Obtaining Hospital and Physician Participation In a Case-Control Study of Colon Cancer

NIRA HERRMANN, PHD, JONATHAN AMSEL, DSC, AND EILEEN LYNCH, BA

Abstract: This paper describes efforts to solicit hospital and physician participation for a case-control study of the etiology of colon cancer in the five Pennsylvania counties of the Philadelphia metropolitan area. Forty-seven of the 70 hospitals in this region were eligible for inclusion in the study. Thirty-seven (79 per cent) agreed to participate, 27 of them within six months of initial contact. The median time to approval of participation was three months and the median number of separate contacts was nine. At least five participating hospitals submitted the protocol to their lawyers and nine required that special procedures be developed for release of patient information.

Two hundred fourteen of 256 listed attending physicians were eligible for participation; 161 (75 per cent) permitted all patients to be contacted; 23 (11 per cent) permitted some patients to be contacted; 30 (14 per cent) refused all patient contact. A significant association between type of specialty and type of permission was found ($p \sim .005$).

Concerns about confidentiality and lack of personal advantage were frequently cited by non-participants. The validity of case-control studies relying on hospital or physician ascertainment of cases is seriously challenged by such lengthy delays and lack of participation which can result in a biased pool of potential cases. (*Am J Public Health* 1981;71:1314–1319.)

Introduction

A common epidemiological method for locating cases for a case-control study when there is no central tumor registry serving the geographical region under investigation is to obtain participation from hospitals or physicians treating such cases. The success of the approach depends heavily upon the willingness of the hospitals and physicians to allow their patients to be contacted. Although access to patient record information has been routinely provided for certain traditional purposes—such as employment, life insurance providers, third-party payers, and the government—there has been an increased awareness of the need to maintain patient privacy and confidentiality.[1] Since passage of the Privacy Act of 1974,[2] there has been growing concern over the availability of patient information for scientific purposes, especially in epidemiologic research.[3-6] Of particular interest to this study are the issues of: the need for informed consent;[3,4,6,7] the determination by individual institutions or physicians of the importance and scientific validity of the research;[3,5] the ownership of patient information;[1] and the approval by Institutional Review Boards of participation in a research study.[3,5,6,8] This paper describes efforts to solicit hospital and physician participation for a case-control study of the etiology of colon cancer in the five Pennsylvania counties (Bucks, Chester, Delaware, Montgomery, and Philadelphia) of the greater Philadelphia metropolitan area. The control group was obtained using an area probability sample.

The five-county area contains 70 hospitals of which 39 are located in Philadelphia and the remainder in the four neighboring Pennsylvania counties. The case population was originally confined to White males and females between 45 and 65 years of age who had resided in the region at least two years prior to being diagnosed with colon cancer.* Certain hospitals were removed from consideration for participation after preliminary investigation indicated that they treat few or no cancer patients, have a predominantly Black or highly mobile patient population, or treat only children. These exclusions resulted in 47 hospitals eligible for the study; representing a bed count of 14,517 or 78 per cent of the total five-county bed count.[9] Their characteristics are noted in Table 1.

Methods

Hospital Participation

Prior to submitting a written request for participation, telephone calls were made to each of the 47 hospitals to

From the Department of Research Medicine, University of Pennsylvania School of Medicine. Address reprint requests to Nira Herrmann, PhD, Assistant Professor, Department of Research Medicine, University of Pennsylvania, Nursing Education Building, 420 Service Drive S2, Philadelphia, PA 19104. This paper, submitted to the Journal March 30, 1981, was revised and accepted for publication July 7, 1981.

Editor's Note: See also related editorial p. 1309 this issue.

*The age range was broadened to include cases 66–69 years of age for the second year of the study to ensure that a sufficient number of cases would be available within the study period.

TABLE 1—Characteristics of the 47 Eligible Hospitals

Type of Hospital	No. of Hospitals	Total Bed Count (Set-up and Staffed)			Total Size of Surgical Staff			Eligible Colon Cancer Cases from Participating Hospitals	
		No. of Beds	% of Eligible Total	% of Participating Total	No. of Surgeons	% of Eligible Total	% of Participating Total	No. of Cases	% of Total
Teaching Hospitals									
Participating	8	3680	25.3	31.2	171	23.1	28.2	94	20.6
Non-Participating	0	—	—	—	—	—	—	—	—
Community Hospitals									
Participating	27	7481	51.5	63.4	409	55.3	67.5	358	78.5
Non-Participating	9	2619	18.1	—	130	17.6	—	—	—
Other (Government or Specialty)									
Participating	2	637	4.4	5.4	26	3.5	4.3	4	0.9
Non-Participating	1	100	0.7	—	4	0.5	—	—	—
Subtotals									
Participating	37	11798	81.3	100.0	606	81.9	100.0	456*	100.0
Non-Participating	10	2719	18.7	—	134	18.1	—	—	—
TOTALS	47	14517	100.0	—	740	100.0	—	—	—

*5 additional cases were obtained from an individual physician at a non-participating hospital.

identify the appropriate contact person. As indicated in Table 2, most of the hospitals specified an administrative officer.

Each hospital contact person was sent a letter requesting participation in the study by identifying to the investigators the hospital's newly diagnosed colon cancer patients and seeking authorization to approach them. Also included were a copy of the protocol describing the study goals, a copy of the informed consent letter which would be given to each patient, and copies of endorsements of the study from the American Cancer Society, Philadelphia Division Inc., the Philadelphia Cancer Coordinating Association, and the Cancer Control Subcommittee of the Philadelphia County Medical Society.

Repeated contacts by letter, telephone, and attendance at hospital committee meetings were made by staff members over a 21-month period to obtain agreement to participate from the eligible hospitals.

TABLE 2—Titles of Initial Contact Persons Specified by the Hospitals

Title of Contact Person	No. of Hospitals
Administrative Officer (President, Vice-President, Executive Director, Administrator)	32
Chief of Staff	6
Medical Executive Committee	3
Medical Director	2
Research Committee	2
Director of Medical Records	1
Director of Tumor Registry	1
TOTAL	47

The non-participating hospitals were contacted until they agreed to participate or adamantly refused. Whenever a change in key medical or administrative staff signaled that a change in policy might be made, non-participating hospitals were again approached. In a final attempt to obtain participation, the non-participating hospitals were sent a letter in November 1978 over the signature of the Chairman of the Cancer Control Subcommittee of the Philadelphia County Medical Society requesting their participation. This letter did not result in any additional participants. At one hospital which refused to participate, an individual physician agreed to participate and submitted all of his patients' names. For the purposes of this report, however, this hospital is listed as non-participating since patients from other physicians were not available for inclusion in the study.

The participating hospitals were given morbidity forms to complete for each case. These forms contained entries for the patient's name, address, attending physician, date of diagnosis, and the diagnosis from the pathology report. Completed forms were submitted to the study staff approximately every three months. If no reports were received from a hospital for four months, or if the number of reported cases seemed unusually small compared to previous reports, the hospital would be contacted by the study staff. In addition, at intervals, letters were sent to the hospital contacts thanking them for their cooperation and urging their continued assistance in the study.

Physician Participation

Upon identification of an eligible case by a participating hospital, a form letter was sent to the attending physician of record as noted on the morbidity form. The letter described

TABLE 3—Distribution of Separate Contacts with Hospitals Made by Project Personnel and Months from First to Last Contact by Type of Hospital

Type of Hospital	No. of Hospitals	Number of Separate Contacts Made				Number of Different Officers/ Committees Contacted			Number of Months from First to Last Contact		
		Total #	Average	Median	Range	Average	Median	Range	Average	Median	Range
Teaching	8	91	11.4	13.0	1–18	2.1	1.5	1–6	5.7	5.9	1.0–10.0
Community	36	371	10.3	8.5	1–51	2.2	2.0	1–4	7.9	3.5	0.5–26.0
Other	3	40	13.3	14.0	3–23	2.0	2.0	1–3	8.8	5.5	0.5–20.5
TOTAL	47	502	10.7	9.0	1–51	2.2	2.0	1–6	7.6	3.5	0.5–26.0
Participating	37	342	9.2	6.0	1–51	2.1	2.0	1–6	4.7	3.0	0.5–26.0
Non-Participating	10	160	16.0	17.0	7–23	2.5	2.5	2–3	18.4	19.5	6.0–20.5

the purpose of the study and advised the physician that a study staff member would call to obtain permission to contact the patient if the patient were selected for participation in the study.

Certain hospitals imposed special procedures for reasons of confidentiality and released only the hospital identification number and the name of the attending physician. The remaining information for those patients was obtained directly from the physician.

Results

Hospital Participation

As shown in Table 3, a total of 502 contacts was made to elicit hospital participation between February 1977 and November 1978. On the average, nine contacts were made with hospitals who ultimately agreed to participate and 16 with those who persistently refused to participate.

Thirty-six of the 47 hospitals required that the study be reviewed by two or more different officers or committees. In one case, six different individuals and committees including the President and senior members of the medical staff were contacted prior to the hospital's approval of participation in the study, a procedure which took 10 months to complete.

On the whole, as seen in Table 3, a number of months elapsed between the initial and final contact. Of the 37 participating hospitals, 27 had agreed to participate within six months of the initial contact, while one agreed only after 26 months and 21 separate contacts from study personnel. Overall, the number of months until agreement to participate was positively correlated with both the number of separate contacts and the number of different officers or committees which had to be contacted.

At least five of the participating hospitals submitted the protocol to their lawyers for consideration of possible confidentiality problems. Legal review delayed final agreement to participate for one year at two of these hospitals. At one hospital, legal counsel insisted that the informed consent letter be modified to include a disclaimer that "no compensation for medical treatment is available and no compensation for physical injury is available as a result of participation"[10] in the study even though no behavioral or biomedical research was involved. At another hospital, demands of an attending physician that his patients not be identified to the study were overruled by a hospital lawyer who maintained that the hospital had a right to participate in research studies. The hospital's research committee upheld the lawyer's decision and the hospital continued to participate.

Nine participating hospitals required that special procedures beyond those specified in the original protocol be developed for release of patient names. These more elaborate procedures included release of only the hospital identification number to study personnel who then had to contact the attending physician to obtain names and addresses and permission to contact the case for interview (four hospitals); consent of the attending physician before release of patient names or addresses (four hospitals); and (in one case) required a staff physician to complete the morbidity forms containing the name and address of each case. An additional two hospitals required a fee for handling of each completed form sent to the study and one requested a copy of the final report as a condition for participating.

The 10 non-participating hospitals cited a number of reasons for their refusals to participate. They included: concerns about confidentiality issues (cited three times but suspected at an additional two hospitals, including one which was being sued by a patient whose name had been released to another study); lack of interest in the study or no advantage to the hospital in participating (cited three times); shortage of time and staff to accept an additional burden (cited four times); and concerns over the validity of the study design and hypotheses despite explanations by study staff of the study goals with supporting references from the literature and peer review acceptance of the study design (cited three times).

The 37 participating hospitals contained over 81 per cent of the bed count from the 47 eligible hospitals and 63 per cent of the total bed count of the five-county study region. The combined surgical staff from the participating hospitals comprised 82 per cent of the total surgical staff at the eligible hospitals.

The percentage of eligible cases for the study did not reflect exactly either the distribution of bed counts or size of surgical staff. Although the teaching hospitals contained 31

TABLE 4—Physician Response to Request for Patient Contact

Physician Response	Physicians		# Requests for Permission to Contact Patients	
	No.	%	Requests	Permissions Granted
All permissions	161	75	228*	228
Some permissions	23	11	74	46
No permissions	30	14	39	0
TOTAL	214†	100	341	247

†Does not include physicians who either had no live patients (27) or who had no patients who were assigned (24).
*An additional 38 requests for permission were made but the patients were subsequently determined to be decedents (18 cases) or were not assigned for interviews (20 cases) because the study sample size was already achieved.

per cent of the bed count of participating hospitals, only 21 per cent of the eligible cases came from them (Table 1). This discrepancy reflects the high percentage of Black patients seen in these urban hospitals as compared to the suburban community hospitals; the high proportion of referrals from outside the five-county study area; and referrals from other area hospitals where the primary diagnosis was made. Since the study was restricted to incident cases, referred cases from within the study area were not eligible if the initial diagnosis were not within the study period.

The community hospitals with only 63 per cent of the bed count of participating hospitals provided almost 79 per cent of the eligible cases. This was due to the large proportion of the patient population meeting the eligibility requirements for the study.

The quality of case reporting varied considerably among the participating hospitals. Using hospital size, patient population characteristics, and estimated number of expected cases as a measure of potential eligible cases, and comparing this to the number of cases reported, 25 of the 37 hospitals were evaluated as having good or excellent reporting. Inadequate reporting by the remaining 12 hospitals appeared to be due to elaborate confidentiality procedures (as imposed by several of the hospitals), refusals by individual physicians to permit release of their patients' names, rapid turnover in medical records personnel, or lack of interest in the study by the hospital contact person.

Physician Participation

Initial letters were sent to a total of 265 physicians listed as attending physicians for the 461 eligible cases.** It was not necessary to request permission to contact patients of 51 of these physicians either because their cases were not needed to complete the study protocol (24 physicians) or all their eligible patients were already deceased (27 physicians). Of the remaining 214 physicians, 161 (75 per cent) permitted all patients to be contacted; 23 (11 percent) permitted some patients to be contacted; 30 (14 per cent) refused all patient contact (see Table 4). In a few instances, the attending physician referred the interviewer to the case's family physician for permission.

The physician responses were categorized by year of graduation from medical school, specialty, and type of hospital affiliation (community or teaching). The only statistically significant association was between specialty and type of permission granted. As shown in Table 5, a somewhat larger proportion of surgeons give only some or no permissions compared to the other specialty groups. The median year of graduation for physicians who gave no permissions is 1948 (interquartile range, 1943–1955); while the median year of graduation for physicians who gave some or all permissions is 1956 (interquartile range, 1944–1961).

Physician refusals were based on an evaluation of the patient's mental and physical capacity to participate, apprehension over legal technicalities, or an unspecified unwillingness to participate in the study. Of the 30 physicians who refused their permission, 50 per cent cited their basis for refusal as "not interested in participating in studies," while two based their refusals on legal aspects of granting permission for patient contact.

Discussion

Obtaining hospital participation in this study was more difficult and took more time, both in terms of research staff effort and elapsed months, than initially expected. Since each hospital used a different procedure in determining participation in extramural research studies, securing authorization for the study required detailed, personalized attention for each hospital. Some hospitals had no pre-established procedure for handling external requests for participation. In some instances, it was necessary to find an affiliated physician willing to sponsor the project or take responsibility for granting permission.

The lengthy delays at some hospitals resulted in the loss of potential cases to death because they could not be contacted right away. These losses can result in a biased sample of cases containing a greater proportion of long-term survivors and fewer short-term survivors than in the general population of cases. The excessive number of contacts also

**Including the five eligible cases from an individual participating physician at a nonparticipating hospital.

TABLE 5—Physician Response Characterized by Specialty

Physician Response	Internal Medicine/ Gastroenterology #	%	Surgery #	%	Other* #	%	Total #
All permissions	53	76.8	75	68.8	32	91.4	161
Some permissions	4	5.8	17	15.6	2	5.7	23
No permission	12	17.4	17	15.6	1	2.9	30
TOTAL	69	100.0	109	100.0	35	100.0	214

*Radiology, oncology, proctology and colon and rectal surgery, family practice.

posed an unanticipated financial burden on the study since so much research staff time was directed at obtaining participation.

The refusal of certain hospitals to participate can create an additional source of bias in the pool of eligible cases. The hospital use patterns were not adequately documented for the assessment of the exact nature of this bias by determining precisely which cases were lost to the eligible pool. The only information available on hospital discharges for area residents was the aggregate data on Medicare patients. This was not sufficiently detailed for this study.

Confidentiality concerns resulted in the involvement of lawyers at several hospitals and in changes to the protocol for releasing patient names, as well as in refusal to participate. In some cases, an attempt to shift or share responsibility was evidenced in the requirement that the patient's name and address be obtained from the attending physician rather than directly from the hospital. Additional delays at this stage of the study resulted in more losses of cases to death.

Issues of confidentiality were further complicated by the question of where the ultimate responsibility for protecting the patient lies and who is authorized to release patient information. For example, although one hospital released patient names over the objections of one of the physicians who did not want his patients' names released, at other hospitals the individual physicians were given final authority in the decision as to whether or not a patient could be contacted. Permission to contact a patient did not constitute any commitment on the part of the patient to participate in this study. The patients were given informed consent letters which stressed the voluntary nature of participation and assured confidentiality of any information which was obtained.

The most disturbing reason for hospital refusal was a perceived lack of advantage to the individual hospital in participating. This lack of interest was frequently expressed independently of any concerns about overburdening staff. Skepticism about the merits of the study (or, on occasion, of any study) was also expressed despite assurances that the study had passed peer review. Although it is the responsibility of each institution to act in an ethical manner in deciding to release patient information, it is not clear that the individual Institutional Review Boards (IRB) are the appropriate bodies for providing peer review.[5]

This wariness to be involved in research was also evidenced among the physicians. Such a lack of interest must be of real concern to epidemiological researchers. Failure to interest a physician in a study may result in a domino effect within a hospital as one doctor's vocal objections to the study may influence others not to cooperate. This was observed on a small scale within the present study: six of the 30 physicians who completely refused to participate were from two small community hospitals. Difficulties had been experienced with a doctor from each of these hospitals in the beginning of the study. One physician was angered that the hospital had released his patient's name; the other complained about "being bothered."

In some cases, physician participation was encouraged by the involvement of senior medical personnel in soliciting cooperation. In five cases, the involvement of the Principal Investigator resulted in agreement to participate where research staff had been unsuccessful. This may indicate a need to exhibit a serious commitment to the study at the highest level in order to elicit additional efforts from already busy physicians.

Obtaining hospital and physician agreement to participate in a research study by releasing the names and addresses of eligible cases proved to be a major undertaking. Many months passed before a reasonable number of hospitals and physicians agreed to participate and the difficulties in assessing sources of bias in the eligible case pool because of delays and incomplete coverage are great.

REFERENCES

1. Ware WH: Old practices in a new age endanger information privacy. Hospitals, JAHA 1977;51:133–140.
2. Privacy Act of 1974. 5 U.S.C. §552A, 1980.
3. Curran WJ: The privacy protection report and epidemiological research. Am J Public Health 1978;68:173.
4. Gordis L, Gold E: Privacy, confidentiality, and the use of medical records in research. Science 1980;207:153–156.
5. Burt BA: Ethical considerations in dental epidemiological studies. J Dent Res 1980;59(C):1289–1291.
6. Cons NC: Interpreting ethical guidelines for dental epidemiological surveys. J Dent Res 1980;59(C):1292–1295.
7. 45 Code of Federal Regulations §46.101–46.401, 1978.
8. Rothman KJ: The rise and fall of epidemiology, 1950–2000 AD. N Engl J Med 1981;304:600–602.

9. Directory of Licensed/Approved Hospitals in Pennsylvania, Harrisburg: Pennsylvania Department of Health, 1977.
10. Title 45. Federal Register 1978;43:51559.

ACKNOWLEDGMENTS

This study was supported in part by funds from the United States Environmental Protection Agency (Grant No. R80459401), Anita K. Bahn, MD, ScD, Principal Investigator. This paper is the result of work begun and sustained by Dr. Bahn before her untimely death. We would like to thank Frank Briglia, Janet Cherry, Judy Kinman, Ira Rosenwaike, Dr. Elaine Zeighami and the participating hospitals and physicians for their time and effort on this study.

U.S. POSTAL SERVICE

STATEMENT OF OWNERSHIP, MANAGEMENT AND CIRCULATION
(Required by 39 U.S.C. 3685)

1. TITLE OF PUBLICATION	A. PUBLICATION NO	2. DATE OF FILING
American Journal of Public Health		10/16/81
3. FREQUENCY OF ISSUE	**A. NO. OF ISSUES PUBLISHED ANNUALLY**	**B. ANNUAL SUBSCRIPTION PRICE**
monthly	12	$50

4. COMPLETE MAILING ADDRESS OF KNOWN OFFICE OF PUBLICATION (Street, City, County, State and ZIP Code) (Not printers)
1015 Fifteenth Street, NW, Washington, DC 20005

5. COMPLETE MAILING ADDRESS OF THE HEADQUARTERS OR GENERAL BUSINESS OFFICES OF THE PUBLISHERS (Not printers)
same as above

6. FULL NAMES AND COMPLETE MAILING ADDRESS OF PUBLISHER, EDITOR, AND MANAGING EDITOR (This item MUST NOT be blank)

PUBLISHER (Name and Complete Mailing Address)
American Public Health Association, 1015 15th St., NW, Washington, DC 20005

EDITOR (Name and Complete Mailing Address)
Alfred Yankauer, MD, MPH, 1015 15th Street, NW, Washington, DC 20005

MANAGING EDITOR (Name and Complete Mailing Address)
William H. McBeath, MD, MPH, 1015 15th Street, NW, Washington, DC 20005

7. OWNER (If owned by a corporation, its name and address must be stated and also immediately thereunder the names and addresses of stockholders owning or holding 1 percent or more of total amount of stock. If not owned by a corporation, the names and addresses of the individual owners must be given. If owned by a partnership or other unincorporated firm, its name and address, as well as that of each individual must be given. If the publication is published by a nonprofit organization, its name and address must be stated.) (Item must be completed)

FULL NAME	COMPLETE MAILING ADDRESS
American Public Health Association	1015 15th St., NW, Washington, DC 20005

8. KNOWN BONDHOLDERS, MORTGAGEES, AND OTHER SECURITY HOLDERS OWNING OR HOLDING 1 PERCENT OR MORE OF TOTAL AMOUNT OF BONDS, MORTGAGES OR OTHER SECURITIES (If there are none, so state)

FULL NAME	COMPLETE MAILING ADDRESS
no capital stock	

9. FOR COMPLETION BY NONPROFIT ORGANIZATIONS AUTHORIZED TO MAIL AT SPECIAL RATES (Section 411.3, DMM only)
The purpose, function, and nonprofit status of this organization and the exempt status for Federal income tax purposes (Check one)

(1) ☒ HAS NOT CHANGED DURING PRECEDING 12 MONTHS
(2) ☐ HAS CHANGED DURING PRECEDING 12 MONTHS (If changed, publisher must submit explanation of change with this statement.)

10. EXTENT AND NATURE OF CIRCULATION	AVERAGE NO. COPIES EACH ISSUE DURING PRECEDING 12 MONTHS	ACTUAL NO. COPIES OF SINGLE ISSUE PUBLISHED NEAREST TO FILING DATE
A. TOTAL NO. COPIES (Net Press Run)	37,000	37,500
B. PAID CIRCULATION 1. SALES THROUGH DEALERS AND CARRIERS, STREET VENDORS AND COUNTER SALES	0	0
2. MAIL SUBSCRIPTION	35,025	35,395
C. TOTAL PAID CIRCULATION (Sum of 10B1 and 10B2)	35,025	35,395
D. FREE DISTRIBUTION BY MAIL, CARRIER OR OTHER MEANS SAMPLES, COMPLIMENTARY, AND OTHER FREE COPIES	200	200
E. TOTAL DISTRIBUTION (Sum of C and D)	35,325	35,595
F. COPIES NOT DISTRIBUTED 1. OFFICE USE, LEFT OVER, UNACCOUNTED, SPOILED AFTER PRINTING	1,675	1,905
2. RETURN FROM NEWS AGENTS	0	0
G. TOTAL (Sum of E, F1 and 2 - should equal net press run shown in A)	37,000	37,500

11. I certify that the statements made by me above are correct and complete

SIGNATURE AND TITLE OF EDITOR, PUBLISHER, BUSINESS MANAGER, OR OWNER
Adrienne Ash