Faculté de Médecine Créteil Paris XII

Liberté • Égalité • Fraternité
RÉPUBLIQUE FRANÇAISE

Ministère de la santé, de la jeunesse et des sports

Informed consent for incapacitated patients and in emergency situations

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Informed consent for incapacitated patients and in emergency situations under EU 536/2014

1. After Nuremberg, consent became the cornerstone of societal acceptance of research ("experimentation") on persons (ethics + legislation)

2. But, when persons are unable to consent for themselves (coma, emergency) … no research ?

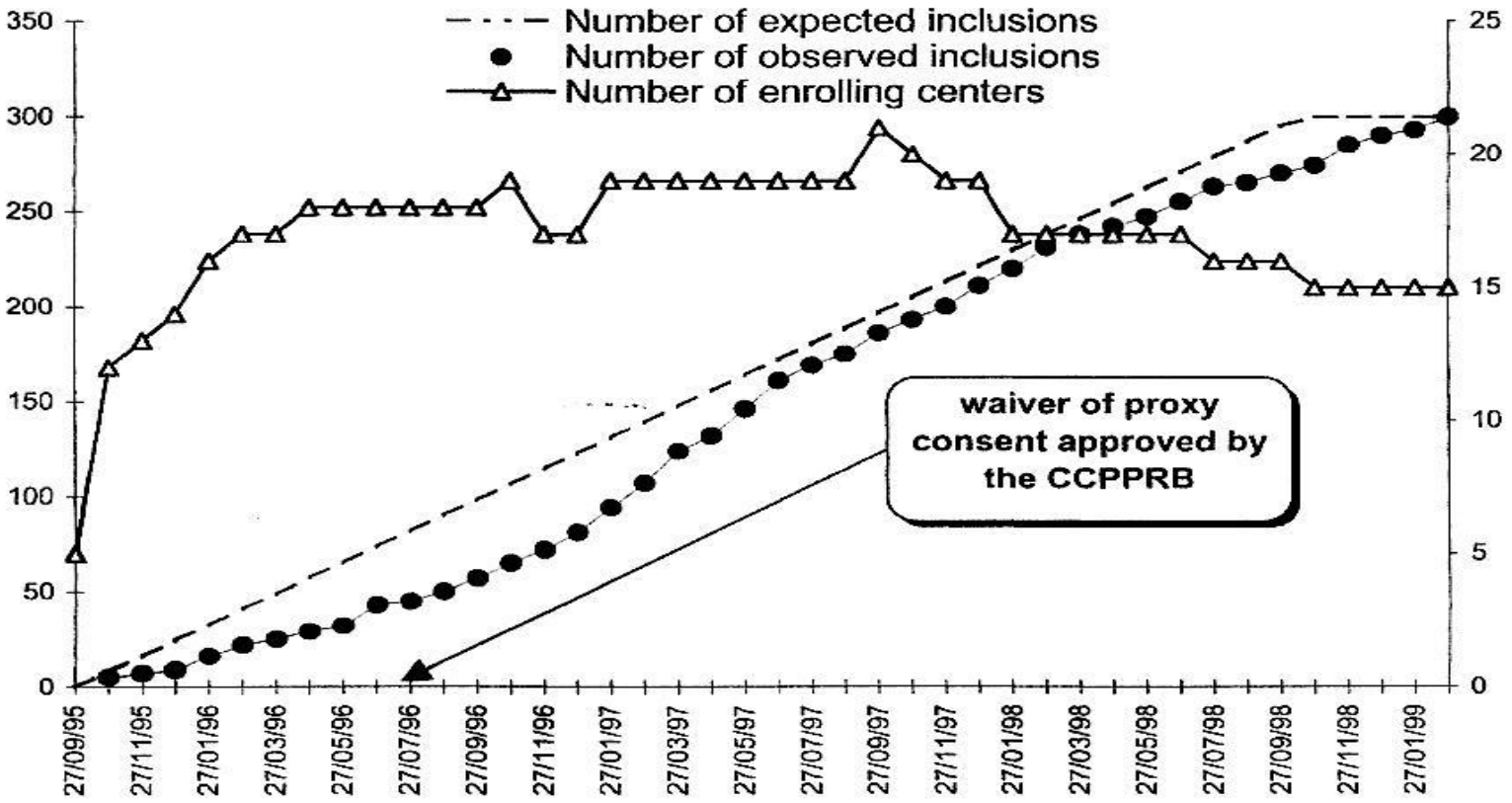
3. Necessary compromises:

- **consent given by surrogates, or no consent at all**
- **level of risk?**
- **notion of direct benefit ?**

4. The counterpart being that security of participants has to be reinforced +++.

Informed consent for incapacitated patients and in emergency situations under EU 536/2014

D Annane et al Intensive Care Medicine 2004



Informed consent for incapacitated patients under EU 536/2014 (1)

Scenario 1

A 30yrs patient has an infectious disease (viral) with encephalopathy; he has a mild coma, doesn't answer to questions. A new anti-viral agent is being tested. The patient himself cannot consent. How research could be done ?

1. Basic conditions:

- The subject has not previously opposed the trial
- No national rule prohibiting such trial
- **Informed consent** from the "legal representative" defined by national laws

- Whenever possible, an only partially incapacitated subject should take part in the consenting process

Informed consent for incapacitated patients under EU 536/2014 (2)

3. Others

- No financial inducement
- The trial cannot be performed in persons able to consent
- Trial relates to the medical condition the subject suffers from

4. The problem of the risk/benefit ratio

Participation in the trial is expected to produce :

- A direct (individual) benefit higher than risks involved

- If not, necessity of a "group benefit"

- In that case, the trial poses only a minimal risk (by comparison to standard treatment)

Informed consent in emergency situations under EU 536/2014 (1)

Scenario 2

A 60yrs man suffers from an an acute cerebral stroke when walking in the street. The emergency ambulance drives him to the nearest hospital. There, a clinical trial testing a new fibrinolytic agent is on going. The new drug (or placebo) has to be delivered within the first 2 hours. The patient cannot consent (deep coma).

What if no family is around?

A clinical trial can be started in emergency <u>without</u> informed consent if :

1. The subject cannot consent due to a sudden life-threatening medical condition,

2. There is a reasonable expectation of a <u>direct benefit</u>

3. The legally representative is not available "within the therapeutic window"

Informed consent in emergency situations under EU 536/2014 (2)

4. The investigator is not aware of any patient's objection

5. The trial relates to the condition which makes consent impossible; primary disease or… sedation ??

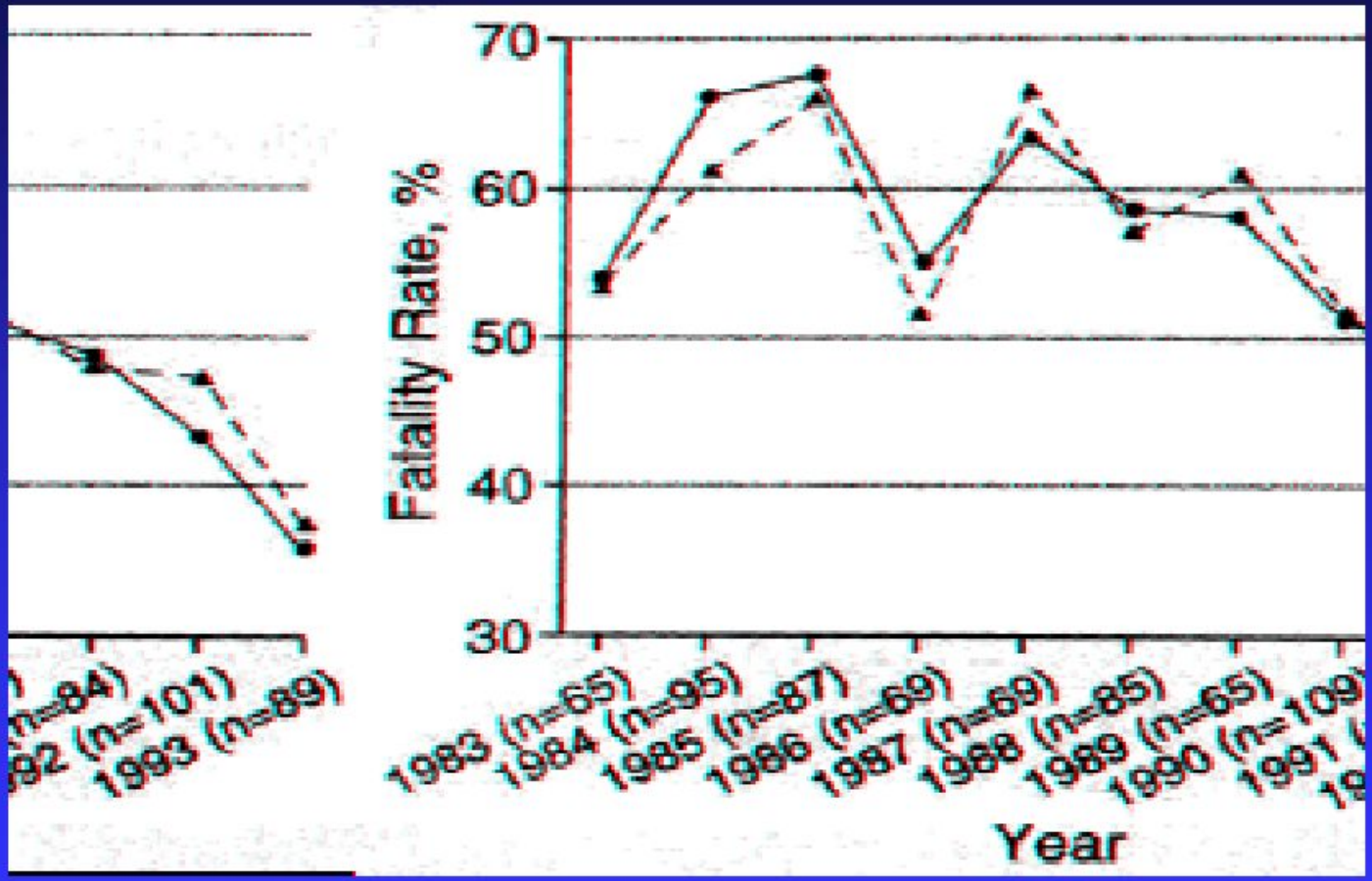
6. Minimal risk in comparison with the standard treatment

7. Continuation of the trial : consent should be asked to:

1. **Patient himself, if he regains consciousness**
2. **Or legal representative, if he comes sooner**

If consent for continuation of trial is denied, data collected before refusal can be used by the investigator if there is no objection.

ARDS outcome



Milberg et al. 1995 JAMA

Informed consent for clinical trials under EU 536/2014

Basic rules concerning information and consent

Art 28

-Data protection according to Directive 95/45/EC (currently under revision)
-Pain, discomfort, fear…are minimized as possible
-Medical care is guaranteed by qualified physician(s)
-Any subject may withdraw from the trial at any time

Article 29

-Consent is written and signed
-After completion of the trial, a summary (understandable to laypersons) of results will be posted in the EMA database in open access