Integrated Clinical Risk Management in Hospitals

Prof. Dr. Rainer Sibbel

Düsseldorf, November 17th, 2016
Hospital Management – key area of tension

Relevance of clinical and business risk management

Clinical risk management – status of implementation

Integrated quality and risk management approach

Perspectives of risk management in hospitals
Hospital management – key area of tension

And...? Is there any room for hope...?

We will calculate it...!

... between quality and cost pressure
The magic triangle of success

Core management issue:

High Quality

Low Costs  Short LoS

Quality – leverage to effectiveness and efficiency
Patient safety and clinical risk management

• “To Err is Human” - Study of the Institute of Medicine (1999): 98,000 US-patients die annually due to malpractice and adverse events (American Hospital Association), in the top 10 of mortality
• Hospital closure Las Vegas 2008 due to multiple use of non-sterile unclean syringes: up to 40,000 harmed patients
• 500,000 to 800,000 cases with nosocomial hospital infections per year in Germany (Robert-Koch-Institut), up to 4000 death per year
• “Tatort Krankenhaus: Erst verpfuschen – dann vertuschen” (ARD) („Crime scene hospital: first hack up – then hush up“)
• Talk shows, TV reports, magazines, newspapers, word of mouth …

Hospitals are high-risk-institutions – increasing awareness
Patient safety and clinical risk management

- 4 million cases of hospital infections per year in the EU (EC)
- 10% of patients admitted to a hospital get infected there (EC)
- 37,000 death per year in Europe (21% more than by traffic accidents) (EC)
- 2.6 million cases of hospital-acquired infections in the EU and 91,000 death per year, 5% of patients get infected (Cassini et al. 2016)
- Costs in Europe: 7 billion Euro (WHO)

High relevance and impact of clinical risks!
Patient safety and clinical risk management are minimal standards of quality management!
What type of human glitches cause harm?
- Root Causes **Sentinel Events by Year**

<table>
<thead>
<tr>
<th></th>
<th>2013 (N=887)</th>
<th>2014 (N=764)</th>
<th>2015 (N=936)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human Factors</td>
<td>635</td>
<td>547</td>
<td>999</td>
</tr>
<tr>
<td>Communication</td>
<td>563</td>
<td>517</td>
<td>849</td>
</tr>
<tr>
<td>Leadership</td>
<td>547</td>
<td>489</td>
<td>744</td>
</tr>
<tr>
<td>Assessment</td>
<td>505</td>
<td>392</td>
<td>545</td>
</tr>
<tr>
<td>Information Management</td>
<td>155</td>
<td>115</td>
<td>202</td>
</tr>
<tr>
<td>Physical Environment</td>
<td>138</td>
<td>72</td>
<td>125</td>
</tr>
<tr>
<td>Care Planning</td>
<td>103</td>
<td>72</td>
<td>75</td>
</tr>
<tr>
<td>Continuum of Care</td>
<td>97</td>
<td>59</td>
<td>62</td>
</tr>
<tr>
<td>Medication Use</td>
<td>77</td>
<td>58</td>
<td>60</td>
</tr>
<tr>
<td>Operative Care</td>
<td>76</td>
<td>57</td>
<td>52</td>
</tr>
</tbody>
</table>

Complex continuous behavioral and managerial issue!

JCAHO Sentinel Event Statistics, 2015
© frankfurt-school.de
Patient safety and clinical risk management

Key reasons for safety issues:

• Increasing workload (increasing number of cases with decreasing length of stay) → **individual reasons**

• Lack of coordination between departments (organisational and communication deficits) → **organisational reasons**

• **System related reasons:** „peoples business“, many (sick) people packed; hospitals are complex social systems, profession based expert organisations

Work pressure and cost pressure are forcing product and handling related risks!

Medical errors are most often system related errors and are caused mainly by organisational deficits!

Risk management is not only a clinical, but also a managerial challenge in hospitals!
Business risk management

- Legal framework: KonTraG, Basel II (Financial risk management)
- Study RWI et al. (2015): 16 % of german hospitals have a high risk of insolvency and are in deep financial trouble
- Accenture (2014): 46 % of hospitals in Europe are financially not viable
- Patient data and IT safety
- Liability cases:

![Graph showing liability cases from 2010 to 2014](image)

Quelle: Bundesärztekammer 2015
Business risk management

Liability cases:

- Hospitals are independent service providers and business entities
- Clinical risk management is very relevant and an essential part of a comprehensive integrated risk management approach!
Drivers of structural changes in healthcare

- Demographic trends
- Medical and technical progress
- Growing competition
- Social value change
- General legal framework

Structural changes force increasing cost pressure and competition (environmental and market related risks)

Traditional leadership and organisational structures as well as cost containment policies as source of internal risks!
Integrated risk management - dimensions

Clinical risks are core business risks!
Clinical risk management in Germany – status quo

• Comprehensive strategic framework often missing
• Increasing awareness and implemented steps of clinical risk management
• Broad spectrum of individual measures in place
• Lack of dedicated and qualified staff
• No lack of knowledge and application of tools and techniques for risk identification and analysis
• Range of quality and safety indicators
• Risk management process not comprehensive and closed
• Documentation and reporting rarely done and communicated systematically
• Additional resources necessary, but safety and management culture more important

Clinical risk management in Germany – status quo

• Relevance, impact and benefit of risk management highly valued
• Interface management, medication, falls and infection as main focus
• Local CIRS systems more and more in place
• Non-integrated clinical view on risk management
• Psychiatric and psychosomatic clinics are different
• Main challenges:
  ▪ Open failure and safety culture
  ▪ Process orientation
  ▪ Top management support
  ▪ Patient empowerment and involvement

Basic maturity, phase of learning and improvement!

Clinical risk management in Europe – impression

• Hugh variety of QM and CRM implementation in european hospitals
• Regulatory framework and national policies have a strong influence
• External assessment and accreditation as major driver for implementation
• Structured comprehensive risk management process hardly in place
• Communication and safety culture as key managerial challenge
• Self assessment and satisfaction: „Half the way done!“
• Hospital size matters in sense of resources, not in sense of process
• Need for more standardized processes and procedures
• Need for external support and trainings
• More focus on prevention and risk related costs

Ongoing european study about risk management: Link at www.eahm.eu.org

Source: Lombarts et al. (2008), own study
Clinical risk management in Europe – impression

Do you quantify the impact of risks in financial terms based on direct and indirect costs (e.g. additional costs for medication, length of stay or loss of revenues)?

- Never: 14%
- Rarely: 26%
- Sometimes: 31%
- Often: 10%
- Always: 19%
Clinical risk management in Europe – impression

How do you rate the general effectiveness and use of the already introduced measures of the clinical risk management?

- Very positive: 13%
- Positive: 69%
- Undecided: 18%
- Negative: 0%
- Very negative: 0%
Clinical risk management in Europe – impression

How do you rate the influence of the clinical risk management for cost effectiveness and the business performance of the hospital?

- Very positive: 6%
- Positive: 39%
- Undecided: 52%
- Negative: 3%
- Very negative: 0%
Risk management process as starting point

1. Risk identification and analysis
2. Risk assessment
3. Risk controlling
4. Risk monitoring
Risk identification and assessment

Risk identification and analysis:
Structured documentation and analysis of essential risks for all different stakeholders

Risk assessment:
Qualitative and quantitative evaluation of single risks

Risk categories:
• Resource and staff risks
• Structural risks
• Prozess risks
• Medical risks
• Financial risks
• CIRS / Risk register

Risk assessment:
• Probabilities of occurrence
• Impact and consequences
• Risk score and prioritization
Risk assessment

Criteria:
- Frequency

Impact/Severity

Measures:
- Number of cases
- Probability of occurrence
- Possibility
- Medical impact and consequences
- QALY, DALY, …
- Direct and indirect costs

Risk scoring, portfolio and prioritization
Risk assessment – direct and indirect consequences

Workplace accidents: **Iceberg Phenomenon**

**Direct vs. Indirect Costs**

**Direct Medical Costs**
- Medical
- Pharmaceutical

**Indirect Costs**
- Presenteeism
- Short Term Disability
- Long Term Disability
- Absenteeism
- Workers Compensation

**Indirect Costs** represents 2-3 times **Direct Medical Costs**

Impact on all affected stakeholder!
Risk controlling and monitoring

Risk controlling:
Active and pro active actions to treat single risks

Risk controlling strategies:
• KPI, Quality plan
• Avoiding (e.g. PCC)
• Reducing
• Sharing
• Covering

Risk monitoring:
Internal comprehensive documentation, analysis and reporting of changes

Risk monitoring:
• Continuous documentation/updated risk register
• Regular focussed reports
• Quality and risk committees
Outlook - integrated risk management

• Clinical risks and non-quality are harmful and expensive!
• Quality – leverage to effectiveness, efficiency and success for hospitals!
• Risk management process as initial starting point for integrative risk management approach!
• Risk assessment should consider medical as well as economic direct and indirect impact!
• Risk management is not a technocratic or instrumental issue, it is a question of organisational culture and leadership!
• “System safety” depends on the interlock of resources, processes, structure and culture!
• Documentation und transparency as essential fundament!

Only an integrated risk management can ensure the existence and success of hospitals in a sustainable manner!
„To Err is human“
– Risks are unavoidable;
the key question is the management of them!

John Wocher, Kameda Medical Center, Japan

Prof. Dr. Rainer Sibbel
Frankfurt School of Finance & Management
Head of the Institute for International Health Management
Academic Director of the MBA – International Healthcare Management
Sonnemannstraße 9-11
60314 Frankfurt am Main, Germany
T +49-69 154008-740
F +49-69 154008-4740
E-Mail: r.sibbel@fs.de
You are kindly invited to the B.Braun booth…

…to provide your insights on Risk Management

…to simulate your individual cost savings potential with the B.Braun Safety Software
Prof. Dr. Rainer Sibbel
Frankfurt School of Finance & Management
Head of the Institute for International Health Management
Academic Director of the MBA – International Healthcare Management
Sonnemannstraße 9-11
60314 Frankfurt am Main, Germany
T +49-69 154008-740
F +49-69 154008-4740
E-Mail: r.sibbel@fs.de
Integrated Clinical Risk Management - A Leadership Challenge

- 26th EAHM Congress -

Prof. Dr. Rainer Sibbel
Bologna, October 13th, 2016
Integrated Risk Register

• Initial Aim: To integrate both clinical and non-clinical risks into a central system
• Risk register to include risks with an organisation-wide impact
• Risks with local impact continue to be monitored by the department involved
• Risk Register allows all risks to be prioritised using the same system – allowing allocation of resources to areas of greatest risk
• Fundament of risk management processes:

```
1. Identify risks
2. Assess risks
3. Evaluate and Prioritise risks
4. Treat Risks
```
Integrated risk management - core issue

• Traditional economical risk management
  • management of financial and organisational risks
  • minimising litigation and financial losses

• Patient safety and quality management
  • often a separate function
  • focus mainly on accreditation requirements

• These two functions are often not well coordinated, although they often worked on the same problems

• Duplication, rework and gaps in the system

Clinical risks are core business risks!
## German hospital statistics 1991-2013

<table>
<thead>
<tr>
<th>Year</th>
<th>No. of hospitals</th>
<th>Full-time employees - nurses</th>
<th>No. of patient cases per year (Mio)</th>
<th>No. of patient cases per year per nurse</th>
</tr>
</thead>
<tbody>
<tr>
<td>1991</td>
<td>2,411</td>
<td>326,082</td>
<td>14,577</td>
<td>44</td>
</tr>
<tr>
<td>2013</td>
<td>1,996</td>
<td>316,275</td>
<td>18,787</td>
<td>59</td>
</tr>
<tr>
<td>± total</td>
<td>-415</td>
<td>-9,807</td>
<td>+4,210</td>
<td>+15</td>
</tr>
<tr>
<td>± in %</td>
<td>-17%</td>
<td>-3%</td>
<td>+29%</td>
<td>+33%</td>
</tr>
</tbody>
</table>

Source: Statistisches Bundesamt, Wiesbaden 2014
Financial Results of Hospitals (Germany)

- Hospitals with profit (in %)
- Hospitals with loss (in %)
- Hospitals with balanced result (in %)

Source: Deutsches Krankenhainstitut, Krankenhausreport 2012 and 2013
Why is Clinical Risk Management important?
Impact of clinical risks

At any time, over 1.4 million people worldwide suffer from infectious complications associated with health care. As patients in hospitals, especially those on the ICU, are very vulnerable, nosocomial infections are one of the leading causes of death. To minimize the risk of microbiological contamination, B. Braun offers safety devices featuring effective barriers for microbiological contamination.

1 error / patient / day

The Institute of Medicine estimated that in hospitals “a typical patient would be subject to one administration medication error per day.” In the ICU those errors represent a high priority healthcare issue. To increase medication safety, our infusion pump systems are available with a medication database.

€ 922,000

— these are the calculated costs in the case of a transferred blood-borne disease after a needlestick injury. With our wide range of devices enabling needle-free access and continuous evolution of our safety IV catheters we help caregivers to increase their safety.

Process Orientation:
Avoiding risks saves costs!

Hospital treatment and nursing process

Admission → Stay on ward → Transport → Diagnosis → Therapy → Relocation → Discharge

Arrival → Welcome → Proceed to admission → Record data → Inform patient → Describe route → Info about ward → Allocate bed → Help to unpack
Process: Standard drug infusion + bolus + flushing

1. **Drug Admixture**  (prepare drug in Solution container)

2. **Drug Delivery**  (prepare IV-set, flush)

3. **Patient Access**  (place IVC, flush)

4. **Drug Delivery**  (connect IV-set)

5. **Drug Admixture**  (prepare bolus)

6. **Drug Delivery**  (infusion)

remark: worst case with glass bottle, needle, glass ampoule
Drug Admixture: 30 steps

Drug Delivery: 40 steps

Patient Access: 35 steps

Drug Delivery: 7 steps

Drug Admixture: 22 steps

Drug Delivery: 43 steps

Total: 177 steps. Sharps Injury risk: in 69 steps.
<table>
<thead>
<tr>
<th>Product Combination</th>
<th>Steps Eliminated</th>
<th>Steps Saved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ecoflac + Ecoflac Connect</td>
<td>30 - 17 = 13</td>
<td>13</td>
</tr>
<tr>
<td>Safeset w. Caresite</td>
<td>40 - 17 = 23</td>
<td>23</td>
</tr>
<tr>
<td>Introcan Safety + Omniflush</td>
<td>35 - 12 = 23</td>
<td>23</td>
</tr>
<tr>
<td>Safeset w. Caresite: 7 st.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Minispike 2 + Combistopper</td>
<td>22 - 5 = 18</td>
<td>18</td>
</tr>
<tr>
<td>Safeset w. Caresite</td>
<td>43 - 21 = 22</td>
<td>22</td>
</tr>
</tbody>
</table>

Eliminated: all potential Sharps Injuries & 72 steps.
Cost savings potential through risk reduction

CURRENT PROCESS

<table>
<thead>
<tr>
<th>Product Cost (Syringe and standard needle) 6,150 €</th>
<th>Microbiological Contamination 41,004 €</th>
<th>Sharps Injury 8,481 €</th>
</tr>
</thead>
<tbody>
<tr>
<td>Process Cost 8,128 €</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

B. BRAUN PROCESS

| Product Cost (Safety products) 14,600 € | Process Cost 4,381 € | Savings by Risk Reduction 44,782 € |