Recruitment in a Multi-center AD Prevention Study: A Mailing-based Approach

Mary-Tara Roth, RN, MSN, MPH
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Background

- Primary prevention trials of late-onset diseases require large study populations that are difficult to recruit.

- Review of a mailing recruitment strategy used for the Alzheimer’s Disease Anti-inflammatory Prevention Trial (ADAPT), a large-scale 7-year clinical trial evaluating the efficacy of NSAIDs (naproxen sodium and celecoxib) in AD prevention. ADAPT is funded by the NIH and conducted at 6 sites within the U.S.

- ADAPT recruitment goal: enroll 2,625 participants (400-500 per site) age 70+ who have first-degree relative with dementia.

- ADAPT Boston enrolled 424 participants (from all recruitment strategies) before study drug was suspended in December, 2004. Of the 424 Boston participants, 306 were respondents to the first-round of mailings (over 16 months) to Medicare beneficiaries.
Recruitment Strategies Utilized

- Mass mailings to Medicare beneficiaries were the main source of recruitment for ADAPT
  - First and second-round mailings
- Launch luncheon and subsequent PR (national and local press coverage)... A very successful event!
- Advertising (print and radio)
- Harvard Co-operative Program on Aging (newsletter and mailings)
- Mailings to city and town resident lists
- ValPak advertisements
- Collaborations with community senior organizations (churches, COAs, etc.)
- Community presentations
- ADC Registry
- National and local websites and toll-free numbers
  - [www.2stopAD.org](http://www.2stopAD.org); [www.bulacresearch.org](http://www.bulacresearch.org); [www.ADEAR.org](http://www.ADEAR.org); [www.alzmass.org](http://www.alzmass.org), etc.
Overall Mailing Strategies

• **Letter contents**
  - Letter about study from study PI
  - Study brochure
  - BRM (postage paid response envelope)
  - Response questionnaire
    - Keep it simple
    - Give people the opportunity to be removed from the mailing list (cost attached…)
    - Give people the opportunity to request information about other research participation opportunities at your center
Overall Mailing Strategy

• Pilot Mailing:
  • ~ 2,000 – 4,000 mailed per site.
  • Helpful in determining rates of response, eligibility, and enrollment
  • Work backwards from enrollment rate and recruitment goal to determine number of mailings to be sent each month.

• Regular mailings:
  • Boston site sent 630K letters over 14 months (21 1st round mailings) and total of 1.2 million letters in 34 separate mailings (including other lists and 2nd round mailings) from 4/01 to 4/04.
  • 9 repeat mailings yielded only .01% enrollment rate compared with .06% enrollment rate from the 1st round mailings.
Overall Mailing Strategies, cont’d.

- Consistency in mailings:
  - Plan for a “Steady State”
  - Prevents site from being overwhelmed by responses and screenings and enables planning for adequate staffing
  - Maintains regular flow of phone screenings, in-person visits, and enrollments
Overall Mailing Strategies, cont’d.

• De-Centralized Strategy Development
  • Each site develops its own mailing strategy, letter, and questionnaires

• Central administration of mailing database
  • 30-day notice by fax from sites to chair’s office of total number to be mailed and targeted zip codes for the mailing

• Local administration of mailing database for smaller lists (resident lists, etc.)

• Seed file for each mailing
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Progression through the Recruitment Process in ADAPT

Step 1:
7,107 subjects with complete information
3,543 ineligible

Step 2:
3,564 subjects undergo phone screening
2,525 ineligible

Step 3:
1,039 subjects contacted for eligibility visit, 582 declined

Step 4:
457 completed eligibility visit
113 ineligible

Step 5:
344 invited to enroll, 38 declined
306 enrolled

627,293 CMS mailings sent (April 2001 - August 2002)
7,256 questionnaires returned (response rate = 1.2%)
Challenges in Using a Mailing-based Strategy

• Minority responses
  • US Census: 6% Americans over age 70 are African Americans; 3% Americans over age 70 are Hispanic.
  • Fewer than half of the census-derived estimate for percentages of African-Americans (<3%) and Hispanics (~1%) are represented on the CMMS roster of Medicare beneficiaries.
  • Because we relied primarily on mailings to the Medicare beneficiary list, we immediately limited our access to the other half, or two-thirds, of potential minority participants who are not on the particular list we used.

• Costs
• Mailing recipient concern about confidentiality
• Management of mailing company
  • Seeded files help
    Ex:
    - mailings sent w/o questionnaire
    - Boston letter sent to some Baltimore recipients