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Tracking and tracing of participants in two large cancer screening trials

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Abstract

Background—Many clinical trials rely on participant report to first learn about study events. It is therefore important to have current contact information and the ability to locate participants should information become outdated. The Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial (PLCO) and the Lung Screening Study (LSS) component of the National Lung Screening Trial, two large randomized cancer screening trials, enrolled almost 190,000 participants on whom annual contact was necessary. Ten screening centers participated in both trials. Centers developed methods to track participants and trace them when necessary. We describe the methods used to keep track of participants and trace them when lost, and the extent to which each method was used.

Methods—Screening center coordinators were asked, using a self-administered paper questionnaire, to rate the extent to which specific tracking and tracing methods were used.

Results—Many methods were used by the screening centers, including telephone calls, mail, and internet searches. The most extensively used methods involved telephoning the participant on his or her home or cell phone, or telephoning a person identified by the participant as someone who would know about the participant's whereabouts. Internet searches were used extensively as well; these included searches on names, reverse-lookup searches (on addresses or telephone numbers) and searches of the Social Security Death Index. Over time, the percentage of participants requiring tracing decreased.

Conclusions—Telephone communication and internet services were useful in keeping track of PLCO and LSS participants and tracing them when contact information was no longer valid.

Keywords

randomized controlled trial as topic; cancer; mass screening; lost to follow-up

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INTRODUCTION¹

PLCO and the LSS component of the National Lung Screening Trial, described in detail elsewhere [1,2], were two large randomized controlled trials designed to assess the ability of certain screening regimens to reduce cancer-specific mortality. PLCO enrolled nearly 155,000 participants from 1993 to 2001, and each participant received a minimum of 10 years of follow-up. The LSS enrolled over 34,000 participants from 2002 to 2004, and each participant received a minimum of five-and-a-half years of follow-up. Participants in both trials were between the ages of 55 to 74 at trial entry and were healthy.

The same ten screening centers participated in both PLCO and LSS. Table 1 displays center name, location, and enrollment for each study. The centers were responsible for collecting vital status information on all participants. This information was collected annually through a self-administered form, the ASU, which was mailed to participants. If the ASU was not returned, the center repeated the mailing; if that failed, the participant was telephoned. If the participant could not be located using these methods, other techniques were employed to find the participant or to determine if the participant was deceased. This process of keeping track of participants and tracing them when lost was intensive and time-consuming, yet it had to be done accurately and thoroughly, as the success of the trials depended on the ability to capture the vital status of all participants.

The PLCO and LSS centers have nearly 20 years of experience in tracking and tracing study participants. This wealth of information is of value to other clinical trials researchers who enroll large numbers of study participants from populations of a similar age and health status. Because the reasons for joining prevention research are likely different from those for joining treatment research, the PLCO and LSS experience are of particular value to researchers who wish to conduct clinical trials in healthy populations, populations that are frequently recruited for large clinical trials of chronic disease prevention in older Americans. To document the tracking and tracing experience of the PLCO and LSS trialists, center coordinators were queried as to the methods that were employed to track and trace participants. We also examined the extent to which the need for tracing changed over time.

MATERIAL AND METHODS

Each center chose its tracking and tracing methods. For the purpose of the current investigation, center coordinators were asked to submit lists of methods employed for tracking and tracing. A spreadsheet was then developed that included all the methods used. Twenty-seven methods were reported. Methods were grouped into three categories: those using information from study forms (PLCO: BLF, FLF; LSS: PCF; 12 methods), those using sources other than study forms not geared towards deaths (9 methods), and those using sources other than study forms that were geared towards deaths (6 methods).

In April 2010, coordinators were sent the spreadsheet and asked to subjectively assess the degree to which each specific method was used by his or her center over the entire course of both studies. They were instructed to leave the box for a specific method blank if the method was not used. If the method was used, the coordinator was to put “+++,” “+,” “+,” or “-“.

¹Abbreviations: Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial (PLCO), Lung Screening Study (LSS), Annual Study Update (ASU), Baseline Locator Form (BLF), Follow-up Locator Form (FLF); Participant Contact Form (PCF), Antihypertensive and Lipid Lowering Treatment to Prevent Heart Attack Trial (ALLHAT), University of Colorado Denver (UCD), Georgetown University Medical Center (GTWN), Pacific Health Research & Education Institute (PHREI), Henry Ford Health System (HF), University of Minnesota School of Public Health (UMN), Washington University School of Medicine (WU), University of Pittsburgh Cancer Institute (UPCI), University of Utah Health Sciences Center and satellite center at St. Luke's Mountain States Tumor Institute (UU), Marshfield Clinic Research Foundation (MCRF), University of Alabama at Birmingham (UAB).

Triple-plus indicated that a method was used extensively, while fewer “+”s indicated that a method was used to a lesser degree. Minus indicated that the method was used but abandoned due to lack of success or other issues. It is assumed that extensive use of a method indicates one that was useful, although one should not assume that an extensively used method was the most cost-effective method or the one with the highest ratio of participants found to effort expended.

To examine whether the need for tracing changed over time, we measured the percentage of participants placed in tracing status for the years 2002–2009 (PLCO) and 2004–2010 (LSS). Although PLCO began in 1993, data on tracing status were unavailable study-wide prior to 2002. A participant was placed in tracing status if no ASU was obtained for two years in a row.

RESULTS

Table 2 presents, by center, tracking and tracing methods and how extensively they were used. Each center used many methods. Telephone contact was the most frequently reported method: all centers stated that they extensively used participants’ home telephone numbers for contact. Telephone contact using a cell phone number, a workplace number, or the number of a person who did not reside in the participants’ house was used extensively by some of the centers. Nine of the ten centers used mailings to the participant to varying degrees. Internet searches were used extensively, especially general internet search engines (searching on name, telephone number, and address), reverse look-up internet search engines (searching on telephone number and address) and the search engine associated with the Social Security Death Index. Names and addresses of specific web sites that were utilized are found in Table 3. Other methods that were frequently used were US Post Office address requests and correction notices, as well as submissions to the National Death Index.

Data in Table 4 indicate that the percentage of PLCO participants in tracing decreased over time. By the start of LSS, centers were experienced with tracking and tracing, and as such the percentage of LSS participants in tracing was low and remained stable throughout the trial. For 2004–2009 (the period of overlap), the PLCO and LSS percentages in tracing were quite similar.

DISCUSSION

In PLCO and LSS, many methods were used to keep track of and trace participants. The most extensively used methods involved telephoning. Mail and internet searches were extensively used by many centers as well.

We know of no other published reports that have explicitly looked at extent of use of specific methods for tracking and tracing participants in large cancer screening trials. Studies assessing other interventions or desiring long-term follow-up, however, have published information on how they kept track of and found lost participants. Lusk *et al* [3] report that in the Antihypertensive and Lipid Lowering Treatment to Prevent Heart Attack Trial (ALLHAT), a participant contact information form was developed and completed each year by study participants. Their contact form has similarities to the FLF and PCF used in PLCO and LSS, respectively; both ALLHAT and PLCO/LSS requested that the participant provide contact information for two additional friends or relatives not residing in his or her home. Lusk *et al* also report that internet and computer searches were an important resource for finding lost participants. This concurs with our findings of the extensive use of web-based searches. While we know of two other studies that have reported on how lost participants were located, the study populations, inner-city children with asthma [4] and

persons who did not attend a tuberculosis clinic after release from jail [5], are dissimilar to PLCO and LSS and therefore detailed comparisons are not warranted. Nevertheless, each study reported at least one method similar to a method used in PLCO and LSS: Senturia *et al* [4] report using reverse-lookup searches and Menendez *et al* [5] report using telephone calls to aid in finding participants.

Because PLCO and LSS participants were healthy when enrolled, and most remained cancer-free throughout follow-up, our results contribute valuable information as to how studies of chronic disease prevention (including secondary prevention) in older Americans can keep track of and trace their participants. A comparison with the ALLHAT study indicates that tracking and tracing methods successfully used in treatment and prevention trials may be similar to those used in PLCO and LSS, but because the motivations for participating in each type of study may differ (personal benefit versus altruism, respectively), it is important to consider whether certain methods are more effective when reasons for participation and continued affiliation differ. There are many challenges in collecting information from an older study population [6]. Decline in physical and mental health, relocation after retirement, placement in assisted living or nursing home facilities, and loss of interest are correlated with advancing age. Therefore, it is of the utmost importance that tracking and tracing activities be flexible enough to handle such situations. Coordinators informally reported that the inclusion of a question on the BLF, FLF, and PCF requesting the names and contact information for two persons who do not reside in the participant's household was very helpful in locating participants who had moved to senior living facilities.

We are not surprised that use of some tracking and tracing methods varied by center. Our centers were different in terms of location, type of facility, and research infrastructure, not to mention lifestyle of participants. For example, persons who live in rural areas change residences less frequently than those who live in inner cities; therefore, mailings to rural participants may be more fruitful, and unique methods may be necessary for transient populations. Screening centers that enrolled many HMO participants may have had access to databases that provided up-to-date contact information, and may not have needed to use other methods. Centers that were located in areas where residents are more trusting and cooperative probably could use direct methods of contact (like phoning or mailing) most of the time. Centers in other locations may have needed to use methods, such as internet searches, that did not involve contacting the participant.

Strengths of our study include that data on tracking and tracing at individual centers was collected through querying of center coordinators, personnel who were on the front line of study activities. Shortcomings of our study include that we were unable to use quantitative data to determine which method resulted in removal of the most participants from tracing status, or prevented the participants from entering tracing status. Furthermore, we were unable to collect data in a prospective, non-subjective manner; the accuracy of our results therefore depends on the recall of the research team members who completed the questionnaire. We believe that our data demonstrating a reduction in the percentage of PLCO participants in tracing status over time indicates that invaluable experience was gained and methods were optimized; however, we cannot rule out the possibility that the decrease indicates the gradual culling of a small, finite group of uninterested participants. The fact that no similar decrease was observed during LSS argues against that possibility.

CONCLUSIONS

Telephone communication and internet services were useful in keeping track of PLCO and LSS participants and tracing them when contact information was no longer valid. While the

majority of our data are not quantitative, our findings will still be of use to other researchers who study persons similar to those who participated in PLCO and LSS.

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Table 1

PLCO and LSS screening centers: location and enrollment

Screening center	Location	PLCO enrollment	LSS enrollment
UCD	Denver and Aurora, CO	13,165	3,743
GTWN	Washington, DC	8,108	1,827
PHREI	Honolulu, HI	10,847	2,359
HF	Detroit, MI	24,665	3,395
UMN	Minneapolis, MN	28,862	6,618
WU	St. Louis, MO	15,042	3,764
UPCI	Pittsburgh, PA	16,930	2,177
UU	Salt Lake City, UT and Boise, ID	14,387	3,159
MFLD	Marshfield, WI	16,740	2,520
UAB	Birmingham, AL	6,811	5,052

Table 2

Methods of tracking and tracing used in PLCO and LSS

		Screening Center										
		UCD	GTWN	PHREI	HF	UMN	WU	UPCI	UU	MFLD	UAB	
Methods using information on study forms	Contact with participant using home telephone	+++	+++	+++	+++	+++	+++	+++	+++	+++	+++	
	Contact with participant using work telephone	++	+++	+	+++	+++	+++	+	+++	+	+	
	Contact with participant using cellular telephone	++	+++	++	+++	+++	+++	++	+++	+++	+++	
	Contact with participant by mail	+++	+++	+++		+	+++	+++	+++	+	+++	
	Contact with participant by mail using an non- primary address	+	+++	+		+++	+	+	+++	+	+	
	Contact with participant using e- mail	+	++	+		+	+	++	+	+	-	
	Contact with member of participant's household by telephone	++	+++	+	+++	+++	+++	+++	++	+	++	
	Contact with member of participant's household by mail		++	+		+			+		+	
	Contact with someone who does not reside in participant's household by telephone	++	+++	+	+++	+++	+++	+++	++	++	++	
	Contact with someone who does not reside in participant's household by mail		+++	+	+				+	+		
Methods other than study forms that are not geared towards deaths	Contact with a physician's office or nursing facility by telephone	++	+	+	+	+++	+	+	+	++		
	Contact with a physician's office or nursing facility by mail	+	-	+	+			+		+		
	General internet search engines, searching on name, telephone number, address	+++	+++	++	+++	+++	+++	+++	+++	+++	+	
	Reverse look-up internet search engines, searching on telephone number and address	+++	+++	++	+++	+++	+++	+++	+++	++	+++	
	Internet search engines that focus on occupations		-	+		+			+			
	Social networking websites		+			+						
	Legal proceedings, vital event, public record websites	+	++	+		+	+++		+++			
	Fee-based internet search engines	++	+++	++	+++	+++	+		++	+	+++	
	Querying of hospital registration systems	+	-		+++		+++	+++	+		+	
	Querying of drivers' licensing bureaus		+			-	+	+				
	Post office address requests and correction notices	++	+++	++	+++	+++	+++		+++	+	+++	

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Table 3

Website addresses for different methods of tracking and tracing

Method	Internet address
General internet search engines, searching on name, telephone number, address	www.google.com, www.yahoo.com, www.bing.com, www.pipl.com, www.zabasearch.com, www.people-finders.ws, search.infospace.com, www.anywho.com, www.dexonline.com
Reverse look-up internet search engines, searching on telephone number, address, neighbors	www.whitepages.com, www22.verizon.com/utilities/reverselookup, www.411.com, www.phonenumber.com
Internet search engines that focus on occupations	www.zoominfo.com
Social networking websites	www.facebook.com, www.myspace.com
Legal proceedings, vital event, public record websites	www.governmentregistry.org, www.UtahsRight.com, web.public-records-now.com, www.vinelink.com
Fee-based internet search engines	www.qclear.com, www.accurint.com
Web-based searches of the Social Security Death Index	ssdi.rootsweb.ancestry.com
Obituary search engines	www.ancestry.com, legacy.com/obituaries.asp

Table 4

PLCO and LSS participants in tracing by study year^a

Year	PLCO N=154,901		LSS N=34,614	
	Number in tracing	Percent of number randomized ^b	Number in tracing	Percent of number randomized ^c
2002	2787	1.8	Recruitment incomplete	-
2003	2372	1.5	Recruitment incomplete	-
2004	1700	1.1	Recruitment incomplete	-
2005	1218	0.8	64	0.2
2006	909	0.6	184	0.5
2007	743	0.5	178	0.5
2008	730	0.5	167	0.5
2009	567	0.4	16	0.0
2010	Not available	-	27	0.1

^a2006 data for UCD were unavailable. Instead, the average of numbers in tracing in 2005 and 2007 was used. Tracing is defined as having no ASU for two years in a row.
^bDenominator for calculation is 154,901 (number of PLCO participants randomized)
^cDenominator for calculation is 24,614 (number of LSS participants randomized)