Risk mapping and patient safety in diagnostics

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Outline of the presentation

- Introduction of Rizzoli Institute
- Project’s reasons and objectives
- Method
- Results
- Opportunities and Limits
Who we are

- Rizzoli Orthopaedic Institute in Bologna, chief town of Emilia-Romagna Region, is the main Italian hospital of orthopedics and traumatology.

- The hospital is set in a monastic monumental complex of great artistic value: Carracci's octagonal cloister, frescoed by Ludovico Carracci and Guido Reni, the monks' ex-refectory decorated by Giorgio Vasari, and the library frescoed in the 1600s by Domenico Maria Canuti.
Who we are

- In 1981 the Italian Health Ministry gave Rizzoli the status of a 'Scientific research hospital' due to its high level of healthcare in orthopedics and traumatology.

The Hospital Rizzoli’s “Sala Vasari” - Monks' ex-refectory decorated by Giorgio Vasari
The Rizzoli in numbers

- N. of beds: 327
- N. total discharged: 20,463 (54% of patients from outside the our Region)
- Percentage of surgical cases (DRG): 66,3%
- N. admitted to Emergency: 25,024
- N. personnel staff total: 1,241

Provenance of hospitalized patients

Risk management at Rizzoli

- Program active since 2007
- Systemic approach to safety
- Integration to Quality system
- Application of proactive and reactive methods and tools (IR, RCA, SEA, Chart Review, FMEA...)

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The project: Mapping risks in diagnostic services

Aims

- Map the main diagnostic processes by proactive risk analysis technique (Fmea/Fmeca)
- Identify potential errors and define prioritary actions for prevention of the risks
The family of patient safety targets that includes diagnostic errors, diagnostic delays, and other diagnostic misadventures is not fully defined with clear boundaries.

A systematic review of 53 different series of autopsies reported a median diagnostic error rate of 23.5%.

Studies report from 25% to 59% of malpractice claims attributable to diagnostic errors.

About 35,000 patients might have survived to discharge from United States hospitals annually had misdiagnosis non happened.
Local background

- Rizzoli’s reporting systems showed a diagnostic error rate of 12.5% from voluntary Incident reporting and of 10.6% from malpractice claims.

Source: Rizzoli Orthopaedic Institute. Risk Management Reports - Year 2011
Project’s steps and Participants

- Literature review
- Education personnel staff
- Diagnostic processes’ risk analysis
- Interventions for prevention of potential errors
- Assessment of efficacy of actions

- Clinical Pathology
- Anatomy and Pathological Histology
- Medical Genetics and Rare Orthopaedic Diseases
- Immunohematology and Transfusion Medicine and Cell and Musculoskeletal Tissue Bank
- Diagnostic and Interventional Radiology & Picture Archiving and Communications System (PACS)
Diagnostic processes

- **Laboratory processes:**
  - "Production manual platelet-rich plasma (PRP)"
  - "Isolation, expansion and release of autologous chondrocytes and mesenchymal stem cells"
  - "Treatment of histological samples"
  - "Path of the biological sample in the clinical pathology laboratory"
  - "Diagnostic activities for patients with rare genetic diseases"

- **Radiological processes:**
  - "Performing Computed Tomography with contrast medium in hospitalized patients"
  - "Acquisition of radiological images produced elsewhere"
Materials

- Failure Modes and Effect Analysis (Fmea) is a proactive risk analysis technique applied in healthcare to identify potential risks in clinical processes (qualitative analysis).
- Failure Modes and Criticality Effect Analysis (Fmeca) adds a quantitative estimation of ‘failure modes’ for identify priority interventions.
# Methods and steps

**Before-after study (January 2011-June 2012)**

<table>
<thead>
<tr>
<th>Description Task</th>
<th>Start</th>
<th>End</th>
<th>Month 2011</th>
<th>Month 2012</th>
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<tbody>
<tr>
<td>Involvement of Diagnostic Departments' Clinical Heads</td>
<td>01/01/2011</td>
<td>15/02/2011</td>
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<td>Selection of diagnostic process to analyze</td>
<td>01/03/2011</td>
<td>31/03/2011</td>
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<td>Setting up and education of multidisciplinary groups</td>
<td>01/04/2011</td>
<td>31/05/2011</td>
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<tr>
<td>Identification of potential ‘failure modes’ into processes</td>
<td>01/05/2011</td>
<td>30/06/2011</td>
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<tr>
<td>Measurement of Index Risk (Risk Priority Number)</td>
<td>15/05/2011</td>
<td>30/06/2011</td>
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<td>Realization of interventions to reduce the risks</td>
<td>01/07/2011</td>
<td>31/12/2011</td>
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<td>Monitoring of indicators</td>
<td>01/01/2012</td>
<td>30/06/2012</td>
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<tr>
<td>Re-evaluation of processes after improvements</td>
<td>01/06/2012</td>
<td>30/06/2012</td>
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Results (1)

- 75 improvement actions were carried out divided into four categories:
  - **Structured process changes**
  - **Educational interventions**
  - **Technology-based interventions**
  - **Infrastructure/Building interventions**
Results (2)

- Reduction of the Risk Index (RPN) for all diagnostic processes (measured after 6 months since improvement actions)
- Reduction of diagnostic errors from a rate of 12.5% to 7.9% (Report Incident Reporting 2012)
Improvements actions: some examples

Barcode printer and write on labels in cryo-resistant polyester (Laboratory)

New informatics mode for acquisition of radiological images produced elsewhere (Radiology & PACS)
Transferability: the success factors

- Get a high commitment of top management and clinical heads
- Carry out educational interventions for all involved personnel
- Have a multidisciplinary approach and close tutoring of working groups
- Give regular feedback and implementation of improvement actions

The Hospital Rizzoli’s Library frescoed in the 1600s by Domenico Maria Canuti
Conclusions and learned lessons

- This collaborative project has proved to be able to improve the safety of the main diagnostic processes
- Need to monitoring processes minimum annually by FMEA/FMECA
- The FMEA/FMECA as operational tool require a local adaptation to the specific settings
Thank you for your attention and we invite all of you to visit us...

The panoramic view of Bologna town from the hill of the Church of S.Michele in Bosco