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Reply to Moser and Røggla

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Sir, We thank Moser and Røggla for their comments [1]. We agree that it is preferable to use study data of patients who died before deferred consent could be sought. As we described, not only does discarding data probably jeopardize study results by introducing selection bias, it also has other negative scientific and ethical effects [2].

However, implementing a policy that allows the use of all data of deceased patients without any consent, principally assuming that patients or relatives do not object, can be undesirable, in our opinion. If a time limit for seeking deferred consent (72 h is our recommendation) is not used, this might prevent researchers from seeking consent as early as possible, provided there are no other laws in a specific country for such situations. From a researchers' point of view, it would be beneficial to postpone seeking consent, as this would increase the chance of including data in the analysis. The only importance of the time limit of 72 h is to prevent

unauthorized use of the obligation to seek consent. If there would be no such obligation, then a deferred consent procedure would be equal to a complete waiver of consent.

We disagree that implementing a time limit of 72 h would be impractical. This is illustrated by the questionnaire among clinicians in the field of neuro-critical care [3], and by the experiences in the early lactate-directed therapy study, in which the median time from randomization to consent was only 1 day (interquartile range 0–3 days) and in which none of the deceased patients without consent had to be excluded due to overshooting the time limit [2]. It is clinically practical to approach relatives within a time period of 72 h.

We support initiatives to explore alternatives for solving this ethical dilemma. In our opinion, instead of using a 72-h threshold, consultation of an independent physician could also ascertain whether sufficient care has been taken to seek consent prior to death, in order to legitimately use the data. Although the idea of Moser and Røggla to create a research objection registry might seem attractive, we remind the research community that objecting to organ transplantation is of post-mortem importance, whereas experimental emergency research may have serious risks during life [4]. Furthermore, individuals can make valid predictions and considerations regarding organ-donation decisions, whereas in a research registry it would be impossible to assess the risk/benefit ratio of a particular future research project beforehand. Lastly, we doubt that such a registry would be more cost-effective and practical than using data of patients who died early (within 72 h) without consent.

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