% of eligible patients being seen through MDLC reducing the impact of CV event prevention, and 4) barriers and facilitators important to MDLC sustainability and future impact. A systematic approach to implementation and continual evaluation of implementation process outcomes and contextual factors is important to implementing these types of programs within healthcare systems. To that end, team members and administrative staff have discussed initiating telehealth appointments as a potential solution to these logistical issues. By utilizing telehealth, patients would be able to join at their home or drive to a local clinic to connect with the providers at the MDLC. This model could also be generalized to other healthcare systems with similar logistical concerns. The COVID-19 pandemic resulted in a system-wide move to telemedicine visits, eliminating many barriers that might have otherwise delayed implementation.

Other MDLCs have found similar clinical effectiveness outcomes to our clinic (6, 7, 19). For MDLCs to improve the health of the targeted population, they must first reach the intended individuals. While the existence of an MDLC is helpful, it is not sufficient to ensure utilization of its services. Most of these MDLCs have been implemented within academic medical centers (9) with fewer in healthcare systems, mostly in Veteran's Affairs (7, 20) or community medical centers (21). However, it is unclear from these studies the potential impact MDLCs have had on reach within their patient catchment areas due to lack of description or analysis on the process for referrals and number of patients with lipid conditions in these systems. To improve generalizability to other healthcare systems it is important to understand contextual factors associated with implementation of a MDLC.

Implementation science frameworks have rarely been applied in the field of lipidology or FH (22). However, their use and benefit have been demonstrated in the implementation of other chronic disease programs such as diabetes control (23). Using frameworks such as RE-AIM will help lipidologists, and others implementing MDLCs, understand the full impact of their programs and where the barriers and facilitators to access or care exist (24, 25). In addition, studies like ours will improve the generalizability of these programs to other sites.

This study has a few limitations. The number of patients seen by the MDLC was limited by clinical location and capacity (one location in the region and twice per month periodicity). However, the Geisinger catchment area spans 45 of Pennsylvania's 67 counties making it over a two-hour drive for some individuals to reach the current MDLC location. Some individuals seen in the MDLC require multiple visits for complex diagnoses or medication changes, thus limiting availability of appointment slots for new patients. In our analyses, we used a follow up period defined by time since the clinic was implemented; therefore, patients seen earlier after implementation had longer follow up intervals than those seen later in the year. Additional analyses conducted farther out from MDLC implementation are needed with larger samples of individuals with a standard follow-up period (e.g. 1-year post visit). Finally, by limiting to the

1-year period after implementation, some individuals with pending genetic test results in the dyslipidemia category may move into a different category once test results are received.

Conclusion

Severe lipid conditions require dedicated care for identification, early intervention and management, and individuals treated within the Geisinger MDLC show improved clinical outcomes one year after MDLC implementation. However, more attention is needed regarding contextual factors, increased referrals, multiple points of contact, duration of visits, extraneous comorbidities and social support, that determine these successful outcomes to improve reach, adoption, sustainability and replication of these clinics within other healthcare settings.

List Of Abbreviations

CVD cardiovascular disease

FH familial hypercholesterolemia

LDL-C low-density lipoprotein cholesterol

MDLC multidisciplinary lipid clinic

PCP primary care provider

RE-AIM reach, effectiveness, adoption, implementation and maintenance

Declarations

Ethics approval and consent to participate. This study was approved by the Geisinger's Institutional Review Board.

Consent for publication. Not applicable

Availability of data and materials. All data generated or analyzed during this study are included in this published article.

Competing interests. The authors declare that they have no competing interests.

Funding. Research reported in this publication was supported by the National Heart, Lung, and Blood Institute of the National Institutes of Health under Award Number K12HL137942.

Authors' contributions. LKJ conceptualized and designed the study, acquired, analyzed, and interpreted the data, and drafted the initial and revised to final manuscript. MM helped to design the study, acquire, analyze and interpreted the data, and added substantial revisions to the manuscript. DK helped to design

the study, interpret the data, and added substantial revisions to the manuscript. ML helped to interpret the data and added substantial revisions to the manuscript. ACS helped to design the study, interpret data and added substantial revisions to the manuscript. NW acquired and analyzed the data, helped to draft the initial manuscript, and revised it. NC acquired, analyzed, and interpreted the data and added substantial contributions to the final manuscript. SSG designed the study, interpreted the data, and added substantial revisions to the manuscript. MSW conceptualized and designed the study and added substantial revisions to the manuscript. AKR conceptualized and designed the study, acquired, analyzed, and interpreted the data, and drafted the initial and revised to final manuscript.

Acknowledgements. Not applicable.

References

1. Silverman MG, Ference BA, Im K, Wiviott SD, Giugliano RP, Grundy SM, et al. Association Between Lowering LDL-C and Cardiovascular Risk Reduction Among Different Therapeutic Interventions: A Systematic Review and Meta-analysis. *Jama*. 2016;316(12):1289-97.
2. Bogden PE, Koontz LM, Williamson P, Abbott RD. The physician and pharmacist team: An effective approach to cholesterol reduction. *J Gen Intern Med*. 1997;12(3):158-64.
3. Kellick KA, Burns K, McAndrew E, Haberl E, Hook N, Ellis A. Outcome monitoring of fluvastatin in a department of veterans affairs lipid clinic. *The American journal of cardiology*. 1995;76(1-2):62A-4A.
4. Konzem SL, Gray DR, Kashyap ML. Effect of pharmaceutical care on optimum colestipol treatment in elderly hypercholesterolemic veterans. *Pharmacotherapy*. 1997;17(3):576-83.
5. O'Donnell DC, Chen NT, Piziak VK. Goal attainment and maintenance of serum cholesterol level in a pharmacist-coordinated lipid clinic. *Am J Health Syst Pharm*. 2001;58(4):325-30.
6. Birtcher KK, Greisinger AJ, Brehm BJ, Wehmanen OA, Furman LM, Salinas CC, et al. A secondary prevention lipid clinic reaches low-density lipoprotein cholesterol goals more often than usual cardiology care with coronary heart disease. *J Clin Lipidol*. 2010;4(1):46-52.
7. Shaffer J, Wexler LF. Reducing Low-Density Lipoprotein Cholesterol Levels in an Ambulatory Care System: Results of a Multidisciplinary Collaborative Practice Lipid Clinic Compared With Traditional Physician-Based Care. *Arch Intern Med*. 1995;155(21):2330-5.
8. Mazzolini TA, Irons BK, Schell EC, Seifert CF. Lipid levels and use of lipid-lowering drugs for patients in pharmacist-managed lipid clinics versus usual care in 2 VA Medical Centers. *J Manag Care Pharm*. 2005;11(9):763-71.
9. Liebeskind A, Warden BA, Sikand G, Duell PB, Guyton JR. JCL Roundtable: Lipid clinic operations. *J Clin Lipidol*. 2019;13(4):511-21.
10. Glasgow RE, Harden SM, Gaglio B, Rabin B, Smith ML, Porter GC, et al. RE-AIM Planning and Evaluation Framework: Adapting to New Science and Practice With a 20-Year Review. *Frontiers in Public Health*. 2019;7(64).

11. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *Am J Public Health*. 1999;89.
12. Psek W, Davis FD, Gerrity G, Stametz R, Bailey-Davis L, Henninger D, et al. Leadership Perspectives on Operationalizing the Learning Health Care System in an Integrated Delivery System. *eGEMs*. 2016;4(3):1233.
13. Grundy SM, Stone NJ, Bailey AL, Beam C, Birtcher KK, Blumenthal RS, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *J Am Coll Cardiol*. 2019;139(25):e1082-e143.
14. Proctor EK, Powell BJ, McMillen JC. Implementation strategies: recommendations for specifying and reporting. *Implement Sci*. 2013;8:139.
15. Glasgow RE, Harden SM, Gaglio B, Rabin B, Smith ML, Porter GC. RE-AIM Planning and evaluation framework: adapting to new science and practice with a 20-year review. *Front Public Health*. 2019;7.
16. King DK, Glasgow RE, Leeman-Castillo B. Reaiming RE-AIM: using the model to plan, implement, and evaluate the effects of environmental change approaches to enhancing population health. *American journal of public health*. 2010;100(11):2076-84.
17. Lobb R, Colditz GA. Implementation science and its application to population health. *Annual review of public health*. 2013;34:235-51.
18. Baigent C, Blackwell L, Emberson J, Holland LE, Reith C, Bhalra N, et al. Efficacy and safety of more intensive lowering of LDL cholesterol: a meta-analysis of data from 170,000 participants in 26 randomised trials. *Lancet*. 2010;376(9753):1670-81.
19. Harris DE, Record NB, Gipson GW, Pearson TA. Lipid lowering in a multidisciplinary clinic compared with primary physician management. *American Journal of Cardiology*. 1998;81(7):929-33.
20. Harris DE, Record NB, Gipson GW, Pearson TA. Lipid lowering in a multidisciplinary clinic compared with primary physician management. *The American Journal of Cardiology*. 1998;81(7):929-33.
21. Birtcher KK, Bowden C, Ballantyne CM, Huyen M. Strategies for implementing lipid-lowering therapy: Pharmacy-based approach. *American Journal of Cardiology*. 2000;85(3 SUPPL. 1):30-5.
22. Glasgow RE, Chambers D. Developing robust, sustainable, implementation systems using rigorous, rapid and relevant science. *Clin Transl Sci*. 2012;5(1):48-55.
23. Nhim K, Gruss SM, Porterfield DS, Jacobs S, Elkins W, Luman ET, et al. Using a RE-AIM framework to identify promising practices in National Diabetes Prevention Program implementation. *Implement Sci*. 2019;14(1):81.
24. Tabak RG, Khoong EC, Chambers DA, Brownson RC. Bridging research and practice: models for dissemination and implementation research. *Am J Prev Med*. 2012;43(3):337-50.
25. Nilsen P. Making sense of implementation theories, models and frameworks. *Implement Sci*. 2015;10:53.

Tables

Table 1. Description of lipid conditions and treatment goals

Condition	Description	Treatment Goal
Familial hypercholesterolemia (FH)	<ul style="list-style-type: none"> · Inherited lipid condition · Lifelong elevations in LDL cholesterol levels lead to premature ASCVD · Important to test family members 	Reduction in LDL-C level
Hypertriglyceridemia	<ul style="list-style-type: none"> · Elevated levels of triglycerides · Cholesterol levels can be normal · At risk for or have had episodes of pancreatitis · Associated with Type II diabetes mellitus · May encompass inherited hypertriglyceridemia 	Reduction in triglycerides
Dyslipidemia	<ul style="list-style-type: none"> · Elevated levels of triglycerides and/or cholesterol · Dyslipidemias that are not FH or hypertriglyceridemia 	According to current guidelines, reduction in the lipid that is elevated (cholesterol, triglycerides)(13)

Table 2. Description based on Proctor's guidelines for specifying implementation strategies: components of the multidisciplinary lipid clinic

Domain	Description
Actor(s)	<p><i>Cardiologist</i></p> <p><i>Pharmacist</i></p> <p><i>Genetic Counselor</i></p>
Action(s)	<p><i>Cardiologist</i> – Evaluates the patient’s symptoms, lifestyle, medications, and past lab results during an initial in-person visit; recommends a treatment plan; orders subsequent testing; requests follow-up visits as needed</p> <p><i>Pharmacist</i> – Evaluates the patient’s current medications; offers input/suggests changes to medications; performs medication reconciliation; Completes medication counseling and education; ensures prior authorizations are submitted.</p> <p><i>Genetic Counselor</i> – Evaluates the patient’s past medical and family histories; assesses the patient’s risk; provides pre-test genetic counseling; provides genetic testing result disclosure and post-test genetic counseling; discusses cascade testing of at-risk relatives.</p>
Target(s) of the action	<p><i>All</i> – Patients with a high-risk lipid condition and knowledge of guideline-recommended treatment for lipid conditions</p> <p><i>Cardiologist</i> – diagnosis of lipid conditions, monitors clinical symptoms</p> <p><i>Pharmacist</i> – optimizes treatment and follow-up on prior authorizations</p> <p><i>Genetic Counselor</i> – Knowledge of familial cardiovascular conditions, improvement of identification methods for concerning past medical/family history, and reassurance to the patient that the testing results will benefit the patient no matter if the result is positive or negative.</p>
Temporality	<p>Patients should be referred as soon as the provider identifies a patient with a high-risk lipid condition who would benefit from evaluation at the clinic. The initial visit to the clinic should take place as soon as scheduling allows after the patient has been referred. Subsequent visits should be scheduled on an as needed basis.</p>
Dose	<p><i>Cardiologist</i> – Once at an hour-long initial visit. Subsequent visits at 6-8 weeks post-initial visit and further if needed. The cardiologist will be available to the patient via phone or through patient portal.</p> <p><i>Pharmacist</i> – Once at an hour-long initial visit. The pharmacist will be available to the patient via phone or patient portal.</p> <p><i>Genetic Counselor</i> – Once at an hour-long initial visit. The genetic counselor will be available to the patient via phone or patient portal</p>
Implementation outcome(s) affected	<p>Uptake of guideline-recommended testing and treatment for high-risk lipid clinic patients; adoption of the clinic among PCPs and other providers; penetration among eligible patients; fidelity to the protocol of the clinic; sustainability of the clinic and its expansion.</p>
Justification	<p>MDLCs improve patient outcomes(2-7)</p>

Table 3. Baseline demographics for all patients seen in the MDLC

	All patients N=82 (ref)	Familial hypercholesterolemia N=24	Dyslipidemia N=42	Hypertriglyceridemia N=16	P- value
Age in years	56 ± 15	53 ± 16	62 ± 13	45 ± 13	<0.001
Male	42 (51%)	6 (25%)	25 (60%)	11 (69%)	0.007
BMI	31 ± 8	27 ± 6	32 ± 7	34 ± 10	
Tobacco status					0.436
Never	46 (56%)	16 (67%)	20 (48%)	10 (62%)	
Former	28 (34%)	5 (21%)	18 (43%)	5 (31%)	
Current	8 (10%)	3 (12%)	4 (9%)	1 (7%)	
Problem list diagnosis of CAD	36 (44%)	6 (25%)	26 (62%)	4 (25%)	0.004
Problem list diagnosis of PVD	7 (9%)	2 (8%)	5 (12%)	0	0.502
No reported MIs	67 (82%)	22 (92%)	30 (71%)	15 (94%)	0.243
Number of appointments					0.011
1	41 (50%)	12 (50%)	16 (38%)	13 (81%)	
2	31 (38%)	11 (46%)	19 (45%)	1 (7%)	
3 or more	10 (12%)	1 (4%)	7 (17%)	2 (12%)	
BMI, body mass index; CAD, coronary artery disease; PVD, peripheral vascular disease; MI, myocardial infarctions, CVA					

Table 4. Lipid levels pre-post implementation of the MDLC

	Baseline			Post			P-value
	N	Mean ± SD	Median (range)	N	Mean ± SD	Median (range)	
Familial hypercholesterolemia (N=12)							
Total cholesterol	12	237 ± 72	247 (133, 361)	12	162 ± 71	150 (86, 346)	<0.001
HDL-C	12	53 ± 14	53 (25, 79)	12	55 ± 11	57 (33, 73)	0.637
LDL-C	12	163 ± 69	166 (71, 296)	12	87 ± 70	84 (9, 279)	<0.001
TG	12	118 ± 59	118 (34, 238)	12	96 ± 44	90 (37, 173)	0.077
Non-HDL-C	12	184 ± 69	186 (87, 316)	12	106 ± 73	95 (26, 302)	<0.001
Dyslipidemia (N=21)							
Total cholesterol	21	213 ± 68	222 (115, 376)	22	168 ± 67	152 (79, 371)	<0.001
HDL-C	21	44 ± 15	40 (25, 83)	21	46 ± 18	40 (27, 105)	0.223
LDL-C	21	135 ± 67	135 (48, 277)	21	87 ± 56	70 (2, 243)	<0.001
TG	21	226 ± 182	176 (69, 927)	21	204 ± 199	140 (79, 1002)	0.266
Non-HDL-C	21	169 ± 63	184 (65, 305)	21	121 ± 64	105 (34, 312)	<0.001
Hypertriglyceridemia (N=4)							
Total cholesterol	4	239 ± 63	264 (146, 284)	4	162 ± 47	148 (121, 230)	NA
HDL-C	4	24 ± 9	27 (11, 31)	4	28 ± 12	32 (11, 37)	NA
LDL-C	4	73 ± 50	84 (4, 121)	3	47 ± 32	65 (10, 65)	NA
TG	4	1123 ± 452	975 (759, 1784)	4	656 ± 613	428 (232, 1536)	NA
Non-HDL-C	4	215 ± 54	236 (135, 254)	4	134 ± 45	112 (110, 202)	NA
HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol, TG, triglycerides							

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [TIDieRChecklistWord.docx](#)