Title

INSIDE Dyslipidemia Management: Improving Risk Assessment, Referrals and Lipid Goal Attainment for High-Risk CV Patients

***IN**spiring **S**ystem **I**mprovement with **D**ata-Driven **E**ducation*

Abstract

A key factor in closing the quality gap between best practice and common practice is the ability of healthcare providers and their organizations to rapidly and constantly identify, test and adopt changes that work for their systems. The University of Chicago (U of C) and Intelligent Medical Decisions, Inc. (iMD) have designed a Quality Improvement Education (QIE) initiative that combines quality improvement (QI) science, tools and techniques with data-driven education in an 18-month curriculum that gives healthcare providers the necessary resources to design, implement and measure sustainable change within their clinical systems.

Our goal is to form a collaborative of primary care and specialty clinics in the Chicago area to implement and study the impact of an 18-month QI initiative focused on improving identification and management of high-risk CV patients toward achieving their lipid targets.

Led by Michael H. Davidson, MD and the U of C Lipid Clinic and facilitated by Intelligent Medical Decisions, Inc. (iMD), we will enroll and train clinical sites in the greater Chicago area to form multi-disciplinary QI Teams to spearhead improvement efforts, perform baseline assessments of their high-risk CV patient populations, and rigorously design, implement and measure the impact of clinical process changes. Two regional live CME/CE meetings will share QI Team findings and efforts with peers to motivate improvement efforts and instill a city-wide culture of change. Results will be evaluated for impact on clinical process and outcomes and will be used to develop publications to scale successful changes to a broader audience.

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Reviewer Comments

"Because Pfizer IGLC and the IAS reserve the right to fund projects based on availability of funds and strength and quality of applications, it is very important for you to state the minimum amount of funding you would accept that would enable you do to a smaller or scaled down version of your project. A large number of excellent applications were submitted with requests for funding that greatly exceed the available budget. The panel asks you to provide a minimum amount that if awarded, would at least make your project viable."

Our funding model is based on prior successful endeavors where multiple industry supporters have contributed to a focused quality improvement effort*. The minimum amount required to execute a viable initiative as described in this grant proposal is the $250,000 we are requesting via the Pfizer IGLC and IAS RFP.

Since the issuance of the Pfizer/IAS RFP and acceptance of our Letter of Intent, Sanofi/Regeneron has also issued an RFP requesting proposals focused on hypercholesterolemia with a deadline of February 16th, 2016. Amgen will be considering proposals with the same focus beginning February 15th, 2016. Our project strategy recognizes funding limitations and the nuances of multi-supported unrestricted grants, and is designed to scale with varied levels of funding. Please see below for our multi-support scaling plan:

Funding Amount	Project Scope
$250,000 (minimum)	• Develop QI protocol and IT infrastructure for data collection/management • Enroll, train and facilitate QI efforts at 3 University of Chicago affiliated primary care practices
$500,000	• Enroll, train and facilitate QI efforts at 3-5 additional Chicago-area primary care and specialty practices • Add a web-based educational component with broad national reach through PeerAudience and OpenCME
$750,000	• Enroll, train and facilitate QI efforts at 3-5 additional Chicago-area primary care and specialty practices • Expanded publication plan and online distribution

* Diabetes INSIDE is a multi-supported national quality improvement effort designed by Intelligent Medical Decisions, Inc. (iMD) and sponsored by the American Diabetes Association. Now in its 3rd year, Diabetes INSIDE has enrolled 5 large health systems across the country to improve care processes for their patients with type 2 diabetes. Diabetes INSIDE is supported by Eli Lilly, Novo Nordisk and Sanofi Aventis.

Objectives

The overall aim of the *INSIDE Dyslipidemia Management* QI initiative is to improve lipid goal attainment for patients at high risk for cardiovascular disease. To accomplish this goal, we will:

1. Establish a rigorous baseline using EHR data, chart abstractions and process mapping to quantify gaps in diagnosis, referral and treatment of high-risk CV patients;
2. Design and implement clinical and system process changes that lead to improvements in diagnosis, risk assessment, referrals and lipid goal attainment for high-risk CV patients;
3. Provide education and training for PCPs and specialists to increase their knowledge and competence in applying recent advances in monoclonal antibodies for LDL lowering to clinical practice;
4. Scale successful clinical changes by leveraging scientific conferences, publications and enduring training and educational materials.

Assessment of Need

There exists a persistent "knowing-doing" gap in the clinical management of dyslipidemia within the US healthcare system. Every clinician *knows* that high LDL-C leads to atherosclerosis and increased CVD risk, yet poor outcomes too often remain the status quo. Our national healthcare system can do much more to address this growing challenge by shifting the focus of professional development programs from *knowing* to *doing* and from individual healthcare providers/patients to entire health systems. Using improvement science methodologies is a proven and sustainable approach to achieve improved population health.

While the below assessment of need briefly covers broad barriers and gaps to dyslipidemia management, the critical first step of any successful QI program is to establish a rigorous *local* baseline; this both identifies actionable areas for improvement and provides the necessary data from which to quantify the impact of clinical process changes. The *INSIDE* model then uses this local baseline to determine content and interventions tailored specifically to address these local needs. This local approach is much more effective than designing interventions based on broad trends, as clinical sites are vastly different in their resources, staffing, record keeping and patient demographics.

The University of Chicago Lipid Clinic provides care to many high-risk CV patients in the 3rd largest city in the US, including secondary prevention patients, high-risk primary prevention patients and patients with familial hypercholesterolemia (FH). A major challenge specific to FH is its under-diagnosis, with estimates that up to 80% of patients with the disease go undiagnosed. Cascade screening of family members of newly-diagnosed FH patients is indicated but difficult to implement when relatives are in different parts of the country. The Simon-Broome diagnostic criteria for FH patients is underused - if not unknown - to many providers, warranting increased education and awareness efforts.

While healthcare providers know that high LDL cholesterol confers increased CVD risk, care coordination gaps and clinical inertia continue to cause high-risk patients to "fall through the cracks." These systemic problems are widely known but often go unstudied and unaddressed. In a city the size of Chicago, these systems gaps are amplified, contributing to increased morbidity, mortality and higher overall costs of CVD care.

While education focused on new therapeutic options and clinical evidence provides the foundation for change, equally important is addressing system and process issues that oppose change and maintain the status quo. Though tools like risk calculators, provider and patient education programs are important, they require implementation support to be effective. Who is responsible for performing and documenting the risk assessment? How is this accomplished without disrupting clinical workflow? Who manages the transfer of information from PCPs to cardiologists? What staffing, process and documentation considerations are required to implement a cascade screening program? Questions such as these require a system focus and the INSIDE QI model – using improvement science techniques – is designed to guide clinical systems to find these answers and make sustainable changes that achieve our collective goals.

Target Audience

As a true QI activity, this initiative will engage an interdisciplinary group of physicians, NPs, PAs, pharmacists, medical assistants, office administrators, nurse educators, residents, IT staff and patients. Each clinical site enrolled will commit to the participation of 3-7 QI Team Members to spearhead institutional change and rigorous chart analysis of their high-risk CV patients to facilitate improvement efforts. iMD will provide data collection technical support and is able to work with any electronic health records (EHR) system, and encourages each clinical site to provide as many patient records as possible, representative of their high-risk CV patient population. We anticipate assessing a minimum of 2000 high-risk CV patients to establish a local baseline.

The educational meetings will target primary care and cardiology providers in the greater Chicago area. Meetings will be scheduled around regularly-occurring events (i.e. grand rounds, quarterly staff meetings) to maximize participation and impact on clinical process.

By publishing the results focused on successes and challenges of our QI efforts, we intend to engage a broader audience of PCPs and cardiologists to improve their own processes to improve lipid management in their high risk patients.

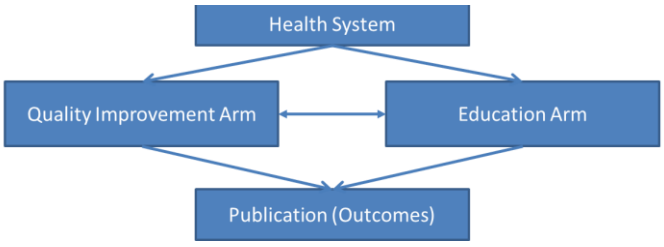
Clinical Site Enrollment

Clinical sites will be interviewed and chosen by The U of C Lipid Clinic and iMD based on a number of important criteria:

1. Sites must have large primary care group(s) and a large population of high-risk CV patients
    a. Our enrollment efforts will focus on integrated delivery networks, such as Accountable Care Organizations (ACOs), Academic Medical Centers (AMCs) and non-profit systems with primary and specialty outpatient care services.
2. Sites must provide pre-agreement to participate from a minimum level of department chair (AMCs) or director (private or non-profit health systems);
    a. Sites must provide commitment that they will guarantee participation at the data-driven meetings and the QI Team teleconferences and sign a QI Participation Agreement.
3. Sites must provide ongoing access to de-identified patient data
    a. IRB approval will be established or waived depending on the requirements of each site.
    b. Preference will be given to sites that can provide data during the interview process to demonstrate need.
4. Sites must identify a multi-disciplinary QI team who will be responsible for designing, implementing and measuring system changes during the 18-month program (see below).
    a. This team will interface with U of C/iMD QI facilitators at least once a month for the duration of this QI project. In most cases, QI teams hold bi-monthly web- and teleconferences with *INSIDE* QI facilitators.

Project Design and Methods

This 18-month facilitated QI project with be run through the University of Chicago Lipid Clinic and overseen by Michael H. Davidson, MD. Primary care and specialty clinics in the Chicago area will be recruited to participate. We are submitting this project to other sources of grant support and the number of clinics enrolled will be determined by the total amount of support received. U of C will work with Intelligent Medical Decisions (iMD) to facilitate this QI study. The two arms of this activity (QI Arm, Education Arm) and the publication plan are described below.



Quality Improvement Arm

This 18-month facilitated QIE project will guide an interdisciplinary QI team of healthcare professionals toward accomplishing the overall project aim: improving the identification and

management of high-risk CV patients toward achieving their lipid targets. Data and observations from the QI Arm of this initiative feed directly into the Education Arm to engage all healthcare professionals at each clinical site with the QI project itself and instill a city-wide culture of change. The QI Arm elements are outlined below:

1. **Getting Started**
   a. QI Team(s) assembly: we will assemble an interdisciplinary team(s) of PCPs, cardiologists, NPs, nurses, pharmacists, allied health staff, IT staff, medical assistants and even patients to design, implement and test system changes.
   b. We will conduct a 2-hour training workshop onsite to start the QI Team(s) on the improvement journey by providing "QI 101" education and introducing the data collection protocol and QI tools.
2. **Defining the Problem**
   a. We will conduct a rigorous baseline using EHR data, chart abstractions and process mapping to quantify gaps in diagnosis, referral and treatment of high-risk CV patients, with a focus on identifying FH patients. This data will be presented at the first live CME meeting described in the Education Arm section below.
3. **Understanding the System**
   a. Once problems are identified, we will formally map and analyze current processes that lead to quality gaps identified above.
   b. A second 2-hour workshop with the QI team(s) will be held to prioritize the gaps, root causes and process maps toward identifying specific solutions to test in the next phase.
4. **Designing & Testing Solutions**
   a. Using the baseline, root cause and process analyses above, the QI Team(s) will design, implement and measure a series of clinical care changes using rapid Plan-Do-Study-Act (PDSA) cycles. The QI Team(s) will interface regularly with iMD during this process and use their data collection and analysis software platform to track progress and objectively measure the impact of clinical process changes.
   b. We propose openly collaborating with other awardees of this Pfizer/IAS grant to implement and test the concepts and tools they design (e.g. risk calculators, training materials, patient education) as potential solutions to overcome the systemic gaps identified in this phase. If funding is awarded and at the discretion of Pfizer/IAS, we propose providing a letter of invitation to Pfizer/IAS outlining our project to other awardees and inviting them to contact us with their ideas and interventions, should they be interested in collaboration. We would then, in turn, present these interventions to our QI Teams for possible implementation.
   c. Participating clinics will design specific solutions that work for their system, such as establishing a local registry to identify high-risk CV patients, instituting cascade

screening protocols for FH patients, assigning staff to perform risk assessments, or performing regular EHR audits to identify at-risk patients.

5. **Implementing & Sustaining Changes**
   a. Once changes are instituted, we will work with participating clinics to continuously monitor the impact of their changes on clinical care processes and outcomes over time, such as regular reporting on the impact of new patient screening initiatives.
6. **Spreading Change**
   a. We will conduct a final 2-hour onsite workshop with the QI team(s) to discuss successes and challenges, and generally story board the QI team's efforts.
   b. Our documented "Improvement Journey" will be used to create abstracts for posters at scientific meetings, manuscripts for submission to peer-reviewed journals, as well as formal presentations to be shared with all sources of grant support.

Education Arm

The education arm of this initiative reinforces the evidence base and provides a forum for the QI teams to solicit change concepts from their colleagues and to spread successful changes system wide. Live meetings will be 60-90 minutes in length, will take place on U of C's campus, and will be held during regularly scheduled grand rounds or other regularly-occurring meetings to maximize participation.

1. **Regional CME Meeting #1 - *From Data to Insight: The High-Risk CV Patient Landscape in Chicago***
   a. 75-150 participants
   b. A regional live CME/CE event will bring together PCPs and specialists and share the QI study baseline findings to motivate and engage participants in the QI process toward improving lipid goal attainment in at-risk patients.
   c. This meeting will also educate participants on advances in LDL-lowering therapies with updates to evidence-based guidelines and clinical studies examining PCSK-9 inhibitors and their role in lipid management. Content from this meeting will be used to create an online CME/CE course for distribution to a broader audience (see below).
2. **Regional CME Meeting #2 - *Impact & Implications: Assessing Improvement and Identifying Persistent Barriers in Achieving Lipid Goals***
   a. 75-150 participants
   b. *Regional Live CME/CE Program:* A second live event will be convened to share successful clinical changes and continued challenges with HCPs in the Chicago area. This meeting will also present updates and results from ongoing research studies examining PCSK-9 inhibitors and their clinical impact.
3. **Online Education Activity**

a. Training and educational materials will be used to create an online CME activity for cardiologists and PCPs and will be distributed through PeerAudience and OpenCME, a trusted and recognized national platform for online CME. We will be requesting funding from Sanofi/Regeneron and Amgen for this online initiative and it is not represented in the budget submitted to Pfizer/IAS.

Publication Plan

This QI study is designed to uncover and overcome the system challenges that prevent and delay the uptake of new therapies, improved guidelines and enhanced technology into real-world practice. Our entire program is predicated on the collection and analysis of many types of data, and using this data to inform changes. IRB will be established (or waived) by each participating clinical site to ensure our ability to continually publish the growing impact of this important QI initiative. The data set we establish as part of this QI program will examine high-risk CV patient outcomes over time at each clinical system and provide valuable insight into population health trends, as well as the impact of our QI efforts on clinical process and outcomes.

1. We will extract, transform, and integrate the all raw data into presentations and reports for use in the data-driven meetings as well as for regular reporting to our sources of grant support.
2. Abstracts will be submitted for posters and presentations at scientific conferences.
3. Manuscript(s) featuring the activity design and outcomes and will be authored and submitted for peer review in clinical journals.

Evaluation Design

Our entire program is predicated on the collection and analysis of many types of data, and using this data to inform changes. An important measure of success will be to look at CV event data with the goal of fewer events over time in high-risk patients. However, this is a lagging indicator that might not readily inform us if the changes we make as a result of this initiative are leading to improvements.

By focusing our intervention and measurement efforts on clinical processes surrounding diagnosis, risk assessment, referrals and treatment, we can be more confident that the changes made as part of this QI initiative are leading to improvements. This will include quantifying improvements in lipid screening, improvements in timely initiation and intensification of lipid lowering therapies, lipid goal attainment, specialist referrals, risk assessment, and cascade screening for FH patients' family members. We will use a combination of "big data" EHR audits as well as smaller, more focused measurement techniques to quantify our impact on clinical processes. Once baseline assessments are performed, quantifiable goals will be determined by each QI Team.

In addition to the clinical process measures described above, documentation of the following QI efforts will provide qualitative data towards the assessment of this program's impact:

- Identification of system-specific goals that may lead to improvement in primary aims
- Completion of QI tools (i.e. driver diagrams, fishbone diagrams, PDSA) that facilitate root cause analysis, barrier analysis and change concept implementation
- Qualitative (i.e. root cause analysis) and quantitative (i.e. statistical control charts) assessment of success and limitations of improvement efforts

We will also assess each clinical site against eight success attributes that high-performing practices possess. These are the following: 1) Motivation to improve care processes for their high-risk CV patients; 2) Having key stakeholder buy-in to participate in the QI program, 3) Scope of QI Plans - sufficiently ambitious, 4) Ability to execute QI plans - quality of Plan-Do-Study-Act cycles, 5) Having influence to effect change in the care process, 6) Commitment to analyze and measure change in the care process, 7) Commitment to monitor change in the care process , and 8) Commitment to on-going improvement in the care process. iMD will rate each clinical practice against these eight attributes and link these qualitative factors with quantitative improvements in process and outcome measures as assessed using baseline and follow-up patient health data.

Data Collection and Analysis

iMD's data-analysis team will deploy a password-protected, data-collection questionnaire-management software system to handle the collection, management, reporting, and storage of research and patient data. All statistical analyses will be conducted using R Statistical Package v.2.13.1. Performance outcomes will be calculated as the percentage of eligible patients at goal, after accounting for patient inclusion and exclusion criterion for each measure. Group outcomes will be calculated as a mean ± SEM of all individual outcomes. Changes between baseline and comparative assessment will be assessed using a paired, one-tailed t-test at 95% power. P-value of .05 will be used to evaluate statistical significance. Qualitative data such as barrier analysis and proposed practice changes will be indexed according to a combination of preset and emergent categories, and plotted as a percentage of frequency. The phi coefficient will be used to measure correlation between binary variables.

Program Management & Timelines

The table below provides additional detail toward implementing the project described in this grant request and includes timelines for each deliverable.

Deliverable/Event	Program Management	Timeline
Clinical Site Recruitment	Should grant funding be awarded, the first step will be to formally enroll clinical sites to participate in the INSIDE program. For each supporter that awards funding,	Months 0-2

Baseline Assessment & Program Development	additional clinics will be enrolled. During the development phase U of C faculty and iMD will determine the detailed study protocol and satisfy all institutional requirements toward implementing the project, which includes IRB submission and staffing considerations. iMD will provide its secure data collection and analysis platform to conduct the baseline analysis and QI data collection. iMD will train health system IT staff and provide technical support.	Months 2-5
QI Team Assembly & Training	U of C leadership will work with iMD to create QI teams by selecting an interdisciplinary team of faculty and staff from each site to coordinate QI efforts. iMD QI facilitators will meet with the QI teams formally to train them on the QI processes and data collection methods.	Months 2-5
QI Implementation	iMD will hold regular teleconferences, webinars and meetings with the QI Team members at each site to guide the QI process and provide the QI teams with appropriate tools to conduct rapid PDSA cycles and data collection.	Months 5-18
Content Development	iMD QI facilitators will meet in person with institution faculty and the QI teams to formally create content to be used at the live CME meetings. This content will rely heavily on data collected during the baseline assessment and QI process.	Months 5-18
Live Meeting #1	iMD, U of C Program Managers and System leadership will work together to determine the optimal scheduling for the live meetings. Meetings will be held on each institution's campus during regularly-scheduled events to maximize participation. Institutions will manage A/V and onsite logistics.	Months 6-8
Improvement Plan Implementation & Comparative Assessment	During this time period institutional providers will be implementing the process changes determined via the efforts of the QI team. Sufficient time must be allowed for these plans to take effect and to show impact on patient outcomes before reassessment. Data collection will occur in the same manner as described above.	Months 14-18
Live Meeting #2	As described in the *Program Details* sections above	Months 17-18
Publication of Results	U of C faculty and iMD will compile and analyze all data toward the development of reports, abstracts and publications. QI Teams will contribute to the manuscript and peer review all content before the manuscript(s) are submitted.	Months 18-24