No Fly Safety Culture

Implementation, Challenges and Outcomes

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North Shore – Long Island Jewish Health System
CONFLICTS OF INTEREST

• None
# Quality Management Team

- Louis Potters, MD: Chairman  
- Ajay Kapur, PhD: Chair, QM  
- Regina Stanzione,  
- Beatrice Bloom, MD  
- Abolghassem Jamshidi, PhD  
- Anurag Sharma, MS  
- Yijian Cao, PhD  
- Linda Mallalieu, MSc  
- Antz Joseph  

- Sherin Joseph, RTT  
- Petrina Zuvic, RTT  
- Catherine Riehl, RTT  
- Nilda Adair, RTT  
- Michael Interrante, RTT  
- Carol Morgenstern, RN  
- Elaine Montchal, RN  
- James Mogavero  
- Nancy Riebling
Introduction

- Tendencies to rush treatments, and environments of care with high operational variability → risk expedited care.

- In the current environment of care in Radiation Medicine, several incidents have occurred that substantiate such risks.

- In this work we focus on methods to rationally counteract these tendencies towards a culture of patient safety.
Outline

I. The Quality Checklist (QCL) Process Map at NSLIJHS

II. Risk Assessment of QCL Process

III. “No-Fly Policy” Risk Mitigation Initiative
Radiation Medicine at North Shore-LIJ

- Paperless and Quality Checklist (QCL) Driven Operations since 2007
- Evidenced Based Treatment Directives for Standardization of Care
- 2800 consults/yr; 2100 Tx with EBRT
- 5 Locations, >100 staff; 195 patients/day
- 8 Linacs; 37000 treatment fields per year (70% with IMRT)
- Variance Rate under 0.01% per year.
- Custom Aspects-of-Care Event Reporting Database
- A Multi-disciplinary Quality Management Team
Methodology and Approach

1. QCL PROCESS IN EMR
2. EVENT REPORTING DATABASE
3. LIBRARY OF QCL FAILURE MODES
4. REVERSE + FORWARD FMEA OF QCL

- DEFINE RISK SORTED QCL MAP : QCL\(^H\)
- MEASURE BASELINE QCL\(^H\) METRICS \([\mu, \sigma, Z]\)
- ANALYZE METRICS, DEFECTS, RCA
- IMPROVE REFINE QCL, INTRODUCE NO-FLY
- CONTROL : RCA STATISTICAL PROCESS

2007-2010

2010-2011
I. The Checklist

“A checklist is a type of informational job aid used to reduce failure by compensating for potential limits of human memory and attention.

It helps to ensure consistency and completeness in carrying out a task. A basic example is the "to do list."

- Wikipedia
# A Quality Checklist in Radiation Medicine

**Demographics**

1. Patient information folder is created by secretary by printing out the patient education materials located on the shared drive.
2. Patient address labels are printed and places on the Patient Acquaintance Form, HIPAA, SW Intake form, Release of Pathology Slides, and Release of Medical records. Package is sent to patient to be completed.
3. On the day of the consult, the patient brings the completed forms. The forms are reviewed by the secretary.
4. If needed, patient demographic screen is updated.
5. The “Patient Acquaintance” form is scanned into Mosaic and encounter in the e-chart under “Patient Acquaintance.”
6. The QCL item “demographics” is completed. The document is approved by the secretary.

**STAGE SPECIFIC QUALITY CHECKLIST (QCL)**

<table>
<thead>
<tr>
<th>STAGE SPECIFIC QUALITY CHECKLIST (QCL)</th>
<th>PERSON APPENDING QCL</th>
<th>PIVOT DATE</th>
<th>QCL GENERIC</th>
<th>DUE DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Which Stage?</td>
<td>CONSULTATION</td>
<td>Date of Consult</td>
<td>Obtain records</td>
<td>4</td>
</tr>
<tr>
<td>B. Who Appends?</td>
<td>Consult Scheduler</td>
<td></td>
<td>Demographics</td>
<td>0</td>
</tr>
<tr>
<td>C. What is the Pivot Date?</td>
<td></td>
<td></td>
<td>Insurance Info</td>
<td>0</td>
</tr>
<tr>
<td>D. What Tasks Needed?</td>
<td></td>
<td></td>
<td>Path requested</td>
<td>0</td>
</tr>
<tr>
<td>E. Pre-requisities?</td>
<td></td>
<td></td>
<td>HIPAA Forms</td>
<td>0</td>
</tr>
<tr>
<td>F. Who is Responsible?</td>
<td></td>
<td></td>
<td>Update MD Directory</td>
<td>0</td>
</tr>
<tr>
<td>G. When should it get done?</td>
<td></td>
<td></td>
<td>RN Education</td>
<td>0</td>
</tr>
<tr>
<td>H. What are the handoffs?</td>
<td></td>
<td></td>
<td>MDC Forms</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Nursing Assessment</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>TX. Prescriptions</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Special TX proc</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Tx Consent</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Review Nutr Response</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Review SW Response</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Screen for Protocol</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Transcription Dict</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Note (MD)</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Transcription Done 2</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Path Slide Read</td>
<td>3</td>
</tr>
</tbody>
</table>

**Physicians**

PHYSICIANS

SIM THERAPISTS

MACHINE THERAPISTS

BILLING

SOCIAL WORKERS

NUTRITIONISTS

**Secretaries**

SECRETARIES

**Nursing**

NURSING

**Research Protocol**

RESEARCH PROTOCOL NURSING

**Physics**

PHYSICS

**Simulation Therapists**

SIM THERAPISTS

**Machine Therapists**

MACHINE THERAPISTS

**Billing**

BILLING

**Social Workers**

SOCIAL WORKERS

**Nutritionists**

NUTRITIONISTS

**North Shore LIJ**

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The QCL Driven Radiation Process

CONSULTATION
SIMULATION
MD DIRECTIVES
TX PLANNING
PLAN VERIFICATION
START TX
TX COMPLETION

Point of Confluence

Tasks
Time

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QCL Assessments – Crystal Reports
II. Risk Assessment of QCL Process
Questions Asked

- How to Identify High Risk Steps in the Radiation Medicine Process?
- How to Create a Proactive “Safety First” Culture?
- What can we learn from 6-sigma best practices for safety?
Cause or Effect?

Error Codes Based Reporting System

What's in a name???

Average # of Monthly Incidents - Aspects of Care Database 2010

Needed better Cause/Effect Relationships
Event Reporting Database

Review QA Monitoring Items

date: 9/26/2011

reporting staff: campus: MD:

reporting staff function:

patient name: report #:

no fly delay proactive delay

Root Cause Analysis

Effect:
1st level cause:
2nd level cause:
3rd level cause:
4th level cause:
5th level cause:

analysis / discussion: action / follow up:

associated QCL item: potential severity rank:
actual severity rank:

meets criteria for no fly delay
meets criteria for proactive delay

completed

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Event Reporting Database at NSLIJHS
Summary of Events Reported

Errors Propagate

- Treatment Planning Issues, 5%
- Misadministrations, 0%
- Isolated Variances, 2%
- Simulation Delays, 2%
- Morbidity, 3%
- Pre-treatment Good Catches, 19%
- Treatment Delay or Interruption, 69%

QCL Task Delays Occur
## FMEA ON NSLIJHS QCL MAP

### NSLIJHS RADIATION MEDICINE QCL PROCESS MAP

**Failure Modes and Effects Analysis Form (FMEA)**

<table>
<thead>
<tr>
<th>Prepared by:</th>
<th>Ajay Kapur, Ph.D.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date: 1999/02/01.</td>
<td>(Two)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>QCL</th>
<th>Process Step / Input</th>
<th>Potential Failure Mode</th>
<th>Potential Failure Effects</th>
<th>Potential Causes</th>
<th>OCCURRENCE</th>
<th>SEVERITY</th>
<th>DETECTION</th>
<th>RPN</th>
<th>Actions Recommended</th>
<th>Resp.</th>
<th>Actions Taken</th>
<th>SEVERITY</th>
<th>OCCURRENCE RPN</th>
</tr>
</thead>
<tbody>
<tr>
<td>QCL</td>
<td>QCL Step/ Sub Step</td>
<td>Failure Mode of QCL</td>
<td>What is the impact on Patient Safety?</td>
<td>What causes Failure Mode?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### QCL PROCESS MAP FMEA

- **Score by Mean A1**: 
- **Occurrence Mean A1**: 
- **Detectability Mean A1**:

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Ajay Kapur, Ph.D.
QCL PROCESS MAP
FAILURE MODES AND EFFECTS ANALYSIS

FMEA: QCL PROCESS MAP
COMPOSITE RISK
(Severity Risk) X (Occurrence Risk) X (Detectability Risk)

Most Physics Tasks, Contours, Path review

High Risk Tasks

Recast Checklist into a Risk Pareto Chart to Identify High Risk Steps
Forward and Reverse FMEA

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Analysis of High Risk Tasks (2009)

SLIP DAYS

CONTOURING DELAYS
- MD Peer Review, 13%
- MD Delinquency, 37%
- Other Imaging Issues, 6%
- Image Fusion problems, 43%
- Management, 2%

PLAN MODIFICATION DELAYS
- Prescription or constraint Modifications, 29%
- Machine Issues, 11%
- Recontouring, 45%
- Other, 16%
Delay-Rushed Processes

- **Standard Process**
  - Rx
  - Contour
  - Plan
  - Review
  - Export
  - QA
  - 2nd Chk

- **Delay-Rushed Process**
  - Rx
  - Contour
  - Plan
  - Review
  - Export
  - QA
  - 2nd Chk

- **Simulation**
- **Treatment**

- **Should the rush to treat ever supersede completing safety checks??**

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III. The “No-Fly” Policy
Risk Mitigation and Workflow Improvement

1. Data Driven QCL Process Remapping / Streamlining
   - Revised Workflow and Task Due Dates
   - Dedicated Task Coordination and Scheduling
2. Process Interlocks – No Fly Policy

<table>
<thead>
<tr>
<th>Forcing Functions and Constraints</th>
<th>No Fly Treatment Policy with Specific Stopping Rules</th>
</tr>
</thead>
<tbody>
<tr>
<td>Automation and Computerization</td>
<td>Paperless Operations</td>
</tr>
<tr>
<td></td>
<td>Via OIS (Mosaq)</td>
</tr>
<tr>
<td>Simplification and standardization</td>
<td>Process Mapping, 6σ Z-score</td>
</tr>
<tr>
<td></td>
<td>Statistical Process Control</td>
</tr>
<tr>
<td>Reminders, Double Checks, Checklists</td>
<td>QCLs with Redundant Check Points</td>
</tr>
<tr>
<td>Policies and Procedures</td>
<td>Custom Policy and Procedure Database Reviewed Monthly</td>
</tr>
<tr>
<td>Training and Education</td>
<td>Transitional Phase Training, Department Blogs</td>
</tr>
</tbody>
</table>

   - “Time Out” extended across process map
   - Tx starts only after ALL QCLs are complete per defined timeline
   - No last minute starts are allowed
   - Cultural shift from ‘just in time’ to ‘cancel if not ready’
The “No-Fly” Approach ...

**Standard Process**

- Rx
- Contour
- Plan
- Review
- Export
- QA
- 2nd Chk

Simulation → Treatment

**Delay-Rushed Process**

- Rx
- Contour
- Plan
- Review
- Export
- QA
- 2nd Chk

Simulation → Treatment

**No-Fly Process**

- Rx
- Contour
- Plan
- Review
- Export
- QA
- 2nd Chk

Simulation → Treatment

Ajay Kapur, Ph.D.
## NO FLY – PROCESS INTERLOCK AND STOPPING RULES

<table>
<thead>
<tr>
<th>Point of Care</th>
<th>Stopping Rule</th>
<th>Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consultation</td>
<td>A consult is rescheduled if records are not obtained 24 hours in advance.</td>
<td>The MD is informed and can veto the cancellation for exceptional circumstances</td>
</tr>
<tr>
<td>Simulation</td>
<td>A ‘Sim_Chart_Check’ is performed the day prior to the simulation and if the prescription, pathology review and/or consent are incomplete, the simulation is rescheduled.</td>
<td>An email is sent to the MD and the on-call MD, either of whom may complete the tasks by 3PM that same day. If not, the patient will get rescheduled when these tasks are complete</td>
</tr>
<tr>
<td>Treatment Start</td>
<td>The MD has 2 days to contour. If there is a delay in contouring, then the start is rescheduled by the same number of delayed days of the contouring.</td>
<td>No recourse</td>
</tr>
<tr>
<td></td>
<td>The MD needs to approve the plan as per QCL due date. If there is a delay, then the start is rescheduled by the same number of days it takes for the MD to approve the plan.</td>
<td>No recourse</td>
</tr>
<tr>
<td></td>
<td>If for any reason during the planning phase, there is a change in the prescription, planning rules or contours, the patient’s start is moved up by 4 business days.</td>
<td>No recourse</td>
</tr>
<tr>
<td></td>
<td>The second plan check identifies a problem with the plan, the patient’s start is moved up by 4 business days.</td>
<td>No recourse</td>
</tr>
<tr>
<td></td>
<td>IMRT QA needs to be complete 48 hours before the patient starts. If not, the patient is rescheduled the following day.</td>
<td>No recourse</td>
</tr>
</tbody>
</table>

Towards a proactive rather than a reactive patient safety culture

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Standardized Process – The Checklist

- Multiple Handoffs Pivoted to Multiple Control Points
- Treatment Start is the Point of Confluence of All Tasks
- Stopping Rules Incorporated into Process Map

Ajay Kapur, Ph.D.
# QCL Compliance Improvements

<table>
<thead>
<tr>
<th></th>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Prescription</td>
<td>69%</td>
<td>27%</td>
<td>1%</td>
</tr>
<tr>
<td>Consent</td>
<td>67%</td>
<td>26%</td>
<td>1%</td>
</tr>
<tr>
<td>Path Reviewed (Sim)</td>
<td>59%</td>
<td>28%</td>
<td>3%</td>
</tr>
<tr>
<td>Contour</td>
<td>21%</td>
<td>6%</td>
<td>0%</td>
</tr>
<tr>
<td>Physics Plan Completed</td>
<td>19%</td>
<td>4%</td>
<td>6%</td>
</tr>
<tr>
<td>2nd Physics Check</td>
<td>8%</td>
<td>25%</td>
<td>8%</td>
</tr>
<tr>
<td>Laterality</td>
<td>91%</td>
<td>16%</td>
<td>0%</td>
</tr>
<tr>
<td><strong>AVERAGE</strong></td>
<td><strong>48%</strong></td>
<td><strong>19%</strong></td>
<td><strong>3%</strong></td>
</tr>
</tbody>
</table>
RESULTS: WORKFLOW IMPROVEMENTS AND STABILIZATION 2009-2011

Combined QCL Performance - All Outliers Included

- **Average Slip Days (Combined QCL Tasks)**
- **Standard Deviation**

**Baseline 2009**  
**Transition**  
**No-Fly**

- **Workflow improvements from Baseline to No-Fly Phases**

Workflow improvements from Baseline to No-Fly Phases
## Improvements in Workflow

### Average Slip Days (STD Deviation)

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescription</td>
<td>10.8 (30.3)</td>
<td>4.1 (11.3)</td>
<td>1.7 (1.0)</td>
</tr>
<tr>
<td>Consent</td>
<td>7.9 (18.6)</td>
<td>4.0 (10.6)</td>
<td>1.6 (1.0)</td>
</tr>
<tr>
<td>Pathology Review</td>
<td>11.1 (21.4)</td>
<td>5.9 (12.3)</td>
<td>(-0.2) (6.4)</td>
</tr>
<tr>
<td>Contour</td>
<td>4.8 (5.9)</td>
<td>3.4 (4.9)</td>
<td>2.8 (3.6)</td>
</tr>
<tr>
<td>Plan Completion</td>
<td>4.8 (7.0)</td>
<td>4.8 (6.8)</td>
<td>4.3 (5.3)</td>
</tr>
<tr>
<td>2nd Physics Check</td>
<td>0.5 (4.5)</td>
<td>0.1 (4.6)</td>
<td>(-0.5) (4.7)</td>
</tr>
</tbody>
</table>
RESULTS – HISTOGRAMS OF SLIP DAYS

HISTOGRAM OF CONTOURING TASK

HIGHER PEAK AT SLIP DAYS = 0

SHIFT TOWARDS 0 SLIP DAYS

HISTOGRAM OF PATHOLOGY REVIEW TASK

HISTOGRAM OF PLAN COMPLETION TASK

MORE EARLY COMPLETIONS

FEWER DEFECTS’ OR DELAYS

HISTOGRAM OF 1st DAY PHYSICS CHECK TASK
Results: Transition to Proactive “Safety First” Culture

- Reduction in Computed Number of No Fly Events
- Most delays are currently proactive
  - Contouring delays, Plan Modifications, Scheduling Errors
- Reporting Efficiency Has Increased
Challenges and Enablers

• Support from Upper Management

• Cross sectional QM Team

• Transitional Phase

• SPC, Monthly Report Outs
Recommendations

- Developing a process map in an EMR
- Quantifying performance of high risk tasks
- Enforcing process interlocks
Discussion

- Analysis of baseline metrics for high risk QCL tasks showed we were at risk, with large variability and last minute rushed completions despite no observed misadministrations.

- Pressures to “treat fast” in environments where upstream tasks are delayed may force rushed physics task completions –such conditions may breed errors.

- Our baseline scores may represent a spectrum of operational efficiencies for many departments.

- Implications for Patient Safety: Detailed QCLs and Operational Procedures may not be enough to mitigate risk

- Quantitative analysis led to Workflow Improvement for Key Stress / Risk Steps ($\mu, \sigma > 3X$; Z score $\sim 20\%$)

- Forced delays for incomplete High Risk QCL tasks support a “Safety First” culture

- 6σ tools led to workflow and safety culture improvements
References


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