Informed consent doesn't exist in AMI trials

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Hilden and Gammelgaard's (H&G) comments on the evaluation and application of statistical trials and on informed consent lead to the same conclusion that there are special circumstances when clinical trials are performed in emergency situations.

The decision to comment on the work that H&G responded to was motivated by the wish to manifest the need to reach a consensus on modifying the conditions in which clinical trials should be performed in special circumstances.

One unquestionable fact must first be addressed: clinical trials are necessary for acquiring new knowledge and consequent improvements in health care services. At the same time, patient participation should be encouraged under conditions that respect patients' decision making capability.

Are these conditions being met at present? An answer to this is given below.

The principle of patient autonomy has become so overriding that treatments can be applied in very few circumstances without the physician first receiving the patient's freely given informed consent. Nevertheless, emergency medicine constitutes precisely one of these exceptional circumstances.

In an emergency in which no informed consent can be obtained from the patient, physicians should use the best possible therapy for the improvement of health. This is their ethical obligation.

Despite this, as stated by Hilden and Gammelgaard (H&G), it has been found that the kind of informed consent that can be obtained in emergencies is influenced and altered by diverse factors. By no means can it be said that this kind of consent is actually informed, even if it is regularly classified as such in research protocols. Admitting that this kind of consent is not actually informed involves changing the basic concepts and theories about its nature. It should be stressed that in emergencies consent is regularly assumed and therefore rendered invalidated and null.

How is it possible, therefore, to test out the efficacy of a given therapeutic measure when such tests have not been consented to? The answer seems to be twofold.

The first part is found in the Helsinki Declaration, which among the basic principles for medical research, states as follows:

Research on individuals from whom it is not possible to obtain consent, including proxy or advance consent, should be done only if the physical/mental condition that prevents obtaining informed consent is a necessary characteristic of the research population. The specific reasons for involving research subjects with a condition that renders them unable to give informed consent should be stated in the experimental protocol for consideration and approval of the review committee. The protocol should state that consent to remain in the research should be obtained as soon as possible from the individual or a legally authorized surrogate.¹

It is true that this precept is usually applied to patients with mental illness, but it is also true that the impossibility of

obtaining informed consent is often a characteristic inherent in the emergency situation.

If reference was made by consensus to this principle in all clinical trial protocols performed in emergency situations, all physicians would be acting in accordance with the Helsinki declaration. They would not, however, be acting in accordance with the declaration where protocols indicated that informed consent had actually been obtained for participation in a trial when in fact it had not.

The second part of the answer, the second possibility, which seems to be less acceptable, is to radically modify the current situation and establish a system of opting in/opting out. In other words, in an emergency situation we could all be considered subjects for investigation as long as we have not previously stated our unwillingness to be so considered. The vast majority would probably be very unwilling to accept this or would outrightly reject it.

The statistics problem is also directly related to informed consent, although the solution here seems to be even more difficult. It is no surprise that H&G state in one of their comments that "The *p*-value game does not belong in the emergency ward"[our italics].

All researchers know that the statistics game can provide widely differing results. Increasing or reducing the sample or opting for a certain type of trial as opposed to another can change the statistics substantially.

But does the target population actually find out about this?

Does the target population know that whatever the alternative, another four, six, ten or more people have to die, for the results of a trial to be considered statistically significant?

If no attempt is made to provide information about the most elementary statistical aspects in a comprehensible way, patients are being given incomplete information. And incomplete information leads to corrupt, invalidated, and null consent.

Our position can be summarised in three points:

1. Scientific research in emergency situations is essential and patients should participate.
2. It would be ethically acceptable to investigate without the initial consent of participants.
3. Research protocols in emergency situations should redefine the information criteria used so that the best consent possible

in the circumstances can be considered as being suitably informed.

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- 1 **World Medical Association.** *Declaration of Helsinki: ethical principles for medical research involving human subjects.* Adopted by the 18th World Medical Association General Assembly in Helsinki, Finland, June 1964. Last revised by 52nd WMA General Assembly in Edinburgh, Scotland, October 2000.

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