Process Improvement Overview

ACCR
August 17, 2012
Mark Schumacher
Outline and Objectives

Five key areas of focus

1. What is process improvement? What does it look like on campus? What does DMAIC mean?

2. Why should we care about process improvement? Does it work in clinical research?

3. What does a project really look like?

4. What do my more experienced peers think about process improvement?

5. How can I get involved in process improvement? What resources are available on campus?
Goal of Process Improvement Program

Deliver Measurable Results which Significantly Impact the Strategic Plan

Three Strategic Goals for Northwestern Medicine:

• Deliver Exceptional Care
• Advance Medical Science and Knowledge
• Develop People, Culture and Resources
Process Improvement Program Overview

The NMH PI program has developed over a 10 year period

- Established DMAIC-based Process Improvement program
- Implemented infrastructure for project selection, oversight and financial benefit reviews
- Trained initial wave of 13 Improvement Leaders

- Doubled the size of Process Improvement Team
- Targeted key drivers of risk
- Increased awareness of DMAIC among Medical Staff
- Incorporated the use of Lean principles into DMAIC framework

- 1st MDs and RNs trained as Improvement Leaders
- Increased use of Rapid Improvement Workshops
- Launched a series of Improvement Portfolios to address complex system issues
- 1st FSM and NMFF based improvement projects
- Integrated Northwestern Lake Forest Hospital into program
Process Improvement Program
Overview

Process Improvement delivers measurable results

2002 — 2011
Cumulative Impact

- 231 projects completed
- Over 90% reduction in avoidable severe harm events
- Roughly 2 million patient interactions impacted
- Over $85 million in annualized financial benefit
- Over 70% of completed projects achieved statistically significant improvement
DMAIC Methodology

DMAIC is a step by step methodology used to solve problems by identifying and addressing the root causes of a problem.

**DEFINE**
What is the problem or improvement opportunity? Who does the problem affect and what are their expectations?

**MEASURE**
How is the process currently measured and what is your performance?

**ANALYZE**
What are the root causes of poor performance and can they be prioritized?

**IMPROVE**
What solutions / improvements can be developed to eliminate or reduce poor performance?

**CONTROL**
How do we sustain improved performance?
DMAIC Methodology

Or in even fewer words…

DEFINE
Identify the problem and goal

MEASURE
Baseline current performance

ANALYZE
Validate key drivers or error

IMPROVE
Fix the key drivers of error

CONTROL
Implement and use mechanisms to sustain improvement
## Defining Team Members

Ownership, Accountability, and Role Definition are critical elements of creating a successful team.

<table>
<thead>
<tr>
<th>Executive Sponsor</th>
<th>Admin Sponsors</th>
<th>Physician Sponsor</th>
<th>Process Owner</th>
<th>Improvement Leader</th>
<th>Team Members</th>
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</table>
| • Provides overall guidance and accountability for the project  
  • Addresses project barriers (organizational)  
  • Provides strategic oversight | • Accountable for timely and successful implementation of the project  
  • Addresses project barriers (departmental)  
  • Provides tactical oversight | • Accountable for timely and successful implementation of the project  
  • Helps for reach consensus on guidelines, protocols, and other workflow decisions | • Accountable for implementing, controlling, and measuring project outputs and improvements | • DMAIC methodology expert  
  • Accountable for using DMAIC to manage the project and complete deliverables | • Makes significant and focused contributions to timely and effective project advancements  
  • Contributes ideas and impacts the direction of the project  
  • May be involved in data collection and analytics |
The “Toolbox”

Six Sigma

Change Acceleration Process

Lean

Rapid Improvement Workshop

- Summary for Cycle Time
  - Anderson-Darling Normality Test
  - A: 1.52
  - P-Value = 0.005
  - Mu: 4.8247
  - Std Dev: 1.4510
  - Variance: 2.1000
  - Skewness: 0.282327
  - Kurtosis: -0.506107
  - N: 50

- 95\% Confidence Intervals

- Leading Change
  - Creating A Shared Need
  - Shaping A Vision
  - Mobilizing Commitment
  - Making Change Last
  - Monitoring Progress

- Changing Systems & Structures

- Six Sigma
  - Change Acceleration Process
  - Lean
  - Rapid Improvement Workshop

- What: Who: When: Resources
What does this have to do with clinical research?

- DMAIC and Lean are proven problem solving methodologies
- The CTSA RFA identifies enhances quality, safety, efficiency, cost and speed!

Specific Objectives of the Institutional CTSA Awards

Institutional CTSA support an academic home that creates an integrated research and training environment across an applicant institution and its partner institutions in order to:

- Promote an institutional environment that enhances quality, safety, efficiency, and cost effectiveness of clinical and translational research for all conditions
- Provide resources and services to support and speed the planning and implementation of clinical and translational research across the entire range of research and communities
- Facilitate the training and career development of a robust translational research workforce
Clinical Trials Process Redesign

**Project Charter**

- **Linkage to Northwestern Medicine**: AMSK: Accelerate the translation of scientific discoveries into breakthrough medical solutions

- **Problem Statement**: The clinical trials process is complex and at times difficult to navigate. Opening a clinical trial, as measured from first IRB or OSR submission to open to accrual, takes ~90 days at the median.

- **Goal/Benefit**: Reduce median time to open a clinical trial by 20% (18 days) at the median.

- **Scope**: OSR and IRB processes required to open a clinical trial

**Key Metric(s):**

- IRB Cycle Time (submission to final approval)
- OSR Cycle Time (contract receipt to full execution)

**Exec Sponsor**: Philip Greenland  
**Process Owner**: Bruce Elliott / Debra Gibson-Tice  
**Sponsor**: David Johnson / Lewis Smith  
**Improvement Leader**: Mark Schumacher
Clinical Trial Process Redesign: OSR – Define / Measure

OSR cycle time from contract received to full execution (median = 98 days) lengthens the overall clinical trial cycle time and at times serves as a dissatisfier for investigators.

Negotiations Process

1.) Back-and-forth communications with time-lags cause negotiation delays

2.) Multiple processes must track together to avoid post negotiations waits on the IRB or budget

3.) Multiple sequential hand-offs are required to complete contract sign-off post negotiations

Administrative Process

- The OSR team mapped the process from receipt to full execution
- Three key cycle time drivers were identified

Other Key Parallel Processes (High Level)

IRB Process

Budget Process

NMH Documentation (Short-Term Lease Agreement) Process
Clinical Trial Process Redesign: OSR – Measure / Analyze

Opportunity to improve overall OSR cycle time existed within all 3 drivers

• The team analyzed the 3 key drivers to quantify the improvement opportunity

• At the median, a contract spends almost 50% of the total cycle waiting on documents or sign-offs AFTER negotiations have already been completed
Clinical Trial Process Redesign: OSR – Improvements

Implemented a suite of improvements in OSR

OSR Improvements:
1. Standardized the process, timing and mechanism for follow-up with sponsors during contract negotiations
2. Standardized two key escalation points to assess needs during extended negotiations
3. Redesigned the contract sign-off process
4. Standardized the administrative follow-up process
5. Re-distributed the workload to improve distribution; created process for workload assessment
6. Added process discussions / audits to normal meeting schedules
7. Posted visual representations of the new processes in the workspace
Clinical Trial Process Redesign: OSR – Results

The percent contracts negotiated within 45 days of submission has risen from 43% in December 2009 to 69% in FY11 Q1. Contracts executed within 90 days has risen from 43% to 62%.
Appendix
Opportunity for improvement:

- Time to enrollment of our first subjects is slow for many studies and overall enrollment is an area that we need to build.
- Enrollment into clinical trials has an immeasurable impact on visibility and reputation of the organization.

Improvement Target Areas:

- Increase trial and coordinator visibility
- Enhance communication
- Build the research team
- Promote the culture of research

Goal/Benefit:

- Increase study recruitment
- Enhance BCVI reputation
Improvement efforts focused on **EXPANDING BILLING CAPACITY** and **DECREASING HOSPITAL OVERHEAD EXPENSES**

**DELIVERABLES BY KEY DRIVERS**

- Finance Model
- Budget Preparation
- Scheduling
- Charge Entry
- Billing Reconciliation

**COMMUNICATION**
- Website
- Mass email
- Town Hall meetings

**FORMS**
- Study budget templates
- Registration forms
- Charge sheets

**PROCESS**
- Educate
- Standardize
- Lean process
NMH Clinical Research Unit Cost Recovery

Implemented Cost Recovery Model

Cost Recovery/ Expense Distribution

<table>
<thead>
<tr>
<th>Expense distribution</th>
<th>NU</th>
<th>CTSA Grant</th>
<th>P.I. Cost Recovery</th>
<th>SUM</th>
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</thead>
<tbody>
<tr>
<td>Grant Year 3</td>
<td>30%</td>
<td>57%</td>
<td>13%</td>
<td>100%</td>
</tr>
<tr>
<td>Grant Year 4</td>
<td>10%</td>
<td>56%</td>
<td>34%</td>
<td>100%</td>
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What if I want to learn more?

- NMH offers two one-day (8:30AM – 4PM) introductory courses for leading process change

- Email Mark (mschumac@nmh.org) or sign-up via NMI

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Introduction to Process Improvement and DMAIC

Introduction to Lean

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What other resources are available?

• Process Improvement offers coaching for key projects across Northwestern Medicine

• NMH opens the full improvement infrastructure (e.g., improvement council) as needed

• Do not hesitate to contact me with questions(mschumac@nmh.org)
Control, Teamwork and the Paper Airplane Challenge
Activity Goals

Walk out today understanding...

• Methods for improving long-term sustainability (i.e., control)
  – Process reliability = Outcome stability

• How effective process correlates to effective teamwork
Reasons for Erosion

• How much time do you spend putting out fires?
• How much time do you spend fixing issues or processes a 2\textsuperscript{nd}, 3\textsuperscript{rd}, 4\textsuperscript{th}, etc. time?
• Why does erosion occur?
  – Infrequent measurement of results
  – Vague ownership of action plans / results
  – Lack of focus on the key drivers
  – Poor communication of the key drivers / actions
  – No recognition or escalation of “small issues”
  – Organizational pressure on the newest / next challenge
Control Mechanisms

Strong

1. Mistake Proofing
2. Statistical Process Control
3. Monitoring
4. Standard Procedures
5. Checklists
6. Vigilance
7. Training
8. Communication

We will start here
8. Communication

• Most common control mechanism –
  – Example: “Remember to submit IRB and OSR materials at the same time!”

• Essential component of a successful control plan

• Strengths
  • Engages staff; creates awareness; low cost

• Weaknesses
  • Requires multiple layers of active and passive communication; people / groups are easily missed; does not prevent errors from occurring
7. Training

- One of the most common forms of control
- Component of many successful control plans

**Strengths**
- Engages staff; exposes staff to (hopefully) the proper process

**Weaknesses**
- Requires continued assessment; high cost; requires documentation for reference; does not prevent errors from occurring
6. Vigilance

• Common form of control (often used on a smaller scale effort)
  • Requires a personal commitment to using proper processes / methods

• Strengths
  • Can inspire personal ownership; can engage staff; low cost

• Weaknesses
  • Requires “heroic” individual effort; can only succeed with successful training / communication; benefits diminish with fatigue; does not prevent errors
Paper Airplane Exercise #1

- Break into teams of 2 and select roles (designer or builder)
- Designer and builder face opposite directions
  - DON’T watch other teams either!
- Instructions
  - Materials consist of one piece of (8.5” x 11”) paper
  - Designer builds a prototype... builder relaxes
  - Designer verbally gives instructions to builder
  - Designer cannot watch the builder during construction
  - Builder cannot look at the prototype
  - Use communication and vigilance to succeed
- Take 5-10 minutes to complete the exercise
- Goal – First production aircraft must look like prototype
5. Checklists

- Somewhat common form of control
  - Serves as a consistent reminder to enhance vigilance

- Strengths
  - Serves as a standard reference; can be used as a record; low cost; can be a basis for SOPs

- Weaknesses
  - Requires individual use and compliance; must accurately reflect the process; does not prevent errors
4. Standard Operating Procedures

• A somewhat common form of control
  • Documents the standard process

• Strengths
  • Provides consistency via a standard process (reduces human variation); assigns responsibilities

• Weaknesses
  • Requires ownership / maintenance; only succeeds with training; requires monitoring for compliance; can frustrate users; does not prevent errors
3. Monitoring

- Common form of control
  - Measures the output / outcome
  - Provides a basis for feedback

- Strengths
  - Assists with accountability; provides feedback to leadership; provides data for problem solving

- Weaknesses
  - Requires timely / structured review of results; requires corrective action ownership; adds non-value added steps to the process; does not prevent errors
2. Statistical Process Control

• An uncommon form of control
  • Plots measurement over time
  • Identifies significant variations

• Strengths
  • Enables identification of changes / variation; minimizes unnecessary use of resources

• Weaknesses
  • Requires disciplined and complex measurement; difficult to interpret; requires timely feedback and corrective action; does not prevent errors
1. Mistake / Error Proofing

- An uncommon form of control
  - Minimizes or eliminates the opportunity for human error
  - “Design out the defect”

- Strengths
  - Can achieve a 0% error rate; robust to human variation; does not require training or feedback mechanisms

- Weaknesses
  - Difficult to create / implement; may require new / different technology; can lead to a false sense of security
# Mistake Proofing Examples

## Non-Health Care
- Auto-shutoff irons
- Airbags
- Anti-lock braking systems
- Auto-system PC back-ups
- Mandatory fields
- Garage door proximity switch
- US versus Euro outlets / plugs

## Health Care / NMH
- Medication locking system
- Smart pumps
- Sharps containers
- Lift equipment
- POC bar coding systems
- Bed rails
Paper Airplane Exercise #2

• Break into teams of 4

• Instructions
  • Materials consist of one piece of (8.5” x 11”) paper
  • Design and build a prototype
  • Mistake proof the process
  • Select two team members to rotate to another team
  • Rotating team members are the builders
  • Builders CANNOT view the prototype
  • Team CANNOT provide verbal instructions

• Take 15-20 minutes to complete the exercise

• Goal – First production aircraft must look like prototype
Summary and Next Steps

• Taking the time to build long-term sustainability plans SAVES time / resources over the long-term
  – Prevents erosion
  – Reserves time for strategic thinking / new projects

• Mistake / error proofing is the BEST method of process control

• As improvement leaders and process owners YOU should push your teams to ensure build an effective control plan