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Innovations in response-adaptive designs for clinical trials

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Clinical trials have traditionally followed a fixed design, in which patient allocation to treatments is fixed throughout the trial. Response-adaptive designs, particularly those following a Bayesian approach are gaining increasing attention as they offer efficiency improvements over traditional designs due to the fact that they allow for dynamic adjustment of patient allocation to various treatments during the course of the trial. Mathematically, adaptive designs belong to a class of problems known as multi-armed bandit problems in an analogy to a decision problem facing a casino gambler who is trying to decide which slot machine (bandit) to play in sequence over time. The general problem then exemplifies the tradeoff between the cost of gathering information and the benefit of exploiting information already gathered. However, existing adaptive designs focus on sequential allocation (one patient at a time), primarily due to computational barriers. Most clinical trials, however, require simultaneous allocation of multiple patients. We propose an adaptive design that uses forward-looking algorithms to fully exploit learning from multiple patients simultaneously. Further, we propose mathematical methods that allow for a computationally efficient implementation of such designs in practice. Our numerical results on relevant datasets demonstrate that our approach is superior to existing designs; this includes retrospective implementation on recently conducted clinical trials on stents as well as on a drug for treating chemotherapy-induced nausea. Our proposed approach makes it practically feasible for trial administrators and regulators to implement response-adaptive designs on large clinical trials with potentially significant gains.