Commentary

Research in critically ill patients: standards of informed consent

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See related review by Huang and Hadian, http://ccforum.com/content/10/6/244

Abstract

Patients in critical care lose their capability to make a judgement, and constitute a 'vulnerable population' needing special and reinforced protection. Even if the standard of informed consent is an essential way of demonstrating respect for the patient's autonomy, the usual informed-consent procedure is not as applicable as required or sufficient to warrant this ethical principle in critical care.

Introduction

The evolution of ethics recommendations in medical research is the result of past history. After each dramatic event that occurred in the context of medical research, the medical community and lawyers reacted by editing standards. These actions allowed defining the conduct that the researchers must follow in order to ensure the respect for human rights. In a recent review article, Huang and Hadian report current controversies regarding ethical standards of research [1]. One of the relevant questions raised about the need for more standards in ethical research addresses the specific issue of informed consent in critical care.

The particular critically ill patient

Because of their acute illness and the special environment, critically ill patients may be temporarily incapacitated. The critically ill lose their capability to understand and to make a judgement, and they therefore constitute a 'vulnerable population' needing special and reinforced protection [2]. The participation of critically ill patients in medical research is particularly important for the community, who will benefit from the ensuing improvement of care in vital situations. In most cases this patient does not benefit from their study participation but endorses the risks. The investigator has the responsibility to protect the patient and to conduct the study according to ethical standards. In order to do so, the investigator should have at their disposal some tools to distinguish competent and incompetent patients. The difficulty is that no objective criterion regarding the decision-making capacity of patients is defined in international and national directives. Investigators usually use their clinical judgement and the Glasgow Coma Scale as guidance. If we had to revise the currently available standards, the definition of the patients' capacity should be a priority.

Informed consent in critical care

Informed consent is considered an essential way of protecting the patient and respecting their autonomy. Informed consent, however, is not sufficient to make a clinical research ethical. The informed-consent procedure must fulfil three conditions: adequate information about the study with a complete disclosure of the risks and benefits, the patient's comprehension, and the voluntary nature [3]. Given at the very beginning of a study, informed consent cannot ensure the protection of the patient throughout the whole study by itself. Indeed, we have shown that even when the mandatory conditions were fulfilled and patients were given a valid informed consent for a study, most of them were unable to recall the study components 10 days after the consent procedure [4,5]. Since the study was ongoing, patients could not use their right to withdraw from the study at any time. We suggested that reconsidering the informed-consent procedure repeatedly during an ongoing study could be useful in order to respect the patient's rights. The ethical role of the investigator does not end at the signature of the consent document but continues throughout the whole study.

Until now, no data have analysed the psychological effect of informed consent in critically ill patients. We could imagine, however, that the informed consent '*per se*' could enhance the anxiety in patients that are already in a stressful environment and in a critical situation [6,7]. Even if obtaining informed consent is in most cases an essential way of demonstrating respect for the patient's autonomy, it can lead to some unnecessary and even silly practices [8]. In such situations, we could question, as did Dreyfuss, whether the informed consent is not more to protect the investigator than the patient [9].

Waiver of consent and estimation of the risk for critical care research

Because informed consent in emergency research was not anticipated in previous regulations, the US Food and Drug Administration recommended in 1996 that research in some emergency circumstances might be conducted using an exception from informed consent (that is, a waiver of consent) [10]. In the study conducted by Annane and colleagues, the waiver of consent probably contributed to the successful completion of the study and could allow one to improve medical knowledge in septic shock [11]. The amendment of the UK's Medicines for Human Use Regulations 2004 recently came into force on 12 December 2006. The regulations now allow, also in the United Kingdom, unconscious patients in emergency situations to be enrolled in clinical trials without prior consent provided that this has been approved by the appropriate ethics committee [12,13].

It is obvious that the risk assessment of the study must be included when considering a waiving of consent. Weijer proposed the concept of components analysis according to therapeutic or nontherapeutic procedures of the research [14]. This way of evaluating the risks imputable to the research itself may help institutional review boards to better balance the potential benefit expected from the study and the real risks endorsed by the patients. McRae and colleagues even suggest that the components analysis would facilitate the approval of emergency research requiring a waiver of consent while protecting vulnerable research subjects [15].

Conclusions

As suggested by Huang and Hadian, we do not need more standards but some current standards have to be revisited because a number of critical care situations were not anticipated in these standards. Informed consent is a good example of such a standard procedure that should be reconsidered. Indeed, the usual informed-consent procedure is not as applicable as required or sufficient to warrant the respect of the patient autonomy in the critical care setting.

Competing interests

The authors declare that they have no competing interests.

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