Teddy Network of Excellence

Lessons learned on scientific-ethical issues from the TEDDY survey among European ECs

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**Background**

Network of Excellence founded by TEDDY

- With the WP7 entirely dedicated to Ethics
- Continues to develop activities in the field of Ethics and Methodology
Survey on ethical and legal frameworks existing in Europe for CTs in paediatrics

- **Objective:**
  to analyse measures enforced by Member States to implement the Clinical Trials Directive and all the other European norms relevant for clinical research in paediatrics

- **Responses from 27 European Countries**

- **Results:**
  Many differences in the protection of children involved in clinical research exist across Europe

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Participation in public consultation on the “European Ethical recommendations”

INTEGRATION principles contained in relevant international/European ethical/legal sources, consistent with the INTERNATIONAL HUMAN RIGHTS LAW
“Survey on the Involvement of Ethics Committees in paediatric research in Europe”

Objectives:

- To identify ECs operating in Europe
- To identify ECs entitled to review paediatric protocols, according to national legislation
- To evaluate how paediatric expertise is guaranteed in ECs
- To assess ECs awareness of the new European paediatric regulatory framework
- To monitor and assess the impact of the new European paediatric regulatory framework on Ethics Committees activities
- To identify future initiatives to increase ECs involvement in paediatric research
## Inventory of Ethics Committees

### Methodology

<table>
<thead>
<tr>
<th>COUNTRY</th>
<th>No. of ECs</th>
<th>Inhabitants (millions)</th>
<th>No. ECs / 1,000,000 inh.</th>
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<tbody>
<tr>
<td>Bulgaria</td>
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<tr>
<td>Iceland</td>
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<td>France</td>
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<td>2</td>
<td>0.50</td>
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<tr>
<td>Hungary</td>
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<td>10</td>
<td>0.10</td>
</tr>
<tr>
<td>Portugal</td>
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<td>10.6</td>
<td>0.09</td>
</tr>
<tr>
<td>Greece</td>
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<td>0.09</td>
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<td>21.5</td>
<td>0.05</td>
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<tr>
<td>TOTAL</td>
<td>1007</td>
<td>504.3</td>
<td>2.00</td>
</tr>
</tbody>
</table>

1007 / 29 ECs/countries

Contact information of 832/28 ECs/countries
Survey on Ethics Committees
Methodology

Electronic Questionnaire
(12 questions, mandatory/optional + filter question on ECs competence)

Two main sections:
- ECs awareness and knowledge of the current regulatory framework in paediatrics and its impact on their activities;
- ECs interest and involvement in paediatric research

Preliminary version shared with the chair and some Members of the PDCO
RESULTS

154
ECs Participants

139/22
ECs in charge of reviewing paediatric protocols/Countries
RESULTS
Data Analysis

- Results expressed as frequencies and percentages
- Subgroups stratified in old EU Member States (EU-15) and new Member States
- Norway and Iceland included in the EU-15 group
RESULTS: Paediatric expertise

Paediatric expertise usually represented by a paediatrician
RESULTS: ECs awareness of the new regulatory framework

- 70% EU-15 (Belgium, Denmark, Germany, Italy, Norway, Portugal, Spain, Sweden)
- 30% new MS (Czech Republic, Latvia, Poland, Slovakia)

**Bar Graph:**
- **Paediatric Regulation:** 85.6% Yes, 14.4% No
- **Ethical Considerations:** 87.1% Yes, 12.9% No

*dedicated sessions or training initiatives*
RESULTS: Declared Impact of new regulatory framework on ECs activities

Paediatric Regulation

Graph showing the impact of new regulatory framework on ECs activities:
- New rules for reviewing paediatric protocols: 38.3%
- New organisation for the Ethics Committee: 23.4%
- Increased number of paediatric protocols: 31.9%
- Increased quality of paediatric protocols: 34.0%
- More time needed for reviewing paediatric protocols: 38.3%
- Other: 10.6%

TEDDY Task-force in Europe for Drugs Development for the Young
RESULTS: Declared Impact of new regulatory framework on ECs activities

European “Ethical considerations”

- Compulsory statute of paediatric expertise
- Increasing number of risky protocols
- Necessity to revise existing consent forms
RESULTS: Impact of new regulatory framework on ECs activities

Other possible global effects, the increase of:

- number of medicines tailored for children
- well designed paediatric trials
- paediatric multicentre clinical studies
- lack of knowledge and studies regarding the risks and burdens really acceptable for children in different age group
- difficulty to adapt information to parents and children in accordance with new requirements
RESULTS:
Major issues to be dealt with

1. Need for additional expertises to evaluate CT protocols
   - sonsuition: 96.1%, no variation 26.0%, decrease 21.9%

2. Measures to minimise pain, distress and fear in children
   - Increase 46.6%, no variation 23.3%, decrease 1.4%

3. Issues related to compensation of parents/children
   - Increase 23.3%, no variation 41.1%, decrease 1.4%

4. Issues related to insurance for paediatric trials
   - Increase 30.1%, no variation 37.0%, decrease 1.4%

5. Provisions for personal data protection
   - Increase 27.4%, no variation 37.0%, decrease 1.4%

6. Use of control groups, including use of placebo
   - Increase 24.7%, no variation 30.1%, decrease 8.2%

7. Risk monitoring procedures
   - Increase 37.0%, no variation 28.8%, decrease 1.4%

8. Risk assessment/minimisation procedures
   - Increase 35.6%, no variation 31.5%, decrease 1.4%

9. Complexity in evaluating the risk/benefit balance
   - Increase 39.7%, no variation 27.4%, decrease 1.4%

10. Complexity in the paediatric consent/assent procedures
     - Increase 39.7%, no variation 31.5%, decrease 2.7%

11. Complexity in evaluating the inclusion/exclusion criteria
     - Increase 43.8%, no variation 24.7%, decrease 1.4%

12. Unnecessary paediatric trials
     - Increase 52.1%, no variation 17.8%, decrease 2.7%

13. Administrative burden
     - Increase 28.8%, no variation 37.0%, decrease 1.4%
RESULTS: ECs involvement and interest in initiatives

Participation in paediatric initiatives

Only 30% participated  74% would like to participate

<table>
<thead>
<tr>
<th>Types of initiative</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conferences</td>
<td>68%</td>
</tr>
<tr>
<td>Training</td>
<td>32%</td>
</tr>
<tr>
<td>Projects</td>
<td>23%</td>
</tr>
<tr>
<td>Debates</td>
<td>18%</td>
</tr>
<tr>
<td>Other</td>
<td>18%</td>
</tr>
</tbody>
</table>

63% EU-15 (Belgium, France, Germany, Ireland, Italy, Luxembourg, Portugal, Spain, Sweden, The Netherlands)

27% new Member States (Cyprus, Czech Republic, Estonia, Latvia, Malta, Poland)
Conclusions

Gap between the European and local level

- lack of knowledge of the European regulatory framework related to paediatric research
- lack of awareness of ethical issues specifically related to paediatric research
- lack of involvement of Ethics committees in paediatric research
Conclusions

- Need to favour the growing of competence and involvement of Ethics Committees in paediatric research as well as of the awareness of ethical aspects.

- Need to promote the implementation of “European ethical recommendations” at local level.
Conclusions

- Need to let parents/children to acquire competencies and awareness on critical issues related to clinical trials
- To empower the role of parents in decision process in order to favour children participation in clinical trials

Recommendations for parents and children

Age appropriate information/assent forms for children
Need to favour initiatives (e.g. debates, training...) aiming at the integration of Ethics Committees interested in paediatric research

E-learning platform

http://www.teddylearning.org/
Conclusions

- Need of more collaboration between PDCO/EMA and Ethics Committees

NETWORKING among Ethics Committees across Europe

Essential tool to enhance collaboration and sharing experiences
Thank you

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