Medicare Health Support Pilot Program

TO THE EDITOR: McCall and Cromwell under-report design and analysis failures in their analysis of the Medicare Health Support Pilot Program. We evaluated their study for Healthways, one of the participating providers, and subsequently published our critique.[1] For example, the investigators violated the intention-to-treat protocol and induced post-treatment bias[2] by adding and removing subjects after randomization. The ad hoc adjustments for this design flaw (only some of which appear to be reported) compounded the bias. Consent was obtained only from members in the intervention group and only after randomization, leading to more bias. The use of an inefficient block-randomization approach (rather than a matched-pair approach) and a 7-month delay in instituting the intervention after randomization left the design underpowered, which was equivalent to discarding data from numerous subjects.[3] Their statistical procedures introduced unnecessary model dependence,[2] and published tables appear to be inconsistent with available data.

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