A pilot study in two regions (Emilia-Romagna and Lombardia) was executed successfully (10). After the successful execution of the pilot study 19 centers in 6 Italian regions were recruited to participate. (see Table 1). The table of all 19 centers participated in the study is available on request (11).

**RESULTS:**

The theoretical model to analyse the subcutaneous versus intravenous therapy benefits in a real life setting in Italy (see figure 2).

**CONCLUSIONS:**

<table>
<thead>
<tr>
<th>Risk class</th>
<th>Probability of event</th>
<th>Reliability of event</th>
<th>Gravity of event</th>
<th>Benefit of event</th>
<th>Probability of event</th>
<th>Reliability of event</th>
<th>Gravity of event</th>
<th>Benefit of event</th>
</tr>
</thead>
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<td>0.6</td>
</tr>
<tr>
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<td>0.9</td>
<td>0.5</td>
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<tr>
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<td>0.2</td>
<td>0.1</td>
<td>0.05</td>
</tr>
</tbody>
</table>

**Figure 1:** Risk levels in a risk matrix for the interventional administration of breast cancer in Italy (A) in comparison to the subcutaneous administration (B) [4]. Simulation of all risk classes included in the Appendix.

**REFERENCE**


[4] 5 Gruppo Policlinico di Monza, Alessandria, Italy, Componente Segreteria Scientifica Nazionale ANMDO, Bologna, Italy


[10] After the identification of the risk levels for intravenous and subcutaneous administration the monetary quantification of the insurance premium reduction was calculated as follows:

**Assumptions:**

- Risk classes of C5 would not require a separate insurance or would not have an impact on the insurance premiums for a hospital.
- For risk level D4 is assumed that a treatment or administration error would impact the patient's permanency (65%); Based on a decision by the Milan court (5) a so-called table 2013 was published showing that such a permanent disability would have a cost impact of 234'271 € for eight risk classes to only 3 risk classes.

- Such risk would need to be insured additionally by a special insurance for each hospital. The exact premiums were not calculated however. It could be calculated whether a reduction in the likelihood of such a monetary impact would also have a proportional impact on the insurance premiums.

**RESULTS**

When the risk classes are followed and calculated there were (see figure 4)

- 8 areas identified to be high risk for the administration of an intravenous therapy in hematology or oncology
- 13 areas would be defined as having a medium-risk
- 14 areas would be classified with a low risk classification.

**METHODS**

- The eight high risk areas identified for the administration of an intravenous therapy in hematology or oncology or in the underlying work is the potential benefit of hospitals from a safety reduction through fixed-dose ready to use subcutaneous therapies in comparison to intravenous therapies with transfusion and haemodialysis.

- For the calculation of risk levels the Fimepla Model and Effect Analysis (FMEA) approach was being applied. Within that approach the critical treatment path is followed and risk classification for each individual step is being evaluated (see Figure 1).

- When the new subcutaneous formulation would be applied different risk levels could be completely eliminated which at a 65% reduction in risk levels (ex-post).

- The theoretical model to analyse the subcutaneous versus intravenous therapy benefits in a real life setting in Italy (see figure 2).

- The eight high risk areas identified for the administration of an intravenous therapy in hematology or oncology or in the underlying work is the potential benefit of hospitals from a safety reduction through fixed-dose ready to use subcutaneous therapies in comparison to intravenous therapies in hematology, intravenous breast cancer and intravenous breast cancer (4).

- The purpose of the underlying study was to analyse at the risk level of a subcutaneous therapy in comparison to an intravenous therapy in an Italian breast care setting breast cancer and breast Hodgkin lymphoma (MDM) with transfusion and haemodialysis, respectively.

- For the ultrasound and transfusion administration there were 35 different risk steps assessed. The summary pathway with detailed levels are available in figure 3, detailed description of all 35 are available on request.

**REFERENCE**

