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## CASE STUDY: TIMELY DIAGNOSIS OF BREAST CANCER

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**Industry:** Health Care  
**Company Type:** Acute Care Hospital  
**Project Title:** Timely Diagnosis of Breast Cancer  
**Tools Used:** Six Sigma DMAIC

**Project Timeline:** Nine months

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### PROBLEM STATEMENT

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A small, not-for-profit hospital understood the stress that a woman with a suspicious breast lesion goes through waiting for an appointment and receiving diagnostic results. A review of 263 charts revealed that less than 15% of these women received a diagnosis within seven days. Once an appointment for the diagnostic mammogram occurred, only 45% of women received their test results within two days from the time of the procedure. For these women, delays in diagnosis resulted in a lot of “sleepless nights” spent worrying about the outcome.

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### PROJECT GOAL

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The project focused on reducing the number of “sleepless nights” a woman spent waiting for a diagnostic appointment and for the results. Specifically, the goals of the project were to:

- Increase the percent of women receiving diagnostic mammogram results within two days of their appointment, from 45% to 80%
- Increase the percent of the time women with a suspicious breast lesion receive their diagnostic results within seven days, from 15% to 80%

## BUSINESS CASE

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Though the primary goal of this project was to improve the quality of care for potential breast cancer patients, the team anticipated that changes to this process would have additional positive impacts on the business of breast cancer care, including:

- Improved patient satisfaction with mammography services
  - Reduced cost per exam through improved scheduling efficiency
  - Reduced dollars paid in overtime, which sometimes run high because of a schedule that under-anticipates mammography volume
  - Increased diagnostic and surgical volume for breast cancer cases, resulting in increased revenue
  - Adjusted pricing and established profit margin for digital mammograms, resulting in increased revenue
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## PROJECT

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### Overview

The hospital's leadership selected a core, multidisciplinary project team to analyze the reasons for delays in communication of the diagnosis and recommend improvements to reduce the number of "sleepless nights." In addition, the core team identified a support team to serve as a resource to the project which consisted of physicians, diagnostic imaging staff, transcription, scheduling, finance, and information services.

The project scope included all process steps to diagnose a suspicious breast lesion for women with a new onset of suspicion and for women with a previous incident of breast cancer. This included imaging studies to diagnose a suspicious breast lesion such as mammogram, ultrasound, radiological biopsy, and surgical biopsy. The communication processes for these studies, such as all pathology and radiology medical reports, appointment scheduling, and communication of results, was also included. The project did not include an examination of the full radiologist workflow. Situations in which the diagnostic process was aborted for any reason were not included in the project.

### DMAIC Process

The team selected the DMAIC process as its improvement method. A **Six Sigma DMAIC** project is defined as a project that eliminates a chronic problem that is causing patient dissatisfaction, defects, costs of poor quality, or other deficiencies in performance.

## Current Process Capability

- Using data from a physician self-report survey (n=38), the hospital determined that the median number of days women waited to hear the results of their diagnostic procedure was three days. The team considered anything over two days a defect, which generated a short term sigma level for this process of 1.37 with a DPMO of 552,632.
- Using data from a comprehensive 30-month chart review (October 2004 to April 2007), the hospital outlined its current process capability from the number of days a suspicious lesion was identified to results of the diagnosis received. The median was 18 days. The short term sigma level for this process was 0.47 with DPMO at 847,909.

## Voice of the Customer

The Voice of the Customer is a key tool in a Six Sigma DMAIC project that methodically determines what will meet and exceed customer expectations. After selecting the key internal and external customers—patients, physicians, pathologists, surgeons, and the tumor board—the team employed various methods to gather the voices of these customer groups.

55 women with a breast cancer diagnosis participated in a focus group, telephone interview, or survey. Their verbatim comments and responses to questions were translated into the critical-to-quality elements of the process:

- An understanding of what the diagnostic process will be like with no surprises
- The ability to schedule tests in a timely manner
- A short time interval between the test and the phone call to communicate results
- A short time interval between “suspicion” and diagnosis

15 physicians were interviewed, and their comments were translated into their critical-to-quality elements:

- Ability for their patients to get tests scheduled in a timely fashion
- Time interval from “suspicion” to diagnosis should be no more than one week
- Rapid distribution of the radiologist’s report

## Process Design

The team spent time understanding and analyzing its current process maps. The team concluded that variability in the process of communicating test results ( $Y_1$ ) was specific to the procedures of the individual physician offices. The radiologists read exams and dictate reports, but do not communicate with patients. This part of the process then depends on the primary care office receiving the faxed report or looking in the computer (Meditech) for the results and then calling the patient. The team identified that busy office practices often lose track of this step.

The cycle time process ( $Y_2$ ) had several key areas of delay that the team was able to identify through the process mapping exercise. Most of the delays were identified in the system of scheduling both mammograms and biopsies. The key issues identified were:

- Scheduling block too long. The basic unit of scheduling was 15 minutes. Screening tests take 20 minutes but would need to be scheduled for two blocks. Diagnostic tests take 40 minutes and were scheduled for three blocks. With each exam, there were valuable minutes lost during the day.
- No dedicated appointments for diagnostic mammograms. Schedule times were not dedicated to either screening or diagnostic tests. Because screening tests are booked months in advance, those slots filled first, leaving fewer openings for the short-term needs of diagnostic appointments.
- Standard set at 14 days. Scheduling staff was told to book diagnostic appointments within 14 days before calling to obtain something on shorter notice. Voice of the customer data from patients and physicians indicated a desire for a two-day turnaround on diagnostic appointment scheduling.
- No confirmation/reminder system. There was no system to confirm screening appointments which were often made months in advance. These patients were no-shows, tying up valuable slots and associated resources more than 11% of the time.
- Alignment of diagnostic modalities. It was difficult to align the mammogram and ultra sound modalities since they are in different modules of the scheduling program.

## Cause-and-Effect Diagram

The cause-and-effect diagram enabled the team to identify other factors that contributed to the  $Y_1$  and  $Y_2$  problems. Several additional potential Xs were added to the list following the cause-and-effect exercise, including:

### $Y_1$ : Communication

- The Bi-Rad letters sometimes presented a confusing message.
- Errors or missing information in transcription can delay the report from being completed.
- The referring doctor does not always get the order right.
- Not all radiologists read mammograms.
- Emergencies have higher priority.
- Radiologists do not always prioritize mammograms.
- The radiologists have a busy daily schedule filled with interventional procedures.
- Patients are not always home when the call comes.

### $Y_2$ : Cycle Time

- Radiologists do not schedule dedicated mammogram dictation time.
- Biopsy decisions require physician-to-physician communication.
- Referring physician does not always order the right tests.
- Radiologists consider mammograms lower priority for reading.

## Vital Few Xs

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With sigma levels for both Ys indicating more than a 50% defect rate, the team decided it was futile to conduct additional statistical analysis on potential variables to determine root causes. Analysis of the process flow diagrams, cause-and-effect diagrams, and impact/control analysis revealed the root cause without advanced statistical analysis – there was not a reliable, standardized process for diagnosing breast lesions that met customer expectations. In order to improve the experience for women with suspicious breast lesions and reduce the number of “sleepless nights” they encountered, the team would have to create a new process from scratch that met the women’s needs and ensured the process was capable of delivering the expected turnaround and cycle times.

Using these analysis tools, the team zeroed in on a few key breakdowns in the existing process that would need to be addressed in a new process to reduce the time from diagnostic exam to results received ( $Y_1$ ). These included:

- The radiologists do not typically devote specific time increments to reading diagnostic mammograms.
- Referring physicians are not always aware that the test results are available in Meditech.
- Radiologists do not have time to communicate with patients, so they rely on the referring physicians to do so.

The team also identified several key breakdowns for the overall process from suspicion to diagnosis cycle time ( $Y_2$ ). These included:

- The need to align the diagnostic mammogram and ultrasound appointments.
- The need to shorten the 14-day window allowed for scheduling diagnostic mammograms.
- The need to separate the diagnostic mammogram slots from the screening of appointments to ensure enough capacity.
- The need to adjust the 15-minute blocks to 10 minutes.

## Implementation and Control

First the team designed a short-term pilot test to guide them in process re-design. They recruited from the active medical staff and obtained 12 recruits. The team developed forms for tracking the patients of those invited physicians.

The team decided that the new process would consist of two key features that provided solutions to many of the root causes. First, the team developed new “if/then” standing orders that expedited a patient getting a diagnostic mammogram if there was something suspicious found on the screening mammogram. Second, the team developed a role for a Breast Health Navigator. This person’s sole responsibility was to help steer the patient quickly through the diagnosis process; providing rapid communication to the patient, assisting with exam scheduling, and serving as a liaison with the referring physician. The team captured data from this pilot process for two months.

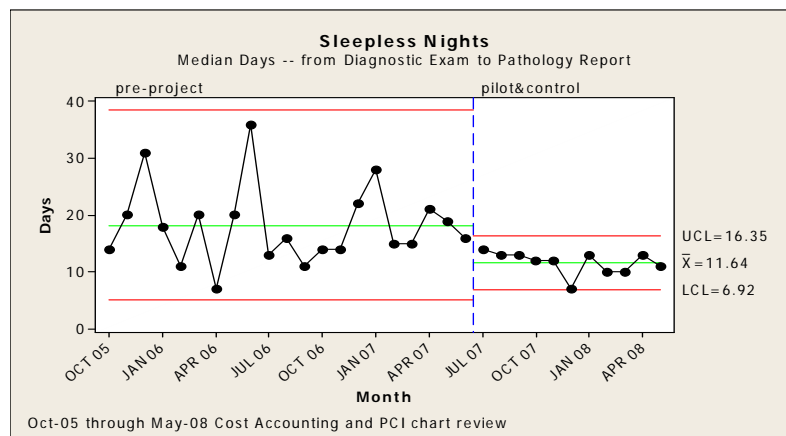
While the pilot was underway, the team also worked to develop a new patient schedule based on 10-minute appointment blocks. They used the two previous year's volume statistics to approximate the number of dedicated diagnostic mammogram slots with the goal of exceeding the demand. During this same time, a new Women's Imaging Center was opened. The team continued to track data, troubleshoot issues with the new facility, and tweak the implementation of the two key features.

## SUMMARY OF RESULTS

During the pilot phase, the median time from the diagnostic appointment to results received ( $Y_1$ ) reduced from three days to zero days. In most cases, women received their results prior to leaving the office. Also, during the pilot phase, the median cycle time from suspicion to communication of diagnosis, or "sleepless nights" ( $Y_2$ ), was reduced from 18 days to 9.5 days.

Eleven months following the completion of the project, the team's  $Y_1$  goal of communicating test results to patients in less than two days has been sustained. The median number of days remains at zero. 91% of all women diagnosed receive their test results the same day. This is due to the role of the Breast Health Navigator (RN) who can act as an extension of the physicians in the role of communicating directly with patients.

The team found they were unable to sustain the pilot results for sleepless nights, but drastic improvements were nonetheless documented. In the 11 months between July 2007 and May 2008, the median sleepless nights held steady at 11.64 days. What is perhaps more remarkable about this result is how consistent it has been, especially when compared to the cycle time performance prior to the project. This control chart shows the improvements in process reliability as a result of the project:



Other results outlined in the business case for the project are summarized below:

- Patient Satisfaction: Mean scores for mammography on Press Ganey surveys increased from 91.2 to 95.1, with an increase in national percentile ranking from the 17<sup>th</sup> to 99<sup>th</sup> percentile.
- Cost per Exam: Efficiencies in the new process should reduce the cost per exam.



- Overtime Dollars: For the first six months following the project completion, overtime costs ran \$5,380 as compared to a prior six-month period when overtime expenses were \$12,500.
- Exam Volume: There was no increase in the volume of diagnostic mammograms over the same time period in the previous year. However, there has been a 29% increase in the volume of screening mammograms.
- Pricing: Under the old pricing structure, we showed a net loss of \$387,454 between October 2006 and May 2007. During that same time period in the current fiscal year, there was a net gain of \$47,693. This was due to the pricing adjustments and volume increases that resulted in the work of the project team.

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## CASE STUDY: IMPROVING COMPLIANCE WITH HEART FAILURE DISCHARGE INSTRUCTION

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<b>Industry:</b>	Health Care Based Companies
<b>Company Type:</b>	Not-for-Profit Health Care System
<b>Project Title:</b>	Improving Compliance with Heart Failure Discharge Instruction
<b>Tools Used:</b>	Six Sigma DMAIC
<b>Project Timeline:</b>	Six months

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### PROBLEM STATEMENT

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A not-for-profit health care system found that adherence to clinical quality observed metrics for inpatient heart failure discharge instruction (HF-1) was consistently below national standards. For FY 2006, the average observed rate of compliance was 45.3%. Noncompliance could result in penalties with reimbursements from the Centers for Medicare and Medicaid Services (CMS), additional costs because of the potential of harm events, and a decrease in patient satisfaction.

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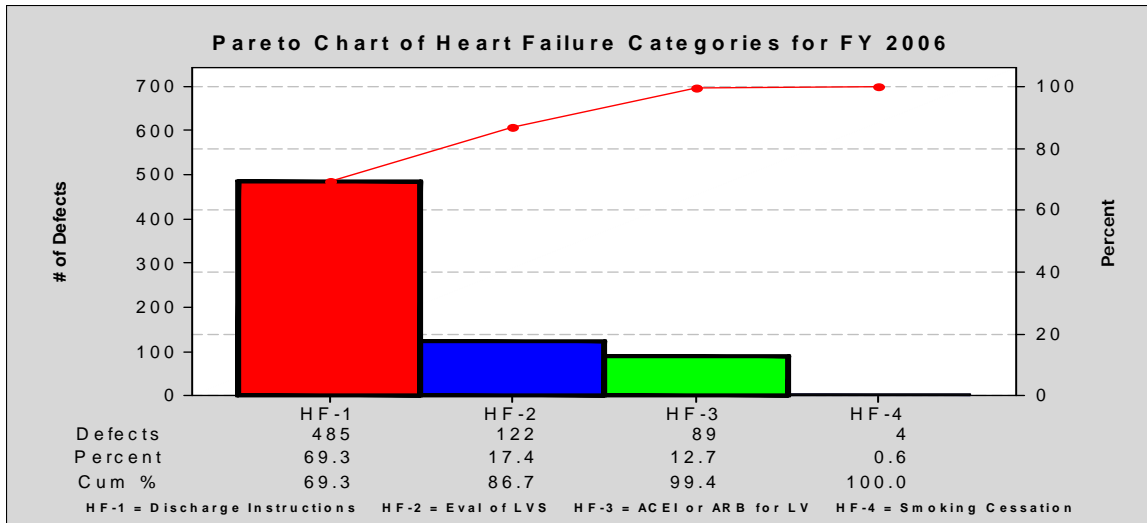
### PROJECT GOAL

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The project goal was to increase the observed rate of compliance for inpatients receiving heart failure discharge instruction from 45.3% to at least 90% by January 2008. Heart failure discharge instruction included written instructions or educational materials addressing a patient's activity level, diet, discharge medications, potential follow-up appointments, weight monitoring, and what to do if their symptoms worsened.

The project also aimed at getting full reimbursement from the Centers for Medicare and Medicaid Services with no paybacks.

Heart failure discharge instruction (HF-1) was selected as the project Y, because it contributed to 49% of defects within the heart failure category. Heart failure defect rate is shown in the following Pareto chart.



HF-1 (DC instructions) had the highest rate of defects compared to the other three heart failure quality measures.

## BUSINESS CASE

The Chief Financial Officer conducted a cost-of-poor-quality analysis and determined that the organization would pay back the Centers for Medicare and Medicaid Services approximately \$68,000 each year if compliance scores remained at or below the 45<sup>th</sup> percentile. There was also an associated revenue bonus opportunity for hospitals that demonstrated the greatest improvement in scores.

## PROJECT

### Overview

The project team was led by the Director of Outcomes Management. The Chief Nursing Officer was selected as the project champion. The team consisted of a wide variety of clinical and support personnel. Its members represented outcomes management, nursing, respiratory, professional practice, medical staff, and finance.

The project Y was the percent of correct discharge instructions for heart failure inpatients. The beginning boundary for the project was the time a patient was admitted to the hospital. The ending boundary was the time a patient was discharged from the hospital. Excluded from the project were heart failure patients discharged from the emergency department and heart failure patients with comfort measures only.

## DMAIC Process

The team selected the Six Sigma DMAIC process as its improvement method. A Six Sigma DMAIC project is defined as a project that eliminates a chronic problem that is causing patient dissatisfaction, defects, costs-of-poor-quality, or other deficiencies in performance.

## Voice of the Customer and CTQ Matrix

Voice of the Customer is at the heart of the Six Sigma DMAIC process – a methodical approach to understanding customer requirements. After selecting the key external and internal customers – patients, family and family caregivers, and Centers for Medicare and Medicaid Services as the most important external customers, and physicians, staff nurses, respiratory therapy, and outcomes management as the vital internal customers – the project team conducted structured interviews with members of each customer group.

Following the collection of the customer “voice,” responses were then translated to the underlying key issues that the customers were communicating. For instance, a nurse stated, “We don’t have a process for heart failure discharge instruction.” The related key issue identified was “variability of discharge instruction.”

Once key issues were identified, the team translated the key issues to “critical-to-quality” (CTQ) needs. The key issue cited in the example above was assigned a CTQ of “having a defined process for heart failure discharge instruction.” Critical-to-quality needs were then translated into project Ys. The project Y for this CTQ was “compliance to a standardized discharge process.” The following is a snapshot of the CTQ matrix.

Customer	Voice of Customer	Key Issues	CTQ	Y
Nurse	“Don’t have a process for heart failure discharge instructions”	Variability of discharge instructions	Having a defined process for heart failure discharge instructions	Compliance to a standardized discharge process
Patient	“Informs me that I can leave at 9:30 am but I couldn’t get the discharge paperwork until 12:00 pm. I kept asking everyone that came by”	Adequate ancillary support	<ul style="list-style-type: none"> <li>▪ Continuum of care</li> <li>▪ Demand match labor</li> <li>▪ Communication among caregivers</li> </ul>	Adequate staffing levels
Unit Secretary/Ancillary Support	“If we remember, we place them on the chart”	Variability of discharge instructions	<ul style="list-style-type: none"> <li>▪ Communication among caregivers</li> </ul>	Compliance to a standardized discharge process
Physicians/OM	“No clear diagnosis of heart failure on admission”  “No cardiac education offered seven days a week”	Unclear diagnosis can cause omissions or unanticipated discharge	<ul style="list-style-type: none"> <li>▪ Evidence based practice</li> <li>▪ Diagnosis trigger</li> <li>▪ Discharge planning</li> <li>▪ Accuracy of discharge education</li> </ul>	Compliance to a standardized discharge process

## Cost-of-Poor-Quality (COPQ)

The Chief Financial Officer calculated the cost-of-poor-quality for the project team:

- The number of heart failure cases in one year = 1,214
- Average Medicare reimbursement/case = \$5,617.54
- Total reimbursement = \$6,819,693.50
- 1% payback to CMS for poor performance = \$68,196.94
- (Below the National Standards and Joint Commission public websites for heart failure discharge instructions compliance)
- Defects per million opportunities (DPMO) = 546,787
- Sigma Level = 1.38 (short term)

## Process Design

The project team spent time understanding and analyzing the current process for completing the heart failure discharge instruction form. Several potential failures to the process were identified, including:

- Assigning heart failure as a working diagnosis
- Not putting the correct discharge instruction form on the patient chart
- Heart failure discharge form not available when needed
- Medication reconciliation not complete at time of discharge
- Heart failure discharge instruction form missing from patient chart
- Physicians discarding heart failure discharge instruction form

## Cause-and-Effect Diagram

Using a cause-and-effect diagram, the project team identified potential causes of non-compliance with the heart failure discharge instructions:

- Lack of a defined process for completing heart failure discharge instruction
- Number of physicians and nurses involved in the process
- Staff-to-patient ratio
- Manual process for completing heart failure discharge instruction form
- Level of staff education and training
- Documentation issues with education, specific orders, unclear diagnoses of heart failure, etc.

## Failure Modes and Effects Analysis (FMEA)

Failure modes and effects analysis (FMEA) is a tool that identifies possible failures in a process or product. Using FMEA, the project team identified the following as potential failures:

- No heart failure discharge form available
- Inadequate discharge planning
- Multiple discharge forms and types
- No single, definitive process owner
- Lack of standardized process
- Physicians discarding the heart failure discharge instructions
- Medication reconciliation incomplete at time of discharge
- No accountability or ownership of process compliance

## Vital Few Xs

Utilizing Juran's Pareto analysis, the project team was able to identify the vital few Xs that were contributing to non-compliance with heart failure discharge instruction. They found that compliance was impacted by:

- The nursing unit discharging the patient
- The specific type of pre-printed physician heart failure discharge instruction form
- The hospital employees' knowledge level of the six discharge instruction elements:
  1. A patient's activity level
  2. His/her diet
  3. His/her discharge medications
  4. Any potential follow-up appointments
  5. His/her weight monitoring
  6. What a patient should do if their symptoms worsened.
- Having all six discharge instructions on the various pre-printed physician cardiac forms

## Implementation and Control

The project team developed improvement strategies for the proven vital few Xs, which included:

- Standardizing the discharge process across all nursing units
- Standardizing the most effective type of discharge instruction
- Improving the knowledge level of the heart failure discharge instruction elements unit-by-unit with one-on-one training
- Standardizing and simplifying the heart failure discharge instruction process

## **SUMMARY OF RESULTS**

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Based on a three-month pilot, the project was able to reach its goal of a 90% compliance rate with heart failure discharge instruction. A control plan was developed to monitor the observed rate of compliance and use of the heart failure discharge form on a monthly basis.

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