Consenting for Research within the Critical Care Unit: a systematic review of patient and public attitudes

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Background and Aims

Consenting for research in critical care is challenging as potential study participants frequently lack capacity. Several frameworks of consent are available: a 'substitute decision maker' (SDM), delaying consent until after enrolment or waived consent. It is unclear which is preferred by either patients or the public. This systematic review aimed to evaluate the attitudes of previous ICU inpatients and the public to the different frameworks of consent available.

Methods

A comprehensive search of PubMed, the Cochrane Library and manuscript references using the terms 'Critical Care' and 'Informed Consent' was performed. 427 results were screened as per PRISMA guidelines, with six studies being identified as eligible for inclusion.

Results

All investigated consent frameworks were deemed acceptable, in that the majority of patient responses were neutral or actively approving of the framework. When capacity is lost, both patients and the public agree that consent provided by a SDM prior to study enrolment is preferable. Interestingly over 70% of both patients and the public view delayed consent as acceptable irrespective of the urgency of enrolment, even when the patient retains capacity. Previous ICU inpatients were more likely to accept waived consent if enrolment was required urgently, particularly when there is no SDM available.

This review identified that the existing use of a study intervention within routine care, the perceived risk of enrolment to a study and both participant age and education status were key influences of participant attitudes.

Conclusion

If the patient retains capacity, patients and the public agree informed consent should be sought. When patients are incapacitated SDM provision of consent is preferable. However, delayed consent or waived consent is generally acceptable, particularly if enrolment is urgent.