The Ocular Hypertension Treatment Study (OHTS): Using a Professional Tracing Service to Locate Participants 6 Years After Study Closeout

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Introduction

The Ocular Hypertension Treatment Study (OHTS) was a treatment trial that randomized 1,636 participants with ocular hypertension in32 clinical centers. Ocular hypertension, which can result in glaucomatous damage and vision loss, primarily affects adults over age 55.

Six years following study close-out, the NIH awarded funds for a 20-year follow-up to determine the clinical and QOL status of participants, now median age 78.

- Study goal is to achieve 80% ascertainment of randomized patients, defined as the sum of the following mutually exclusive categories: core visits, telephone QOL surveys, declines, or confirmed deaths).
  - This goal was set to minimize bias due to sampling[1-3] and to protect statistical power[2, 4-7].
- A professional tracing service was utilized to identify contact information of participants who could not be located by clinic study coordinators.

We report the success of this professional tracing service in locating participants lost to follow-up and its effect on ascertainment rate, and cost.

Methods

- OHTS Coordinating Center sent last known information of participants lost to follow-up to Battelle Memorial Institute's Tracing Department.
- Battelle searched proprietary databases (TransUnion TLOxp Tracing Tool, LexisNexis Tracing Tool, Ancestry) for contact information and vital status up to three successive times.
- Data collected: completion of core visits, telephone QOL surveys, declines, and confirmed deaths from traced participants.

Results

	Total To Date
Participants Submitted For Tracing	380
Status Pending†	187 (49.2%)
Death Confirmation	77* (20%)
Core Clinic Visits	44 (11.6%)
Telephone QOL Surveys	35 (9.2%)
Declines	24 (6.3%)
No Contact Data Found	13 (3.4%)
Cost	
Per person Cost	$159.84
Total Cost	$60,739

*Includes deaths directly reported by Battelle, and deaths determined by clinical coordinators using information gained from Battelle

- Battelle traced 380 participants in up to 3 successive rounds of tracings, which resulted in 81%, 16% and 3% of Battelle's findings, respectively.
- Overall ascertainment rate increased by 11% from 66.6% (1,089/1,636 of randomized participants) to 77.6% (1,269/1,636).
- †Of the 187 (49.2%) participants pending: 35 are pending trace results from Battelle; 152 have been traced by Battelle, but no ascertainments have been made.

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Discussion

The Ocular Hypertension Treatment Study (OHTS) faced the task of re-engaging elderly participants six years after study close-out, and set an ambitious goal of an 80% ascertainment rate to maintain study power and minimize bias.

OHTS employed the use of the Battelle Memorial tracing services. Our findings demonstrate the following:

- Battelle Memorial tracing provided contact information and vital status for 20.3% (332/1636 randomized participants) who otherwise would have been lost to study follow-up.
- Information from tracings increased our overall ascertainment rate by 11%, from 66.6% to 77.6% of study participants randomized more than 20 years prior.
- Information from tracings resulted in 6.9% of core clinic visits to [freeze] date and 25% of telephone QOL surveys.
- 52.6% of participants submitted for tracing have not been ascertained. We expect additional ascertainments as participant contact information is utilized by clinic coordinators.

Due to expense, researchers must weigh the costs and benefits of using a tracing service. Single, rather than serial tracing, seems most cost effective.

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