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Presentation Abstract

Session: APS.212.01-Improving Outcomes After Cardiac Surgery

Presentation: 12251 - Enrollment Challenges in Cardiovascular Surgical Trials: Experience of the Cardiothoracic Surgical Trials Network

Pres Time: Sunday, Nov 13, 2011, 9:30 AM -11:00 AM

Location: West Hall A4, Core 2, Poster Board: 2063

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Specialty: +212. Quality of Care, Outcomes Research and Health Policy

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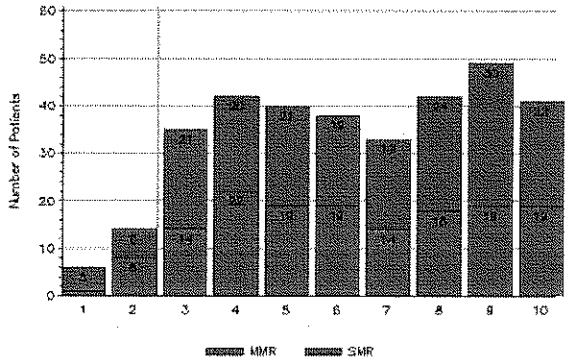
Abstract: **Objective**: The clinical research enterprise is plagued by widespread failure to meet recruitment goals in trials, and surgical trials are especially challenged. This study identifies barriers to enrollment and strategies to overcome them.
Methods: Screening/enrollment data, and reasons for screening failure, were analyzed in 2 comparative effectiveness trials for ischemic MR, and data were supplemented by structured interviews with investigators.
Results: During the first 6 months, the accrual rate (3.3 pts/mo) was significantly less than targeted. Enrollment barriers included lack of engagement of referring cardiologists, equipoise concerns, inefficient screening procedures, dynamic nature of the degree of MR, and suboptimal site recruitment "systems." Major reasons for patient refusal were unwillingness to randomize (36%) and follow-up burden (21%). A portfolio of strategies was implemented; enrollment improved to 13.3 pts/mo. Screening became more efficient; the screened-to-eligible pt ratio improved from 22:1 (<6/1/09) to 16:1 (>6/1/09). Enrollment also became more effective; the % randomized of eligible pts improved from 36 to 48%.
Conclusion: Maintaining equipoise among investigators, and their referral networks, is critical in surgical trials where treatment arms may be vastly different and associated with strong physician/patient preferences. This challenge is greater if procedures are available outside of clinical trials, and argues for novel partnerships with referring physicians. Prospective screening logs are valuable for refining eligibility criteria, and ascertaining reasons for non-participation that are useful in re-directing recruitment efforts. Trials require up-front investment in "enrollment toolkits." Site visits, involving surgical/cardiology subspecialties and the institution's leadership, are key to adjusting site-specific enrollment strategies and creating a robust institutional trials culture.

Graph 1. Overall Enrollment by 3-Month Time Intervals from Dec 08 to May 11



Note: 341 patients enrolled as of 06/01/11: MMR (154); SMR (187).

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