Participants' Views of Delayed Consent for a Randomised Controlled Trial in Intensive Care

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Certificate of Authorship/Originality

I certify that the work in this thesis has not previously been submitted for a degree nor has it been submitted as part of requirements for a degree except as fully acknowledged within the text.

I also certify that the thesis has been written by me. Any help that I have received in my research work and the preparation of the thesis itself has been acknowledged. In addition, I certify that all information sources and literature used are indicated in the thesis.

Signature of Student

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Abstract

Each year many people experience critical illness and require a stay in an intensive care unit. Critical illness has a high mortality, making evaluation of therapies a priority for research in this area. Research conducted in the critical care environment is difficult with respect to obtaining first person informed consent. Patients who are critically ill have diminished capacity for decision making and consequently they are rarely able to provide informed consent before enrolment in a clinical trial. In Australia, critically ill patients are enrolled into clinical trials using delayed consent. However, there is a paucity of research on the opinion of clinical trial participants about consent obtained following enrolment.

The aim of this study was to determine the opinion of participants enrolled in the NICE-SUGAR study, under the provision for delayed consent, of the delayed consent process. A secondary aim was to investigate their opinions of third party consent and their preferences for decision makers. Former ICU patients who were enrolled in the NICE-SUGAR study at the Royal North Shore Hospital (RNSH) with delayed consent, who were cognitively intact when screened, and were judged to have sufficient proficiency in the English language, were contacted and invited to participate in this study. Willing participants completed a questionnaire regarding their opinion of the delayed consent process. The questionnaire was developed for this study and contained fixed response and open ended questions.

There were 634 participants in the NICE-SUGAR study at the RNSH, 256 of these former ICU patients were contacted and responses were received from 210 (response rate 82%). Participants were 37.6% female with mean±SD age of 61±16 and APACHE II scores of 18±6.79. Delayed consent was obtained from participants (57/210; 27.1%) and the substitute decision maker (152/210; 72.4%). Most respondents (195/204; 95.6%) reported they would have consented to participate in NICE-SUGAR if asked before enrolment. Most respondents (163/198; 82.3%), ranked first (mean=1.49) “the person who consented on their behalf for the NICE Study” as most preferred to make decisions on their behalf. Most (177/202; 87.6%) agreed with the decision made by their relative/friend.

In conclusion, most former ICU patients who had been enrolled in the NICE-SUGAR study from the RNSH with delayed consent, would have provided consent to participate had they been capable. Furthermore, most respondents agreed with the decision made by the substitute decision maker.