



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Involvement of Children/Young People in PDCO Activities

Presented by Elin Haf Davies

PCWP/HCPWG joint meeting – 27/28 February 2013





UN Convention on the Rights of the Child (1989)

- ... requires all states to ensure and respect children's rights in all their life settings, by taking into account children's **participation in accordance with their evolving capacities.**
- ... Participation (article 12): You have a right to have your say in decisions that affect you, and to have your opinions taken into account.

**BECAUSE
EVERY CHILD
IN THE WORLD
HAS ONE THING
IN COMMON.
THEIR RIGHTS.**



Children ... may express their views freely. **Such views shall be taken into consideration on matters which concern them in accordance with their age and maturity.**

Art. 24 (1) of the Charter of Fundamental Rights
European Union, 7 December 2000



Council of Europe Programme

"Building Europe for and with children"

Children should be considered as active members of society, and **not as mere passive subjects of decisions taken by adults.**

This implies, taking into consideration their age and maturity, being informed, consulted and given the opportunity to take part in social decision-making processes on health care issues, including assessment, planning and improvement of health care services.



Committee of Experts on Child Friendly Health Care



Child-Friendly Health Care:
Building a Healthy Future for and with Children
9th Council of Europe Conference of Health Ministers
29-30 September 2011, Lisbon, Portugal



COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

Identify children's specific needs in order to promote their well-being in the health care setting, with special emphasis on their rights to child-responsive and child friendly health care, taking into account the social and family environment.

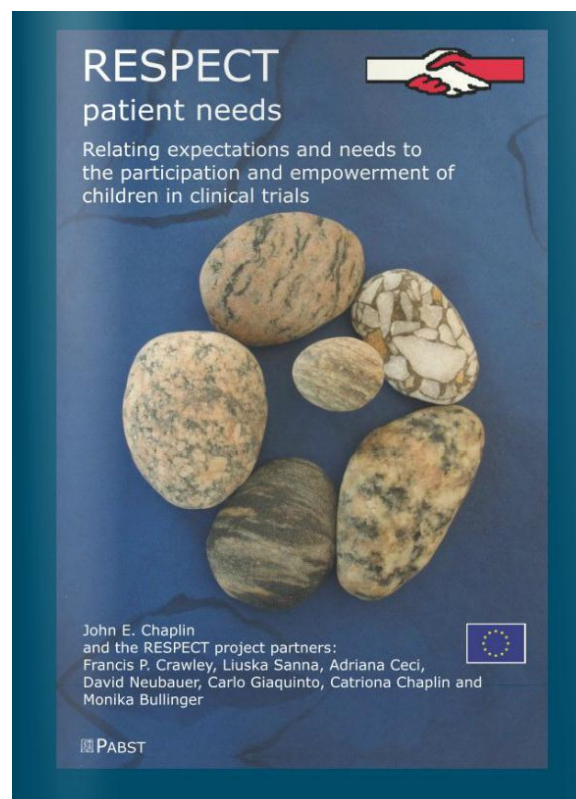
Find ways to promote children's participation in decision-making in their own health care and in broader children's health care.

Council of Europe Programme
"Building a Europe for and with children": 2009-2011 Strategy



EU 7th Framework programme: Identifying patient's need in the clinical trials context

(HEALTH-2007-4.14)





27.12.2006

EN

Official Journal of the European Union

L 378/1

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(Acts whose publication is obligatory)

REGULATION (EC) No 1901/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 12 December 2006

on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004

(Text with EEA relevance)



EUROPEAN MEDICINES AGENCY
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23 November 2012

EMA/PDCO/388684/2012

Paediatric Committee (PDCO)

Concept paper on the involvement of children and young people at the Paediatric Committee (PDCO)

Agreed by PDCO	August 2012
Adopted by PDCO for release for consultation	5-7 September 2012
Start of public consultation	17 September 2012
End of consultation (deadline for comments)	19 November 2012



Involving children and young people in PDCO Activities - **Benefits**

- ❑ Children as **active stakeholders**: right to be informed, consulted and heard, their perspective sought independently from their parents and doctors.
- ❑ The level of child participation depends on the age, evolving capacities, maturity and on the importance of the decision being undertaken.
- ❑ **Listening to children/youth opinions before making decisions may help increase their adherence.**

McDonagh JE, Bateman B. Arch Dis Chil Educ Ed 2012; 97: 55-60



Involving children and young people in PDCO Activities - **Benefits**

□ **Understanding their views of:**

- their condition
- therapeutic needs perception: devices, formulations, palatability, route of administration
- burden of diagnostic/therapeutic procedures
- the perceived efficacy of treatment
- understanding and preferences on clinical trial design features, including acceptability, timing and burden of procedures
- potential impact of a clinical trial on them (direct/indirect benefit)



Involving children and young people in PDCO Activities - Challenges

■ Ensuring confidentiality

- To give fully informed assent, must be given information appropriate for development.
- Confidentiality must be maintained (exceptions?)
- Privacy should be guaranteed
- Parental permission inappropriate in certain situations (e.g. contraception)

Klein & Wilson, J Adolescent Health, 2002

Thrall et al., Archives of Pediatrics & Adolescent Medicine, 2000



Involving children and young people in PDCO Activities - Challenges

- **Access** – how do we identify/ approach children
- **Ethnic and cultural differences** - broad European coverage required
- **Language** - ability to express oneself
- **Discrepancies between chronological age and actual maturity**
- **Ill-informed or preconceived notions about a child's level of understanding and maturity.**
- **Appropriate tools/media (e.g. verbal/written/online)**



Involving children and young people in PDCO Activities – **How?**

- **Clear pre-determined agenda** with agreed objectives, realistic timeframes.
- Use of a **language** that is appropriate.
- **Training** on the content of the discussion previous to the session
- **Feedback:** about how their views were incorporated into the work of PDCO (system in place).



Involving children and young people in PDCO Activities – What?

- ❑ In the evaluation of individual Paediatric Investigation Plans;
- ❑ To define significant therapeutic needs according to therapeutic areas: not product specific / in the development of guidelines /specific to therapeutic areas/disease;
- ❑ Clinical assessments used as endpoints: invasiveness of tests / frequency of tests, duration of tests;



Involving children and young people in PDCO Activities – What?

- ❑ Preferences on clinical trial design features: randomisation / placebo / frequency of visits / duration of study / number of tests;
- ❑ Medicines of choice: Acceptability of route of administrations / Acceptability of formulations / Preferred formulation type / Palatability / Frequency of dosing / container closure systems and other packaging issue.



Involving children and young people in PDCO Activities: next steps

- Input comments received on Concept Paper by eight different stakeholders into first draft of 'Reflection paper'



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20 November 2012
EMA/746293/2012
Paediatric Committee (PDCO)

Overview of comments received on Concept on the involvement of children and young people at the Paediatric Committee (PDCO)' (EMA/PDCO/388684/2012)

Interested parties (organisations or individuals) that commented on the draft document as released for consultation.



Stakeholder no.	Name of organisation or individual
1	U.S. FDA/CBER
2	F. Hoffmann – la Roche Ltd
3	European Federation of Allergy and Airways Diseases Patients' Associations (EFA)
4	International Diabetes Federation European region
5	EFPIA – Pär Tellner (par.tellner@efpia.eu)
6	Medicines for Children Research Network (MCRN), UK
7	GRiP (Global Research in Paediatrics)
8	Velizara Anastasova ^{a,b} , Aurélien Mahalatchimy ^{a,b,c} , Emmanuelle Rial-Sebbag ^{a,b} , and Anne Cambon-Thomsen ^{a,b} ^a Inserm, UMR1027, Epidemiology and analyses in Public Health, Toulouse, F-31073, Cedex 7, France ^b Université de Toulouse III Paul Sabatier, UMR 1027, Toulouse, F-31073, Cedex 7, France ^c IRDEIC, Université Toulouse 1 Capitole, Manufacture des Tabacs, 21 allée de Brienne 31042 TOULOUSE Cedex 9



Involving children and young people in PDCO Activities : **next steps**

- ☐ Propose a work plan
- ☐ Action a “pilot phase/trial run” of basic questions – **your comments wanted!**
- ☐ Define PDCO expectations;
- ☐ Define our expectations from the children and young people;
- ☐ Develop guidance on how the interaction
- ☐ Identify organisations that have the skills and experience to support the on-going objective



Involving children and young people in PDCO Activities : **next steps**

- ☐ Identify best way to consult e.g. social media
- ☐ Develop clear criteria on which situations need the consultation of and/or dialogue
- ☐ Put mechanism in place to ensure on going involvement and interaction
- ☐ Publish 'Reflection Paper'



We welcome your thoughts,
comments and contributions.

Thank you

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