From local to national: compensation management and the Italian patient safety law

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A model for patient safety management

**Risk analysis**
- Risk identification
  - Clinical processes
    - Clinical risk manager
  - Management processes
    - Patient safety manager

**Risk anticipation**
- Safety assessment
  - Safety measurement
    - PSI Outcomes Record review
    - Patients

**Safety Control**
- Accreditation Walkarounds
  - RCA FMEA

**Safe practices**
- CPD
  - SEA M&M
  - Reporting Triggers Observations Patients

Bellandi T et al 2011, *In Handbook of Human Factors and Ergonomics in Health Care and Patient Safety*
Patient safety in Tuscany

*The public healthcare service of the Tuscany Region*
> To serve 3.6 millions citizens, with 50000 employees, 36 hospitals and more than 100 primary care districts

*The Human Factors for patient safety*
> 2498 facilitators on the front line, distributed in each ward
> 38 risk managers and patient safety managers
> 53 expert patients trained in quality ad safety at the citizens academy
> 48992 participants in patient safety CPD courses in one year

*Learning curve*
> 2004> 443 incident reports
> 2015> 10447 systems analysis of incident reports
> 2006> 2 safety practices
> 2015> 32 evidence based safety practices
Integrate communication and compensation

*Training on difficult communication of adverse events*
> 2009 > A problem-based training programme targeted to doctors included in the professional and organizational requirements  
https://www.youtube.com/channel/UC0fyJs8gtLBe_pBSX9FE1uA
> 2014 > Active participation of patient champions as simulated patients in training sessions for risk managers

*Dedicated information system for clinical risk management*
> 2007 > Regional software for the registration of claims
> 2016 > Integrated system to manage claims and reporting of adverse events  
https://sigrc.sanita.toscana.it/

*Second opinion on catastrophic events*
> For claims over 100K€ volountary consultation of the second opinion, when over 500K€ second opinion is mandatory before the compensation
Trend of claims

Trend of claims in Tuscany is slightly decreasing, with a rate of 0.1% on hospital admissions. Average cost is also decreasing from 43 to 35 €.

The annual cost of in-house compensation management system is about 45 M euros per year, of which 20 paid and 25 reserved. According to brokers’ esteem, a private insurance would cost around 70-80 M euros per year.

Vainieri M et al 2015
The burden of unsafe care in Italy

Retrospective record review of 7573 hospital admissions in 5 hospitals, 5.3% of adverse events, 9.5% of AE resulting in death or severe harm.

AE incidence = 5.3%

Preventable adverse events 53.2%

Costs for extra hospital days € 2,869,728,312.51

Estimated cost for compensation: 1bln euros
Estimated cost for defensive medicine: 10bln euros
## Prevention through safety practices

<table>
<thead>
<tr>
<th>Safety practice</th>
<th>Pilot studies in Tuscany (2006-2016)</th>
<th>Outcome measures from third parties</th>
</tr>
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<tbody>
<tr>
<td>Intensive care</td>
<td>+ 50% compliance with CVC bundle</td>
<td>Lowest mortality rate in Italian ICU registry (<a href="#">Giviti, 2015</a>)</td>
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<tr>
<td>Surgical safety</td>
<td>+ 70% compliance with checklist and anticipation of more than 300 errors</td>
<td>- 7.4% in PSI post-op sepsis (<a href="#">MeS, 2016; World sepsis award 2016</a>)</td>
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<tr>
<td>Maternal safety</td>
<td>+ 28% quality of the partogram</td>
<td>Lowest maternal mortality in Italy, 4 on 1000 newborn (<a href="#">ISS, 2014</a>)</td>
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<tr>
<td>Falls prevention</td>
<td>- 60% of falls - 4 days of hospital stay</td>
<td>- 59% of claims related to patient falls (<a href="#">MeS, 2016</a>)</td>
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<tr>
<td>Medication safety</td>
<td>- 40% of medication errors due to transcriptions</td>
<td>- 26% in PSI post-op deep vein thrombosis (<a href="#">MeS, 2016</a>)</td>
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</tbody>
</table>
Law on patient safety

Patient safety is a fundamental right of each individual within any healthcare service and it is a primary goal of the National Healthcare Service.

Healthcare providers promote the continuos evaluation of clinical risks and appropriate delivery of care, in order to prevent harm and defensive medicine.

The guidelines recognized by the National Institute of Health assume the role of fair and balanced recommendation for health care professionals, that when applied protect the healthcare professionals from legal prosecution.

Documents from Reporting and Lerning Systems can not be acquired or used as part of legal actions against healthcare professionals.
Past, present and future challenges

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