

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

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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; www.bualzresearch.org; www.ADEAR.org; 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

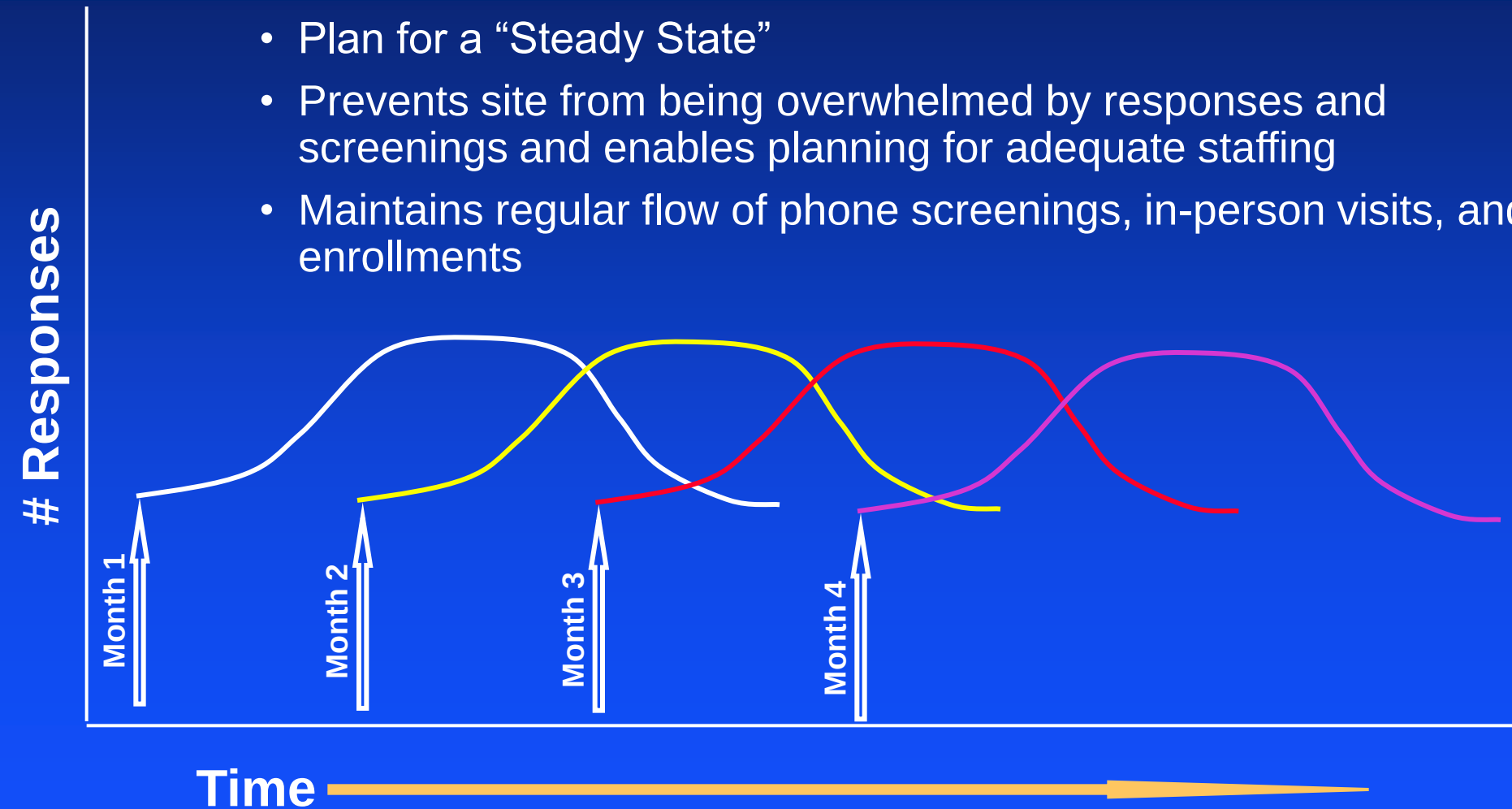
Overall Mailing Strategy

- 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



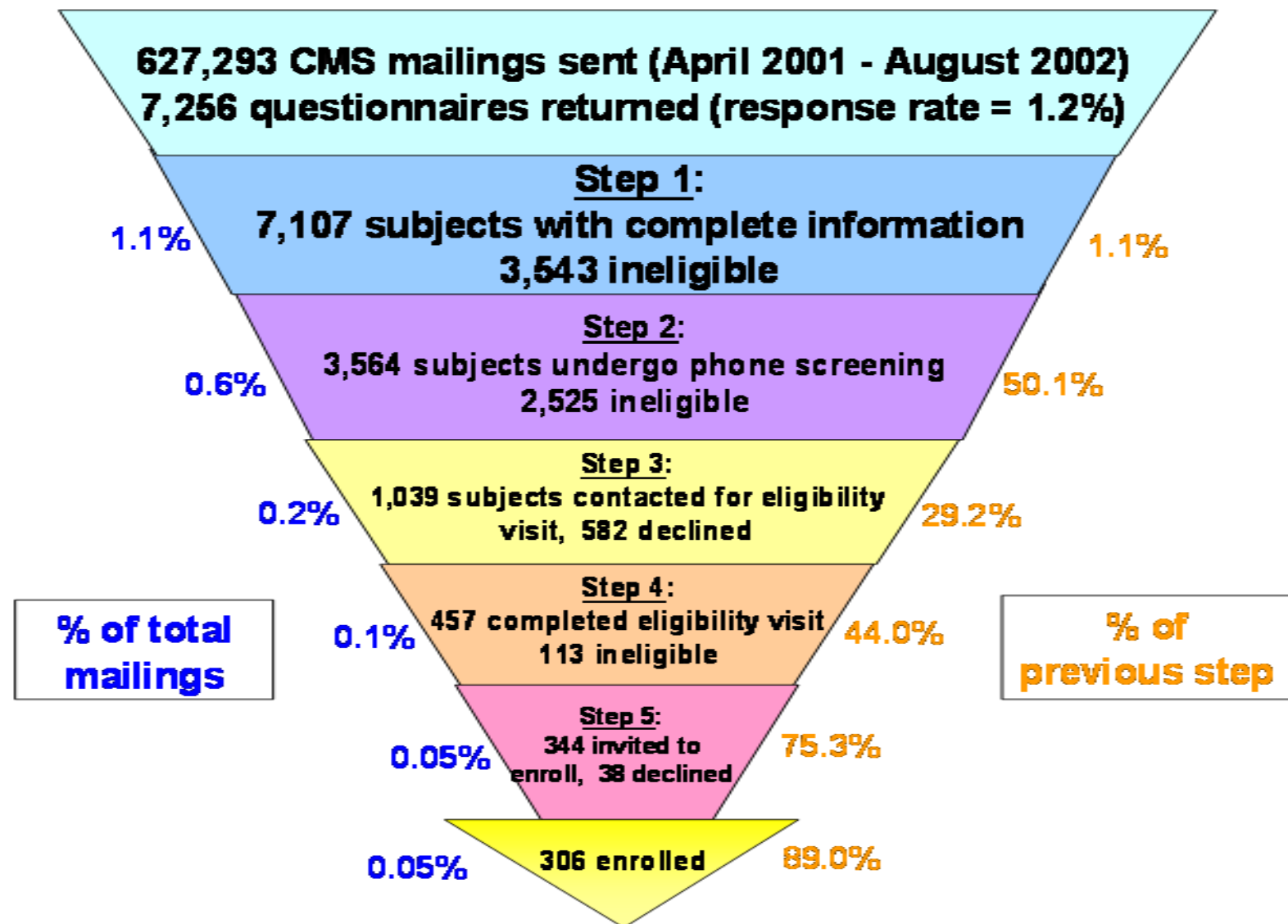
Overall Mailing Strategies, cont'd.

- 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

Mailing Strategies and Response/Enrollment Rates by Site

	Boston	Johns Hopkins	Sun Health	Univ. Rochester	Roskamp	Univ. Wash.
Response Rate	1.33% (.87 – 2.04%)	2.3%	1.7	2.6% (est.)	1.75-2%	Not available
Enrollment Rate	.07%	.06% av (1.5% in DC area; .01% in Balt. City)	.16%	.06%	.24%	Not available

Progression through the Recruitment Process in ADAPT



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