Active Quarantine Haemovigilance programs multiply the adverse events rates. The HEMACUA project.

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I hereby declare the following potential conflicts of interest concerning my presentation:

- **Grifols**
  - Consultancy
  - Honoraria

- **Janssen**
  - Consultancy
  - Honoraria

- **PRoPosit**
  - CEO
  - Medical Director

- **Sanofi**
  - Consultancy
  - Honoraria
  - Medical writing
  - Advisory Committees

- **Onega+**
  - Consultancy
Puerta de Hierro-Majadahonda Hospital. Transfusions 2008-2017

<table>
<thead>
<tr>
<th>Year</th>
<th>RBCs</th>
<th>Plasma units</th>
<th>Platelet units</th>
</tr>
</thead>
<tbody>
<tr>
<td>2008</td>
<td>10136</td>
<td>4138</td>
<td>1346</td>
</tr>
<tr>
<td>2009</td>
<td>12172</td>
<td>4543</td>
<td>1906</td>
</tr>
<tr>
<td>2010</td>
<td>13897</td>
<td>4141</td>
<td>2718</td>
</tr>
<tr>
<td>2011</td>
<td>15081</td>
<td>4466</td>
<td>2962</td>
</tr>
<tr>
<td>2012</td>
<td>14610</td>
<td>4693</td>
<td>2798</td>
</tr>
<tr>
<td>2013</td>
<td>12914</td>
<td>3348</td>
<td>2259</td>
</tr>
<tr>
<td>2014</td>
<td>13160</td>
<td>3556</td>
<td>3211</td>
</tr>
<tr>
<td>2015</td>
<td>13690</td>
<td>3494</td>
<td>2943</td>
</tr>
<tr>
<td>2016</td>
<td>14436</td>
<td>3647</td>
<td>2798</td>
</tr>
<tr>
<td>2017</td>
<td>13461</td>
<td>2929</td>
<td>2516</td>
</tr>
</tbody>
</table>

Total RBCs: 20,881
Total Plasma units: 18,906
Pasive HV program
Acute Transfusion reactions

- Transfusion-Related Acute Lung Injury (TRALI)
- Transfusion-Associated Circulatory Overload (TACO)
- Allergic Reactions
- Febrile Non-Hemolytic
- Bacterial Sepsis
- AHTR ABO error
- Delayed Hemolytic Transfusion reaction
- AHTR Hemolytic Syndrome
Hemovigilance Protocols

**PASIVE**
- Transfusion reactions are detected by the nurse or MD that perform the transfusion.
- They report to the blood bank the transfusion reactions.
- Reactions not reported to the Blood bank “do not exist”
- Reactions that occurs after the end of the transfusion are rarely reported.

**ACTIVE**
- Transfusion reactions are detected by the Blood Bank staff when transfusion is finished.
- Most of the reactions that occurs during transfusion are recorded.
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**ACTIVE AFTER QUARENTINE**
- Transfusion procedure DO NOT FINISH until 24h after the end of the transfusion.
- Nurses or MD can report hiper-acute or acute transfusion reactions.
- BUT
- 24h after the end of the transfusion, Blood Bank staff review clinical history from transfused patients looking for late transfusion reactions.
# Haemovigilance Report. 2010-2012

## Hemovigilance between 2010 y 2012 HUPHM

<table>
<thead>
<tr>
<th></th>
<th>RBC</th>
<th>%</th>
<th>PLT</th>
<th>%</th>
<th>FFP</th>
<th>%</th>
<th>Total</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>HTR (ABO)</td>
<td>4</td>
<td>0,9</td>
<td>0</td>
<td>0,0</td>
<td>0</td>
<td>0,0</td>
<td>4</td>
<td>0,6</td>
</tr>
<tr>
<td>Febrile or hypotensive non hemolytic</td>
<td>37</td>
<td>8,5</td>
<td>4</td>
<td>4,7</td>
<td>1</td>
<td>0,8</td>
<td>42</td>
<td>6,4</td>
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<tr>
<td>Allergic</td>
<td>5</td>
<td>1,1</td>
<td>3</td>
<td>3,5</td>
<td>25</td>
<td>18,8</td>
<td>33</td>
<td>5,0</td>
</tr>
<tr>
<td>TRALI/TACO</td>
<td>0</td>
<td>0,0</td>
<td>0</td>
<td>0,0</td>
<td>0</td>
<td>0,0</td>
<td>0</td>
<td>0,0</td>
</tr>
<tr>
<td>Bacterial Contamination</td>
<td>1</td>
<td>0,2</td>
<td>0</td>
<td>0,0</td>
<td>0</td>
<td>0,0</td>
<td>1</td>
<td>0,2</td>
</tr>
<tr>
<td>Near error</td>
<td>1</td>
<td>0,2</td>
<td>0</td>
<td>0,0</td>
<td>0</td>
<td>0,0</td>
<td>2</td>
<td>0,3</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>48</td>
<td>11,0</td>
<td>7</td>
<td>8,3</td>
<td>26</td>
<td>19,5</td>
<td>81</td>
<td>12,4</td>
</tr>
<tr>
<td><strong>Units transfused</strong></td>
<td>43588</td>
<td>8478</td>
<td>13300</td>
<td>65366</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>By 10.000</strong></td>
<td>11,0</td>
<td>8,3</td>
<td>19,5</td>
<td>12,4</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Transfusion mortality in four Hemovigilance systems

**FDA 2008-2012**
- Allergic: 3%
- Hemolytic Transfusion Reaction (HTR): 39%
- Lung Related (TACO/TRALI): 49%
- Bacterial Infection: 9%
- Other: 21%

**SHOT. 2006-2012**
- Microbial Infection: 3%
- Hemolytic Transfusion & incorrect transfusion: 17%
- Lung Related (TACO/TRALI): 50%
- Other: 5%

**TRIP 2006-2012**
- Microbial Infection: 7%
- Other: 21%
- Allergic: 4%
- Hemolytic Transfusion Reaction: 18%
- Lung Related (TACO/TRALI): 50%

**Spain. 2006-2013**
- Microbial Infection: 3%
- Hemolytic Transfusion Reaction (HTR): 39%
- Bacterial Infection: 9%
- Allergic: 3%
- Lung Related (TACO/TRALI): 49%
Transfusion informatic Optimization (OPINTRA project) 2012-2016

- Reducing errors in transfusion
  - Specially Red Blood Cells
- Optimazing blood component use
  - Hospital Transfusional Guide
  - “Single unit Blood Transfusion”
- Improving Hemovigilance
  - Pasive to Active with quarantine
- Reducing staff work load & costs
OPINTRA Project

- Hospital Hemotherapy Commission
- New Transfusional Safety System
- New Transfusion Lab equipment
- Transfusional Guide
- Transfusional Informatic network
- Hospital Staff Training
- Transfusional procedure
- New Active & Quarantine Haemovigilance protocol
Transfusion process DO NOT END until 24h after the end of the blood component infusion
Haemovigilance Nurse
Transfusion Related Acute Lung Injury (TRALI)

Transfusion Associated Circulatory Overload (TACO)

Allergy reactions

Febrile Non-Hemolytic

Bacterial Sepsis

AHTR ABO error

AHTR Hyperhemolytic Syndrom

Delayed Hemolytic Transfusion reaction

Transfusional procedure

0H  1H  6H  12H  24H
Hemovigilance Protocols

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- Transfusion procedure **DO NOT FINISH until 24h after** the end of the transfusion
  - Nurses or MD can report hiper-acute or acute transfusion reactions
  - *BUT*
  - 24h after the end of the transfusion, Blood Bank staff review clinical history from transfused patients looking for late transfusion reactions
Objectives

Compare the incidence rate of adverse events related to transfusion with a new Active Quarantine HV program vs a Passive HV program
Methods

• Observational, descriptive, one center study

• Compare a Passive HV program (2010-2016) vs an Active & Quarantine HV program (2016-2017)

• Passive 2016 vs Active & Quarantine 2016

- Passive Hemovigilance
  - 2012-2017

- Retroactive Active Hemovigilance

- Active & Quarantine Hemovigilance Program
  - 2016-2017
Results
Adverse Events related to transfusion.
2010-2017. PDH

- **Pasive Hemovigilance:** 10.9 events/10,000
- **Quarantine Active Hemovigilance:** 48.2 events/10,000
- **Retrospective Active Hemovigilance:** 143 events/10,000

YEAR 2010: 17 events
YEAR 2011: 8 events
YEAR 2012: 23 events
YEAR 2013: 43 events
YEAR 2014: 20 events
YEAR 2015: 24 events
YEAR 2016: 102 events
YEAR 2017: 74.8 events/10,000
Transfusion reactions are detected by the nurse or MD that perform the transfusion. They report to the blood bank the transfusion reactions. Reactions not reported to the Blood bank “do not exist”. Reactions that occurs after the end of the transfusion rarely are reported. 

Transfusion procedure DO NOT FINISH until 24h after the end of the transfusion. Nurses or MD can report hiper-acute or acute transfusion reactions. BUT 24h after the end of the transfusion, Blood Bank staff review clinical history from transfused patients looking for late transfusion reactions.

Haemovigilance 2016

**PASIVE**

- 13 reports

**ACTIVE AFTER QUARENTINE**

- 102 reports

Ratio: 7,9

6,1 events per 10.000

48,2 events per 10.000
Acute transfusion reactions 2010-2017


- AHTR-ABO (ERRORS)
- ATR-NON ABO
- FEBRILE
- DIGESTIVE
- ALLERGIC
- PULMONARY
- BACT SEPSIS

Transfusional Safety System

Pasive Hemovigilance

Retrospective
Active & Quarantine H
Transfusional events. Hours from the transfusion beginning to the event. 2017

Median time from the transfusion beginning (h)

<table>
<thead>
<tr>
<th>Event</th>
<th>Median Time (h)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fever</td>
<td>5.5</td>
</tr>
<tr>
<td>Allergic</td>
<td>5.5</td>
</tr>
<tr>
<td>Disnea</td>
<td>5.5</td>
</tr>
<tr>
<td>Digestive</td>
<td>5.5</td>
</tr>
<tr>
<td>HRT non ABO</td>
<td>5.5</td>
</tr>
</tbody>
</table>

Median time 5.5 hours
Transfusional events. 2017

- Febrile, 67, 46.85%
- Allergic, 32, 22.38%
- Transfusion-associated dyspnoea, 26, 18.18%
- Nausea, vomiting, diarrhoea, 17, 11.89%
- HTR (non error), 1, 0.70%
1. Mild. The patient do not need medical intervention, 32, 24.81%

2. Mild. The patient need one simple medical intervention, 88, 68.22%

3. Moderate. The patient need more than one medical intervention, 6, 4.65%

4. Severe. The patient require intensive medication or Intensive care, 1, 0.78%

5. Patient death, 2, 1.55%

Transfusional events. Severity 2017

Reactions rate (per 10,000)

- 2006: 6.65%
- 2007: 6.88%
- 2008: 7.39%
- 2009: 8.35%
- 2010: 8.73%
- 2011: 10.06%
- 2012: 10.06%
- 2013: 10.17%
- 2014: 10.06%
- 2015: 10.33%

PDH 67

Death rate (per million)

<table>
<thead>
<tr>
<th>Year</th>
<th>Death Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006</td>
<td>2.97%</td>
</tr>
<tr>
<td>2007</td>
<td>4.06%</td>
</tr>
<tr>
<td>2008</td>
<td>1.66%</td>
</tr>
<tr>
<td>2009</td>
<td>1.63%</td>
</tr>
<tr>
<td>2010</td>
<td>2.16%</td>
</tr>
<tr>
<td>2011</td>
<td>1.65%</td>
</tr>
<tr>
<td>2012</td>
<td>2.25%</td>
</tr>
<tr>
<td>2013</td>
<td>2.26%</td>
</tr>
<tr>
<td>2014</td>
<td>1.06%</td>
</tr>
<tr>
<td>2015</td>
<td>1.61%</td>
</tr>
</tbody>
</table>
Conclusions

• An Active Quarantine HV program multiply the number of events associated to transfusion
  – Specially those that occurs after the end of the transfusion
  – Pulmonary complications (TACO, TRALI, dispnoea...)
  – Digestive

• More events detected, do not means an incidence increase, but a better HV program

• The HEMACUA program do not detect late events, after 24h

• Future objectives in our Center are to improve diagnosis of pulmonary and digestive complications
Thanks....