Informed consent in clinical trials in emergency settings: Experiences and attitudes of Polish investigators

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Warsaw, 02 June 2006
Emergency research…
…investigate the investigators!

SCIENTIFIC LETTER

Obtaining informed consent from patients in the early phase of acute myocardial infarction: physicians’ experiences and attitudes

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It is possible to question whether patients suffering from the early phase of an acute myocardial infarction (AMI) are able to give free and informed consent and whether or not it is ethically defensible to include them—those patients suffering from more severe symptoms, in particular—in research projects. It has been shown that a reasonable number of patients who have given their consent in this situation are only able to recall very little of the information they received about the study and that only a minority read through the consent form before signing it.

The aim of this study is to determine how physicians, who have been involved in including patients in intervention trials in the early phase of their AMIs, experienced the informed consent procedures. In our view, data obtained from those people who are actually confronted by the research subjects and who are responsible for carrying out the consent procedure should also be taken into account, when the most

Fifty six per cent felt that it should also be compulsory to provide written information in the acute situation. Male doctors were more inclined to prefer only to provide verbal information compared with their female counterparts (question 7: 45% vs 33%, p < 0.01). Half the male physicians felt that the need to obtain informed consent could be abandoned when the patients were unable to understand information, whereas only a third of their female colleagues felt the same (question 8: 50% vs 32%, p < 0.01).

Most of the respondents had not experienced patients reacting negatively to being asked to participate in a trial, at least not to any great extent. Fifteen per cent felt that the patients’ trust in the physicians was affected negatively by the process of obtaining informed consent, whereas 34% actually felt the contrary.

It was apparent from the written comments that the physicians act in different ways when they obtain informed consent. Moreover, the large variation among patients, for
Methods

- Anonymous questionnaire of 14 items for investigators experienced in emergency trials, designed in cooperation with Centre of Postgraduate Medical Education, Dept. of Cardiology, Warsaw and Institute of Psychiatry & Neurology, Warsaw

- Distribution (April-May 2006), approx. 1000 copies:
  - sent out to 43 cardiology and 22 stroke Polish centres
  - distributed personally by monitors of 6 pharmaceutical companies / CROs
  - mailed to 39 cardiologists (e-version)
  - completed at investigators meetings organised by one company
ANKIETA ANONIMOWA

Zgoda chorego na badanie kliniczne leku w stanach nagłych – opinie i doświadczenia badaczy

Ankieta skierowana jest do lekarzy, którzy kiedykolwiek prowadzili – jako badacz lub współbadacz – badanie kliniczne leku fazy II do IV (sponsorowane przez przemysł lub badanie akademickie) u chorych przytomnych w stanie nagłym / zagrożenia życia (np. ostrym incydencie wieńcowym, udarze mózgu).

Badania kliniczne dziś
Badania kliniczne leków na dobre wpiszały się w działalność naukową polskich lekarzy. Udział polskich badaczy w międzynarodowych programach, często we współpracy z przemysłem farmaceutycznym, sprawia, że stajemy się współtwórcami postępu w farmakoterapii. Mimo ogromnego postępu ostatnich lat, oczekiwania tak świata medycznego, jak i ogółu społeczeństwa, co do bardziej skutecznych i bezpiecznych metod leczenia są coraz większe. Dotyczy to szczególnie terapii stanów nagłych zrozumienia przekazywanej im informacji i podjęcia świadomej decyzji.

Cel niniejszej ankiety
W obecnym stanie prawowym prowadzenie takich badań w oparciu o ogólne standardy badań klinicznych jest mało realne. Opracowania naukowe badające postawy chorych w stanach nagłych / zagrożenia życia wobec badań naukowych są nieliczne, jeszcze mniej wiadomo o postawach samych badaczy. Dlatego Stowarzyszenie na Rzecz
Results

• 171 questionnaires returned
• Informative responses: 97.0 to 100.0% per question
Investigators by industry / academia

- 95.2% industry-sponsored trials
- 30.7% academic trials

N = 166
Investigators by therapeutic areas

- 76.6% acute coronary syndromes
- 9.94% other syndromes
- 22.8% stroke
- arrhythmia
- heart insufficiency
- migraine
- Guillain-Barré syndrome

N = 171
What was the **scope** of information and **how** it was delivered to trial participants?

- full-size information (like non-emergency trials), verbal + written 50.9%
- abbreviated info, verbal and written 36.8%
- full-size verbal info + abbreviated written info 15.8%
- abbreviated verbal info + full-size written info 10.5%
- only abbreviated verbal info 4.7%
- only proxy consent (social court) 0.0%

* N = 171
Did you additionally seek consent of participant’s relative(s)?

- yes, always: 15.9%
- yes, sometimes: 44.7%
- rarely or exceptionally: 26.5%
- never: 14.1%

N = 170
Following enrolment, did you inform participant’s relative(s), if available, on trial participation?

- yes, always: 50.3%
- yes, sometimes: 35.7%
- rarely or exceptionally: 11.1%
- never: 2.9%

N = 171
Did involvement of participant’s relatives influence the time necessary to obtain informed consent?

- yes, delayed: 56.1%
- yes, shortened: 5.8%
- no influence: 29.2%
- not applicable (no involvement): 8.8%

N = 171
How do patients react to a trial proposal in an emergency condition?

- Very / somewhat positively: 63.7%
- As frequently positively as negatively: 30.4%
- Very / somewhat negatively: 1.2%
- Uncertain: 4.7%

N = 171
Is an emergency patient able to understand the nature of the trial and consciously decide to participate?

- always / most often: 33.9%
- some patients are able: 44.4%
- no or few patients are able: 17.0%
- uncertain: 4.7%

N = 171
How much of the **verbal** information received by the patient is really **understood**?

- **all / almost all**: 30.4%
- **some**: 60.2%
- **none / almost none**: 2.3%
- **uncertain**: 7%

N = 171
How much of the written trial information does an emergency patient actually read?

- All / almost all: 14.0%
- Some: 60.2%
- None / almost none: 21.6%
- Uncertain: 4.1%

N = 170
The amount of information supposed to be given to patient was in general:

- too comprehensive: 84.2%
- adequate in regard to patient’s condition: 14.0%
- too laconic: 0.0%
- uncertain: 1.8%

N = 171
How does a trial proposal to an emergency patient affect their trust in the physician?

- Increases trust: 24.6%
- Neither increases nor decreases trust: 49.7%
- Compromises trust: 11.1%
- Uncertain: 14.6%

N = 171
Does informing participant’s relative(s) on trial participation make sense at all?

- Yes: 66.5%
- No: 14.7%
- Uncertain: 18.8%

N = 170
Which of the following models of informed consent in emergency settings would be the best?

- Full-size information (like non-emergency trials), verbal & written: 12.3%
- Abbreviated info, verbal and written + abbreviated consent form, with obligatory full-size written consent to continue the trial once the participant’s status has sufficiently improved [ICH GCP-based]: 78.4%
- Abbreviated oral info + only verbal consent, with obligatory full-size written consent to continue the trial once the participant’s status has sufficiently improved: 8.2%
- Other: 1.2%

N = 171
Conclusions

• Patients’ reactions to emergency trials predominantly positive
• Most patients only partially able to understand the nature of the trial
• Better understanding of verbal than written communication
• Amount of information far too comprehensive in to-date trials
• Patient trust not compromised in most cases
Conclusions

• The preferred model for emergency consent procedure:

  Abbreviated verbal + written consent in emergency + obligatory full-size deferred consent (to continue the trial once the participant’s status has sufficiently improved)

• Involvement of patients’ relatives in consent procedure should be considered (definitely: passive information, questionable: parallel consent, proxy consent?), even if slowing down the procedure
... thanks to:

• Prof. Andrzej Budaj and Dr. Wojciech Wąsek, Centre of Postgraduate Medical Education, Dept. of Cardiology, Warsaw
• Prof. Anna Członkowska, Institute of Psychiatry & Neurology, 2nd Dept. of Neurology, Warsaw
• Dr. Beata Kozłowska-Boszko, GCPpl and Bayer HealthCare
• Polish departments for clinical research of:
  ➢ Astra-Zeneca
  ➢ Johnson & Johnson Pharmaceutical R&D
  ➢ MDS Pharma Services
  ➢ PPD Development
  ➢ Sanofi-Aventis
  ➢ Servier