Invited Commentary

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There is no ethical dilemma with current RCT participant unblinding practices

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In their Editorial, Jane, Davis and Bell argue that a dilemma exists in the case where a randomised controlled trial (RCT) participant requests to be unblinded to their treatment allocation in circumstances other than where a serious adverse event (SAE) has occurred. The authors pose a number of what they regard as key questions about participant and investigator rights and ethics.

Unfortunately, the authors ignore what is surely the most important question here – What is the current need for a generalised right for RCT participants to be unblinded? What do we know about how common such requests are? By not addressing these issues, the authors fail to establish why we would consider such a proposal in the first place.

Successfully arguing a case for a generalised right for RCT participants to be unblinded would require that we first clarify the circumstances beyond adverse events where this may be warranted. The likely uptake of a 'no adverse event unblinding' option, and possible negative effects, would also need to clarified (e.g. the introduction of participant or investigator bias; potential impact upon participant beliefs about RCT allocation and subsequent in-trial behaviour).

Making such a case in the absence of empirical evidence on these points is difficult. This leaves us with what I think is the central question in this issue – why would an RCT participant request to be unblinded in the absence of SAEs?

The authors acknowledge that requests for unblinding typically occur in the context of serious adverse events. However, they do not present any evidence of other common reasons for unblinding requests in the absence of SAEs. One conceivable justification for such a request might be that some participants are simply curious, and have a preference to be informed of their RCT treatment allocation. That seems reasonable at first glance, but it is difficult to see why such a preference should be satisfied if doing so would undermine trial integrity and outcomes.

Reporting on the meager results of their 1980-2012 Medline search, the authors confirm "there is no mention of the process of unblinding within a study unless for the rare occurrence of a serious adverse event". Without any empirical data to suggest otherwise, this finding is reason enough to conclude that there is no ethical dilemma with current RCT participant unblinding practices.

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