Diabetes Disease Management and Accountable Care Organizations: A Lean Approach to Improving Patient Outcomes and Reducing Cost

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Integrated Project
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David Dinette SELP 695 Spring 2013
Agenda

- Background and Need
- Problem Definition
- Project Scope and Goals
- Project Description
- Stakeholder identification
- Assumptions
- Alternatives
- Trade/Cost Analysis
- Requirements
- Architectural Design Process
- Implementation/Integration/Verification
- Risk management
- Ethical Issues in Healthcare
- Lessons Learned
Background and Need

Patient Protection and Affordable Care Act (PPACA) was passed by Congress to reduce the number of uninsured Americans and reduce the overall cost of healthcare.

- PPACA encourages physicians to form Accountable Care Organizations (ACO).
- PPACA implements a Medicare shared savings program where physicians are "paid for performance".

Centers for Medicare and Medicaid services (CMS) is responsible for writing, implementing and managing the rules of the Affordable care Act.

- ACOs will be able to participate in the Medicare shared savings program if they meet the performance measures required by CMS.
- CMS sets performance standards and manages the shared savings program.
Problem Definition

• **Current State:** physicians and ACOs are paid per services performed, not the health outcomes.

• **Future State (ACO model):** Physicians work in a group setting where they are paid for performance:
  - Improving patient outcomes
  - Reducing Cost of Service

• CMS requires the ACO to submit a plan on how it intends to improve patient outcomes and reduce the cost of service.

• **ACO must generate performance reports:**
  - 33 “Pay for Performance” metrics
  - Submit reports to CMS through an Electronic Medical Record (EMR).

• Many ACOs don’t have a model of care in place that will meet the administrative or performance requirements of CMS.
Pay for Performance Metrics

There are 33 required metrics that are found in four key domains:

- Patient/caregiver experience of care (7 measures)
- Care coordination/patient safety (6 measures)
- Preventative health (8 measures)
- At-risk population:
  - Diabetes (6 measures) – Project Scope
  - Hypertension (1 measure)
  - Ischemic Vascular Disease (2 measures)
  - Heart Failure (1 measure)
  - Coronary Artery Disease (2 measures)

- Diabetes at risk population is "all or nothing" scoring:
  - Requires the ACO to receive the maximum score on all diabetes metrics or they will get "zero" for the entire composite.

- "Pay for Performance" metric baselines: Determined by CMS
Medicare Shared Savings Program Participation

The ACO can elect to participate in either the One or Two sided model:

- **One-sided model** (sharing savings, but not losses, for the entire term of the first agreement)
  - Minimum Savings Rate (MSR) to qualify for participation = 2% to 3.5%
  - Maximum Shared Savings Rate = 10% cost reduction
  - ACO keeps up to 50% of the savings from the cost reduction
  - Example: ACO Medicare cost of services = $100,000. Annual Savings is $10,000. ACO keeps $5,000

- **Two-sided model** (sharing both savings and losses of the entire term of agreement)
  - Minimum Savings Rate to qualify for participation = Flat Rate of 2%
  - Maximum Shared Savings Rate = 10% cost reduction
  - ACO keeps up to 60% of the savings from to cost reduction
  - Example: ACO Medicare cost of services = $100,000. Annual Savings is $10,000. ACO keeps $6,000.

- **CMS will withhold 25% of any profits until the contract is complete to assure the ACO can fund potential losses.**
Project Scope

Project Scope:
- Medicare Patient Population
- Electronic Medical Record Utilization
- Diabetes Performance Metrics
  - 27% of adults over age 65 have diabetes
  - 50% of adults over age 65 have pre-diabetes
  - Cost healthcare system $116 Billion per year
  - Complications lead to other chronic diseases
## Scope of Reporting Requirements by ACO to CMS for Diabetes population

<table>
<thead>
<tr>
<th>CMS metric Number</th>
<th>Metric</th>
<th>Method of Data Submission</th>
<th>Baseline: Year 1</th>
<th>Pay for Performance: Year 2</th>
<th>Pay for Performance: Year 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>22</td>
<td>Hemoglobin A1C (&lt;8 %) All or Nothing</td>
<td>GPRO Web Interface</td>
<td>Reporting</td>
<td>Performance</td>
<td>Performance</td>
</tr>
<tr>
<td>23</td>
<td>Low Density Lipoprotein (&lt;100) All or Nothing</td>
<td>GPRO Web Interface</td>
<td>Reporting</td>
<td>Performance</td>
<td>Performance</td>
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<tr>
<td>24</td>
<td>Blood Pressure &lt; 140/90, All or Nothing</td>
<td>GPRO Web Interface</td>
<td>Reporting</td>
<td>Performance</td>
<td>Performance</td>
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<tr>
<td>25</td>
<td>Tobacco Non Use, All or Nothing</td>
<td>GPRO Web Interface</td>
<td>Reporting</td>
<td>Performance</td>
<td>Performance</td>
</tr>
<tr>
<td>26</td>
<td>Aspirin Use, All or Nothing</td>
<td>GPRO Web Interface</td>
<td>Reporting</td>
<td>Performance</td>
<td>Performance</td>
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<tr>
<td>27</td>
<td>Hemoglobin A1C Poor Control (&gt;9%)</td>
<td>GPRO Web Interface</td>
<td>Reporting</td>
<td>Performance</td>
<td>Performance</td>
</tr>
</tbody>
</table>
Project Goals

Design an ACO care model that can be submitted to CMS that demonstrates:
- Improve patient outcomes
- Reduce the cost of service
- Improve quality of care
- Increase the annual patient volume
- Enable participation in the Medicare shared savings program.

Electronic Medical Record System:
- Enable Continuous Patient Flow
- Ease of communication across the care continuum
- Implement standardized care plans
- Provide access to patient care plans
- Serve as a visual control board
- Measure and improve patient outcomes
- Manage cost of services
Project Description

Design a disease management care model:
- Implemented into new or existing ACOs
- Allow the ACOs to participate in the shared savings program

Implement disease management and standards of care:
- Diabetes Care Team
- Clinical Practice Guidelines Flow Charts (CPG)
- Master Decision Pathways Flow Charts (MDP)

Incorporate Lean systems engineering:
- Eliminate waste
- Increase Patient Volume
- Continuous Improvement

EMR Data Management:
- Make Standards of Care (CPG/MDP) Visible
- Enable communication across the patients care continuum
- Data Analysis
- Access Patient Data
- Patient Safety Alert System (PSA)
Stakeholders

1. Federal Government
2. Centers for Medicare and Medicaid Services (CMS)
3. The Accountable Care Organization providers
4. Diabetic patient population
5. Electronic Medical Record Users
Stakeholder Identification

Federal Government

Patient Protection and Affordable Care Act (PPACA)

Congressed passed the PPACA

Government assigned CMS to manage the PPACA

Centers for Medicare and Medicaid Services (CMS)

Manages PPACA through the Medicare Shared Savings Program

ACO must submit quality reports to CMS

Diabetes Disease Management Program Goals
- Shared savings program participation
- Improve patient outcomes
- Reduce cost of service
- Improve quality of care
- Increase the annual patient volume

Electronic Medical Record Goals
- Enable continuous patient flow
- Ease of communication across the care continuum
- Implement standardized care plans
- Provide access to patient care plans
- Serve as a visual control board
- Measure and improve patient outcomes
- Manage cost of services

STAKEHOLDERS

ARTIFACTS

ACO must generate quality reports on performance

Quality Reports

Performance metrics for Shared Savings Program Participation

Improve performance metrics set by CMS to participate in shared savings program

Accountable Care Organization

ACO improves patient outcomes and quality of care, reduced cost

Patients
Assumptions

ACO meets the general eligibility requirements established by CMS:
- 3 year participation agreement
- Minimum of 5000 Medicare beneficiaries
- Clinical Management Team
- Organizational structure to adequately care for patient population

ACO meets the Electronic Medical Records eligibility requirements established by CMS:
- Implement care plans
- Coordinate care among providers
- Evidence based medicine
- Submit performance and quality reports to CMS

ACO is participating in the One-sided model (sharing savings, but not losses, for the entire term of the first agreement)
# Alternatives

<table>
<thead>
<tr>
<th></th>
<th>Alternative 1</th>
<th>Alternative 2</th>
<th>Alternative 3</th>
</tr>
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<tbody>
<tr>
<td>EMR</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
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<tr>
<td>Report on 6 Required Metrics</td>
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<td>✔️</td>
<td>✔️</td>
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<tr>
<td>Evidence Based Medicine</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Diabetes Care Team</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Diabetes Disease Management</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>EMR patient portal</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>EMR Quality reports</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Implement Lean Healthcare</td>
<td>✔️</td>
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<td>✔️</td>
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<tr>
<td>Standards of Care (CPG/MDP)</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Additional short term metrics (Optional)</td>
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<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Additional long term metrics (Optional)</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
</tr>
</tbody>
</table>
Trade Study

Short Term Measures
Mandatory: (Alternatives 1, 2, 3)
- HbA1c Controlled
- HbA1c Uncontrolled
- Blood pressure
- Lipid Profile
- Smoking Cessation
- Aspirin Use

Optional: (Alternative 1)
- Hypertension management
- Body mass index
- Blood glucose (SMBG)
- Medical nutrition plan
- Foot examination
- Referral for diabetes education
- Referral for medical nutrition therapy

Long Term Measures
Optional: (Alternative 1)
- Retinal changes
- Renal changes
- Neurological changes
- Cardiovascular disease
- Peripheral vascular disease
- Foot problems
- Other diabetes related complications
Cost Analysis
Diabetes Management Implementation

- According to CMS, each Medicare Patient consumes an average of $10,143 in services Per Year.
- $10,143 will serve as the baseline cost of each patient
- According to the Cummings Study, Diabetes Disease Management Programs (DDM) can save the ACO between $672 and $2,647 Per Member Per Year (PMPY)

<table>
<thead>
<tr>
<th>Annual Savings (PMPY) Cummings Study</th>
<th>$672 Cost Savings PMPY</th>
<th>$2647 Cost Savings PMPY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implementation Cost (Centers for Disease Control)</td>
<td>$500 PMPY</td>
<td>$500 PMPY</td>
</tr>
<tr>
<td>Simple Payback period SPP</td>
<td>$500/$672 = 0.74 Y</td>
<td>$500/$2647 = 0.18 Y</td>
</tr>
<tr>
<td>Annual Savings Opportunity: Medicare Patient = $10,143 PMPY</td>
<td>$672/$10,143 = 6% cost reduction PMPY</td>
<td>$2647/$10,143 = 26% cost reduction PMPY</td>
</tr>
</tbody>
</table>

- Utilization of DDM program will yield at least a 6% cost reduction in services provided.
- ACO is eligible for profit sharing by achieving the Minimum Shared Savings Rate (MSR) of 3%
Cost Analysis: Lean Implementation

- Arthur suggests a 25% increase in patient volume with lean implementation.
- Estimated average of 250 working days per year
- Average physician sees 20 patients per day (PPD)
- Implementation cost includes hiring a lean consultant and training of ACO members

<table>
<thead>
<tr>
<th>Improvement: Lean Implementation</th>
<th>Lean improvement @ 25% increase in patient volume</th>
<th>Profit sharing @ 3% (Minimum to Qualify)</th>
<th>Profit sharing @ 10% (Maximum Allowable)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients seen per day per physician (average)</td>
<td>20 PPD*25% = additional 1250 office visits/yr (OVY)</td>
<td>(1250 OVY*10143) *3% = $380,300 yr</td>
<td>(1250 OVY*10143) *10% = $1,268,000 yr</td>
</tr>
<tr>
<td>Implementation Cost</td>
<td>*$250,000</td>
<td>*$250,000</td>
<td>*$250,000</td>
</tr>
<tr>
<td>Simple Payback period</td>
<td>IC/AS</td>
<td>$250,000/380,300 = 0.65 Y</td>
<td>$250,000/m$1.268 = 0.20 Y</td>
</tr>
</tbody>
</table>
Examples of profits under CMS rules

CMS implementation cost estimates:
- Small ACO (5000 patients) = $60K
- Large ACO (150,000 patients) = $1.5M
- Minimum profit sharing 3% (50% of 3% savings)
- Maximum profit sharing 10% (50% of 10% savings)

<table>
<thead>
<tr>
<th>Improvement: ACO Shared Savings Participation</th>
<th>Implementation Cost (IC)</th>
<th>3% Shared Savings (Minimum to Qualify)</th>
<th>10% Shared Savings (Maximum Allowable)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AS @ 5K Patients</td>
<td>$60,000 at 5K patients</td>
<td>((10,143*5K)*3%) * 50% = 760K</td>
<td>m$2.5</td>
</tr>
<tr>
<td>AS @ 150K Patients</td>
<td>m1.5 at 150K patients</td>
<td>((10,143*150K)*3%) * 50% = m$23</td>
<td>m$76</td>
</tr>
<tr>
<td>Simple Payback Period</td>
<td>IC/AS</td>
<td>$60K/$760K = 0.08 Y</td>
<td>$60K/m$2.5 = 0.024Y</td>
</tr>
<tr>
<td></td>
<td></td>
<td>$1.5M/m$23 = 0.09 Y</td>
<td>m$1.5/m$76 = 0.019Y</td>
</tr>
</tbody>
</table>
## Preferred Alternative

| Lean Implementation @ 3% Profit Sharing | $380,300 Per physician per year (PPPY) | $0 | $0 |
| Lean Implementation @ 10% Profit Sharing | $1,268,000 PPPY | $0 | $0 |
| Diabetes Disease Management Program: Small ACO (5,000 patients) | @3% Profit Sharing = m$1.5  
@ 10% Profit Sharing = m$2.5 | @3% Profit Sharing = m$1.5  
@ 10% Profit Sharing = m$2.55 | $0 |
| Diabetes Disease Management Program: Large ACO (150K patients) | @3% Profit Sharing = m$23  
@ 10% Profit Sharing = m$76 | @ 3% Profit Sharing = m$23  
@ 10% Profit Sharing = m$76 | $0 |
| Bottom Line $ @ 3% | Small ACO = m$1.8  
Large ACO = m$23.5 | Small ACO = m$1.5  
Large ACO = m$23 | $0 |
| Bottom Line $ @ 10% | Small ACO = m$3.7  
Large ACO = m$77.3 | Small ACO = m$2.55  
Large ACO = m$76 | $0 |

**Alternative #1 provides greatest profit sharing therefore is the preferred alternative**

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Requirements

Requirements are broken down into 3 sections:

1. EMR System requirements
2. ACO reporting Requirements
3. Diabetes Disease Management Requirements
EMR System Requirements


Verification Method: Demonstration

Requirement Classification: Functional Requirements
Requirement Classification: Performance requirements.  
Verification Method: Demonstration and Analysis  
Traceability: CMS and Core Clinical Management Team
Diabetes Disease Management Requirements

Traceability: Diabetes Clinical Team Leader
Requirement Classification: Functional
Verification: Inspection and Demonstration
Architectural Design Process

Net-Centric Approach:

- Enable timely and trusted access to information and collaboration
- Lean Healthcare
- Robust and Resilience
- DoD Architectural Framework Tools
Concept of Operation

Four Operational Concepts will be presented:
1. High level Operational Concept
2. Diabetes Disease Management ConOps
3. Electronic Medical Record ConOps
4. Patient Portal ConOps
High Level Operational Concept Diagram (OV-1)

- Accountable Care Organization
  - Core Diabetes Management Team
  - Direct Patient Interaction
  - Diabetes Care Team
- Centers for Medicare and Medicaid Services (CMS)
- Diabetic Patients
- Electronic Medical Record System
Diabetes Disease Management Program ConOps

Core Clinical Management Team

Clinical Practice Guidelines  Master Decision Pathways

Responsibilities

Diabetes Care Team

Responsibilities

- Diagnose, treat and manage patients health
- Hormone therapy and insulin management
- Counsel patients on the management of diabetes
- Counsel patients on nutrition Provide meal plans
- Counsel patients on medications
- Help patients cope with diabetes

- Primary Care Physician
- Endocrinologist
- Diabetes Educator
- Registered Dietician
- Pharmacist
- Psychologist/Social Worker

- Neurologist
- Nephrologist
- Podiatrist
- Optometrist
- Physicians Assistant
- Medical Assistants

Electronic Medical Record

Manage diabetic neuropathy
Manage diabetic kidney complications
Manage diabetic foot complications
Manage diabetic eye complications
High level assisting of care team members
Record vitals and gather basic patient information
Patient Portal Concept of Operation

Electronic Medical Record Patient Portal

- Check Laboratory Test Results
- Request Appointments Online
- View Health Record/Medical Information
- Communicate with Diabetes Care Team
- Access Care Plans
- Explore Educational Resources
- Prescription Refill Request
SV-1 System Interface Diagram

Hardware and Software needed to support Operational Functions

- **Software**
  - **Hardware**
  - **Data Storage Server**
  - **Patients Computer**
  - **CMS Physician Quality Reporting System (GPRO) Server**

- **Electronic Medical Record Software**
  - **Wireless Internet Connection**
  - **Software Installed on Tablet Computers**

- **Wireless Tablet Computers**

- **Internet Connection**
  - **Data Management Software**
  - **Desk top Computers**

- **Installed**
Implementation Stages

Implementation stages:

- Create a lean culture
- Define and build quality into the system
- Implement diabetes disease management program
- Implement Electronic Medical Record system
- Implement quality management tools
Implementation Timeline

- Train and Prepare for Lean/Quality
- Disease Management Program: 6 Months
- Electronic Medical Record Utilization: 6 Months
  - User Interface
  - Practice Guidelines
    - Decision Pathways
    - Patient Safety Alert
  - CMS reporting metrics 22 to 27: 3 Months
  - Short and Long-Term performance Metrics: 3 Months
- Performance Baseline: 3 Months
- 12 to 18 Months
Lean Healthcare

- **Value**: is defined by customer in terms of specific products or services (or both).
- **Value stream**: Eliminate waste by mapping out all end to end linked actions, processes and functions necessary to delivery care to the patient.
- **Flow**: Patient flow must be continuous, linking value created steps without disruption.
- **Pull**: let customers (internal or external) pull when needed, enabling efficient just in time care or delivery of service.
- **Perfection**: Make imperfections visible, continuous improvement, enabling just in time delivery of care.
- **Respect for people**
Identifying Waste

- **Defects**: making errors, correcting errors, inspection work already done for errors
- **Waiting**: for test results to be delivered, for an appointment, for a bed, for release paperwork
- **Motion**: searching for supplies, fetching supplies from other rooms, looking for forms or care plan action items
- **Overproduction**: excessive diagnostic testing, unnecessary treatment
- **Over processing**: a patient being asked the sample questions or having to explain problems multiple times, filling out duplicate forms, writing too much in charts, rather than noting only pertinent information relevant to care plan
“Quality cannot be tested in; it must be built in” - Eberhardt Rechtin

“If a patient doesn’t need a procedure or treatment, then, no matter how well it was performed, “there is no quality”” - Jay Arthur.

**Quality Attributes:**

- Free from defects
- First-time right
- Consistently predictable outcome
- Measurable and verifiable results
- At a minimum cost
- Demonstrate healthcare excellence
System Integration

ACO will hire consultants to assist with the Integration process.

- **EMR Software Developer:**
  - User interface design
  - System Functionality
  - Report Generation

- **Lean/Six-Sigma Black belt:**
  - Implementation of Lean/Quality

- **Healthcare Consultants:**
  - Experts in policy, procedures and standards
System Verification

Test system/design functionality vs. requirements:

- EMR System Requirements (Demonstration)
- ACO Reporting Requirements (Demonstration/Analysis)
- Diabetes Disease Management (Inspection/Demonstration)
  - Electronic chart audits (pulling random patient charts for evaluation)
  - Six Sigma
  - Control Charts
Control Charts

Hemoglobin A1C < 8% Control Chart

Hemoglobin A1C % per patient population

Time Weeks

X UCL 8%
X Bar %
X LCL 6%
XCL 7%
Risk Analysis and Management

![Risk Analysis Grid](image-url)
Risk #13

- All patient data shall be submitted into the EMR. There will be a learning curve and some providers will be resistant to the technology.

- *Risk classification: Technology*
- *Likelihood/Consequence: L3, C4*
- *Mitigation*
  - Formal employee training
  - Poke Yoke design – system guides provider through the data entry process
  - Continuously evaluate the user interface design
  - Encourage suggestions for improvement
Risk

Risk #4

- Disease management programs have not been completely successful in the past because of patient non-compliance

- **Risk classification: Political**

- **Likelihood/Consequence: L3, C4**

- **Mitigation:**
  - System identification of non-compliance
  - Monitor patients closely
  - Provide additional resources
  - Psychologist interaction
Risks

Risk #9

- Patient data availability could cause HIPPA privacy law violations and lead to litigation

- *Risk classification: Cost, Technical, and Legal*

- *Likelihood/Consequence: L3, C5*

- *Mitigation:*
  - Conduct periodic data security audits and risk assessments
  - Train all members of the ACO on HIPPA privacy rules.
  - Communicate with the patient
    - What information will be available
    - How the information will be used
    - How the ACO intends to protect the information
    - How the patient can protect their information
Ethical Issues in Healthcare

- Patient Privacy
- Utilitarianism vs. Cost Benefits
- Social Justice
Lessons Learned

- Scope Changes
- Architecture Changes
- Challenge Requirements
Questions
Sources

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