

How should children's autonomy be recognised in the research context ?

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What is autonomy ?

- The word **autonomy** comes from the Greek autos-nomos **meaning** “self-rule” or “self-determination”.
- **Autonomy** can be **defined** as the:
 - Ability of the person to make his or her own decisions.
 - An individual's right to self-determination

My beliefs

- Children need to be viewed as people who, in the context of their own family and social environment, have the potential from an early age to play an active role in determining their own lives, voicing their opinions and in engaging with others. (Archard 2004; Mayall, 2002; James & James, 2004; Pufall & Unsworth 2004; Corsaro 2015)

Untested treatments

- ‘Standard’ care procedures may turn out, when compared with alternatives in a properly-conducted study, to be far from optimal, and even harmful
- Many medicines given to children have not in fact been tested in children

Harmful effect

- **Cisapride** has been prescribed to over 36 million babies and young children worldwide to treat gastro-oesophageal reflux (movement of stomach contents back into the oesophagus).
- Withdrawn from routine use in the UK and USA in July 2000 because of concerns about rare, but very serious, adverse effects: sudden death, death from cardiac arrhythmia (abnormal heart rhythms) and serious non-fatal arrhythmia.
- A review by the UK Cochrane Collaboration to establish whether these risks of serious adverse events were outweighed by the benefits found no clear evidence that cisapride had significant benefits compared with placebo.

Value of clinical trials

- Trials have led to 75% survival rates in childhood cancer, compared with 10% fifty years ago.
- Vaccine trials have led to routine vaccination and subsequent reductions in, for example, pneumococcal infections.

Need to include children

- It may be oppressive or unethical ***not*** to invite children to participate. Young children and babies, for example, may be treated in intensive care units with equipment and multiple drugs, few of which have been tested in their age group or with their particular condition.

So.....

- Clinical research involving children, from babies to adolescents, is essential if we are to improve our understanding of childhood diseases and conditions, and provide care for children and young people based on the best possible evidence

But children are a 'vulnerable' group

- Lack capacity to understand
- Cannot always recognise their best interests
- Cannot see the consequences
- Cannot express their needs
- Cannot defend their rights
- Need protection

However....

- There is considerable empirical evidence that children are much more capable than they are given credit for and many are keen to be involved
- Recent work suggests that if information is presented in an appropriate manner, younger children can cope (Ulph et al 2009).

Age 'imperfect bar'

- Age is a very imperfect 'bar' given how much children vary.
- Where children are individually assessed for competence, the 'bar' is set much higher for children than for adults

Role of parents

- In most cases, children are assumed to be unable to make their own decisions, and authorisation is required instead from a parent or another legally-authorized proxy.

However parents' capacity ...

- Proxies are likely to act with caution but in practice their understanding of factors such as risk, randomisation, or the nature of research may be weak; they may be under severe stress; and they may feel that a decision to consent to research is the only 'parental' decision left to them.

Shades of grey.....(not 50 !)

- A 'black and white' approach to children's competence may not be helpful. 15 year olds may welcome having their parents involved, even if judged to have capacity to decide for themselves, because of the benefits of parental support. This doesn't change overnight at 16.

Consent Process – tick box

- There is a real risk that processes designed to protect children just become boxes to be ticked.
- We also need to balance protection with participation – children are sometimes excluded when they could have been involved.

Need to consider....

- Nature of the research (e.g. related to condition or not, time, risks, discomfort, opportunity, timing of request)
- Children and family situation (knowledge, attitudes)
- Relationship between families and researchers (trust and communication)

Respect, recognition, concern

- Respect for children as **individuals**, regardless of their age or capacity.
- Recognition of children's **developing capacity** for autonomous agency
- Concern for children's **immediate and longer-term welfare**.

Key points

- ✓ Crucial role of good communication
- ✓ Maximising a child's ability to participate
- ✓ Identify the tools/expertise required
- ✓ Use a family-based model of decision-making
- ✓ Take account of the child & context
- ✓ Ensure safeguards against abuse are in place
- ✓ Professional discretion & judgement

Need better regulation

- “Government, industry, funding agencies, and clinicians are responsible for research priorities being adult-focused because of the greater burden of disease in adults, coupled with financial and marketing considerations. This bias has meant that the equal rights of children to participate in trials has not always been recognised” (Caldwell et al, 2004) .

Review of research ethics committees Ireland

- Over 70% membership (n=36/72) from the following backgrounds: legal advisor (81%), medical doctor (78%), nurse (75%) and lay persons (72%).
- Dedicated research ethics training for members is not the norm
- Lack of consistency in relation to operating procedures and review processes between RECs
- Range of structural models of RECs in the Irish context is striking
- Inconsistencies over the exact legal requirements of informed consent for mature minors.
- Widespread perception that REC members felt less competent to review children's research than research with adults.

Recommendations for REC's

1. Creation of a central research ethics resource
2. A comprehensive governance system and national standardization
3. Development of structures for the review of children's research
4. Implementation of a limited number of RECs with special expertise in children's research
5. Meeting specific information needs
6. Involving children in research and dialogue processes

Take home message

- Clinical research must always be **with** children and young people, not 'on' them: they are not mere passive subjects but rather active participants in a joint enterprise of research.

Children should be included in clinical research

- Research that is scientifically sound and ethically robust, that addresses questions of importance to the health of children and young people, should be seen as essential part of care

Resources

- bioethics@nuffieldbioethics.org
- <http://nuffieldbioethics.org/project/children-research/key-questions/>
- <https://www.youtube.com/watch?v=aJfS3GPehyk>
- <https://www.youtube.com/watch?v=e2k6eA0dn9Q&t=61>

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