Medical Research involving Children: a Children’s Rights Perspective

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Program

- Legal framework on medical research involving children
  - International Human Rights / Biomedical Law
  - Dutch legislation as a point of reference

- Developments in policy

- Children’s rights perspective

- Conclusion
MOMS-Trial
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Prenatal vs. Postnatal repair of Myelomeningocele

* 158 women pregnant of child with spina bifida => 2 GROUPS:
prenatal surgery between 19-25 wks. (N=78) vs. postnatal closure of spina bifida within 48 hrs after birth. (N= 80).

Conclusion: prenatal repair may result in better neurological function than repair after delivery. Still,

- fetal surgery is unexplored area of medicine, and
- goes with serious maternal and fetal risks and burdens.
Medical research involving humans

- **Basic notions:**
  - observation / intervention research
    - mere spectating or actual intervening?
  - therapeutic / non-therapeutic research
    - of medical benefit to participant or not?

- **Special attention to non-therapeutic intervention research involving children.**
Normative framework

- **Ethical Codes:**
  - WMA-Declaration of Helsinki; CIOMS-Guidelines

- **International Law:**
  - Article 7 ICCPR
  - Articles 15 - 17 Eur. Conv. on Human Rights & Biomedicine (Oviedo, 1997)
    
    => Additional Protocol on Biomedical Research
  
  - EU-Directive on Clinical Trails
A point of reference: Dutch law

- Dutch Act on medical research involving humans
  - Apart from general conditions, special regimen for minor subjects prohibits research involving minors, unless:
    - therapeutic research
    - non-therapeutic: 1) group related
      2) minimal risks and negligible burdens

- Dissatisfying review practice on non-therapeutic paediatric research lead to set up Doek Committee
Developments

- Doek Committee concluded
  - abandon absolute norm of minimal risks & negligible burdens for non-therapeutic research
  - allow more than minimal risks and negligible burdens, proportionate to the relevance of the research

- Critical response of Central Committee on medical research
Recent development

- Dutch Minister of Health accepts norm for non-therapeutic research involving children stated in EU-Directive on Clinical Trials
  
  - Article 32 (1gii): “…impose only minimal risk to / burden on the minor concerned in comparison to the standard treatment of the minor’s condition.”

Earlier debated norm of “no more than a minor increase over minimal risks and burdens” applicable to all non-therapeutic non-drug research on minors?
Children’s Rights perspective

- Non reference to medical research in CRC
  - General Comments No. 3 and 15

- Apart from choosing right wording of regulation, paediatric practice and ethical review practice remain to provide new hard cases with new difficult questions:
  - Toxic, yet promising drugs in very sick babies for whom there is no cure?
  - Experimental vaccine treatment to combat Ebola?
Conclusion

- To ensure a child’s right to health cannot do without due account of the interests of children involved in medical research

- Topic requires broad recognition as a children’s rights issue!

Groningen Center for Children’s Rights in Health Care:

=> towards a more children’s rights related framework for medical research involving children