



SERVIZIO SANITARIO REGIONALE
EMILIA - ROMAGNA
Istituto Ortopedico Rizzoli di Bologna
Istituto di Ricovero e Cura a Carattere Scientifico



Risk mapping and patient safety in diagnostics

Patrizio Di Denia, Maurizia Rolli, Elisa Porcu, Stefano Liverani
Rizzoli Orthopaedic Institute in Bologna, Italy

Wien, October 2nd, 2014



▶ 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.



The Hospital Rizzoli and the church of San Michele in Bosco

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.

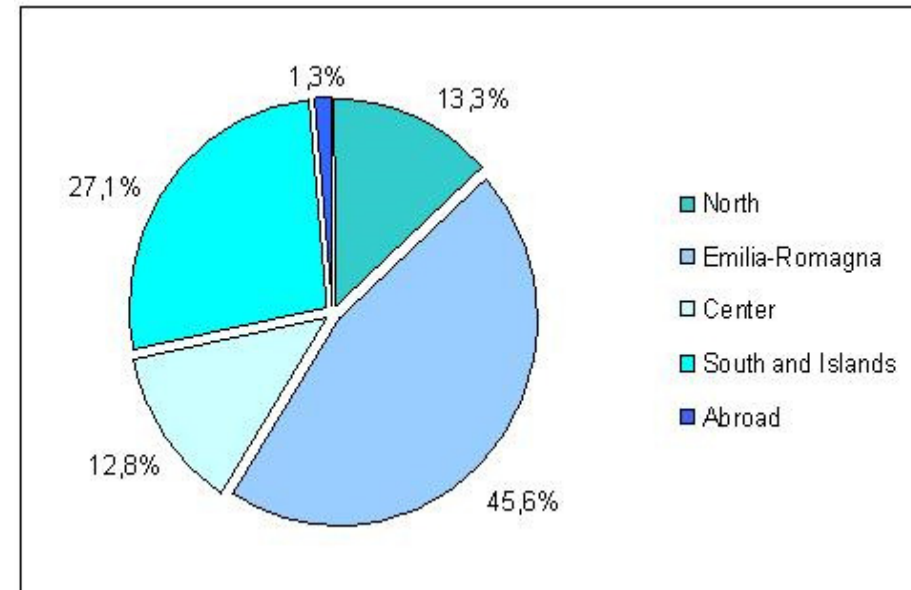


The Hospital Rizzoli's "Sala Vasari" - Monks' ex-refectory decorated by Giorgio Vasari

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

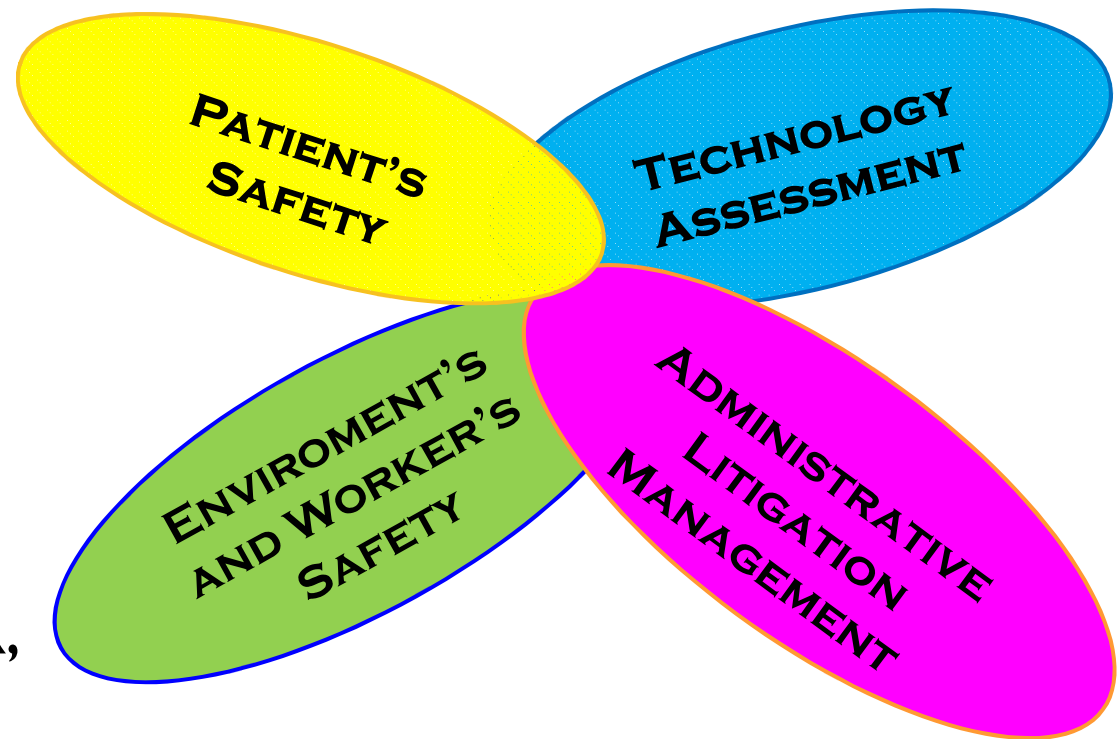
Provenance of hospitalized patients



Source: Rizzoli Orthopaedic Institute.
Annual Report - Year 2012

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...)



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 priority actions for prevention of the risks



How important is the problem?

A recent evidence

Annals of Internal Medicine

SUPPLEMENT

Patient Safety Strategies Targeted at Diagnostic Errors

A Systematic Review

Kathryn M. McDonald, MM; Brian Matesic, BS; Despina G. Contopoulos-Ioannidis, MD; Julia Lonhart, BS, BA; Eric Schmidt, BA; Noelle Pineda, BA; and John P.A. Ioannidis, MD, DSc

- ▶ *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 not happened.*

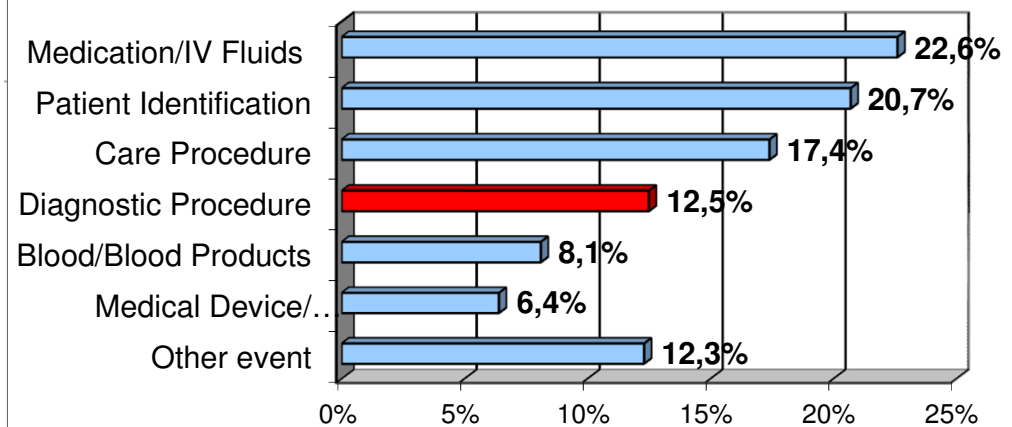
5 March 2013 | Annals of Internal Medicine | Volume 158 • Number 5 (Part 2) |

Local background

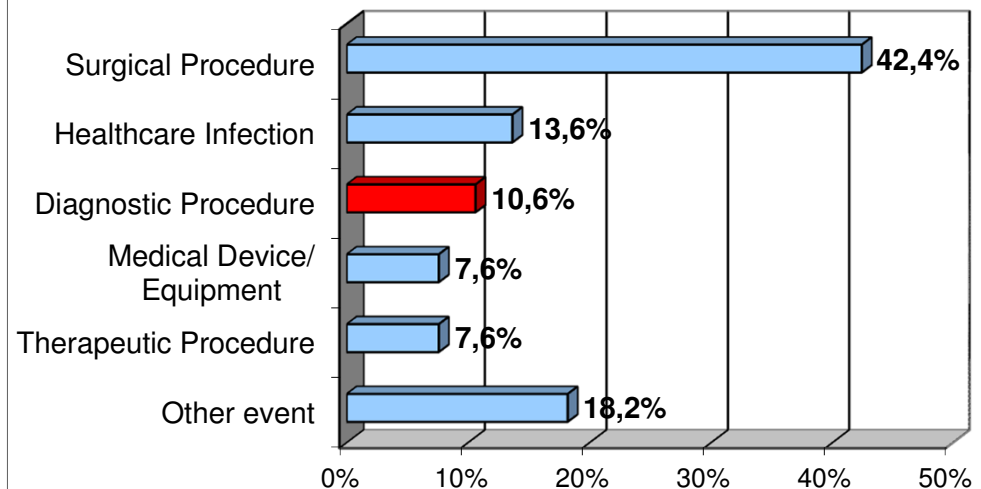
- ▶ Rizzoli's reporting systems showed a diagnostic error rate of 12,5% from voluntary Incident reporting and of 10,6% from malpractice claims

Source: Rizzoli Orthopaedic Institute. Risk Management Reports - Year 2011

Incident Reporting - Year 2011



Malpractice Claims - Year 2011



Project's steps and Participants

- ▶ Literature review
 - ▶ Education personell 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 health care 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

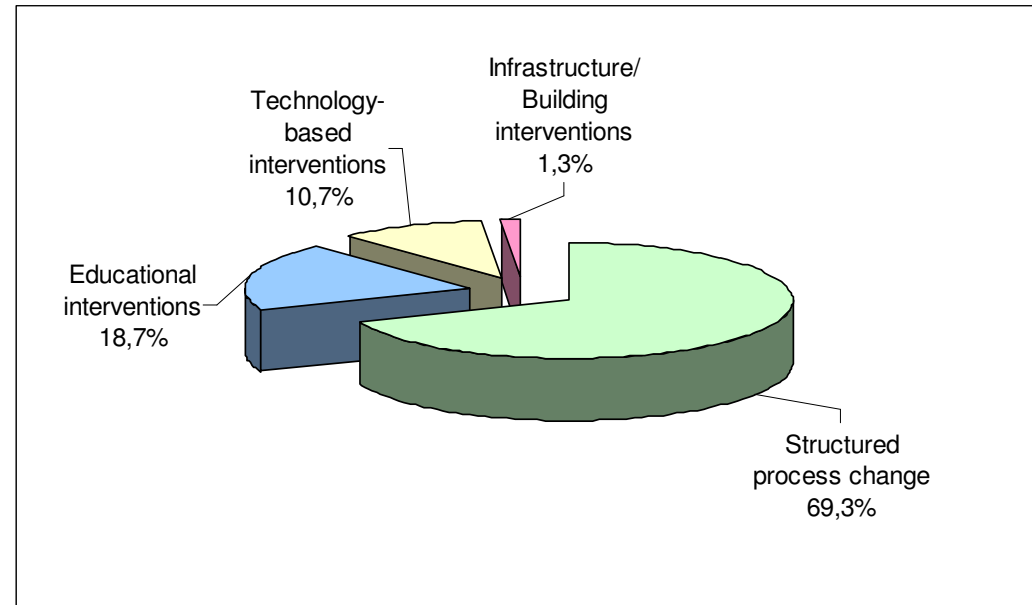
Before-after study (January 2011-June 2012)

Description Task	Start	End	Month 2011												Month 2012							
			1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6		
Involvement of Diagnostic Departments' Clinical Heads	01/01/2011	15/02/2011	█	█																		
Selection of diagnostic process to analyze	01/03/2011	31/03/2011		█																		
Setting up and education of multidisciplinary groups	01/04/2011	31/05/2011			█	█																
Identification of potential 'failure modes' into processes	01/05/2011	30/06/2011				█	█															
Measurement of Index Risk (Risk Priority Number)	15/05/2011	30/06/2011				█	█															
Realization of interventions to reduce the risks	01/07/2011	31/12/2011						█	█	█	█	█	█	█								
Monitoring of indicators	01/01/2012	30/06/2012													█	█	█	█	█	█		
Re-evaluation of processes after improvements	01/06/2012	30/06/2012																			█	



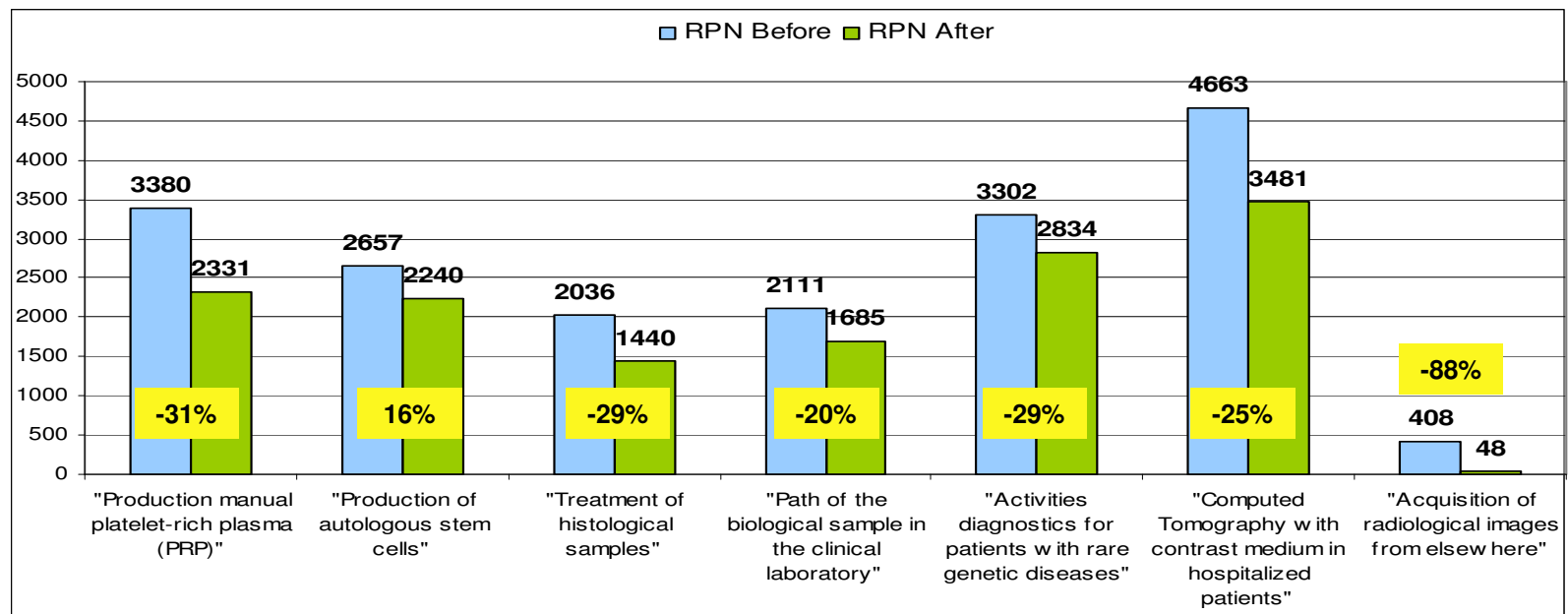
Results (1)

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



Results (2)

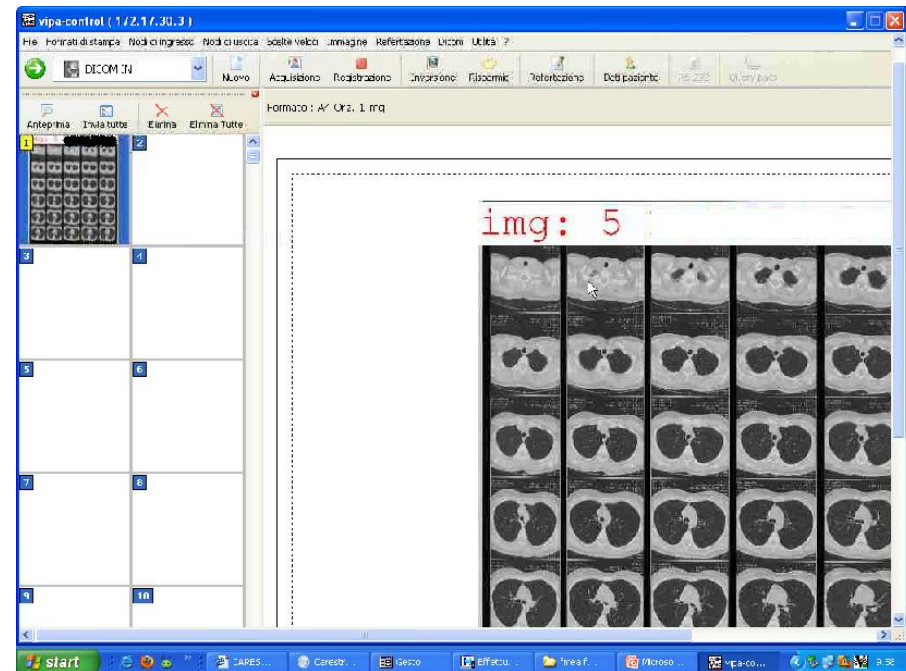
- ▶ Reduction of the Risk Index (RPN) for all diagnostic processes (measured after 6 months since improvement actions)
- ▶ Reduction diagnostic errors from a rate of 12,5% to 7,9% (Report Incident Reporting 2012)



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



The Hospital Rizzoli's Octagonal Cloister, frescoed by Ludovico Carracci and Guido Reni

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