Notification of a Cohort of Workers at Risk of Bladder Cancer

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Surviving members of occupational cohorts studied in retrospective analyses of mortality usually are not notified individually of positive study results. However, concern has arisen that such results may contain risk information pertinent to study subjects. To evaluate the effects and implications of individually notifying survivors of such cohorts, we conducted a pilot notification study. Members of a cohort of 1,385 chemical workers who had handled carcinogenic amines were notified by mail that they were likely to be at increased risk of bladder cancer. Also a bladder cancer screening and follow-up program was established. The study demonstrated that notification is a complex action and that much care needs to be taken when communicating information on risk. Notification requires development of (1) criteria as to what constitutes a notifiable risk and (2) programs to meet the medical and social needs of the various parties involved in notification.

In 1979, the National Institute for Occupational Safety and Health (NIOSH) undertook a pilot study to evaluate the issues and practical problems involved in individually notifying members of a cohort of chemical workers of their possibly increased risk for occupationally induced bladder cancer.[1] This cohort had worked at a plant in Augusta, Ga., where carcinogenic amines, such as β-naphthylamine (BNA), benzidine, and *o*-toluidine, had been manufactured or used since the 1940s.

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This study derived its impetus from a congressional inquiry concerning the question of whether NIOSH routinely notified study subjects of epidemiologic results.[1] Of particular concern to the Congress were retrospective cohort mortality studies that involved linkage of personnel records to mortality records. While such linkage requires no informed consent, it does involve individually identified records. NIOSH routinely notifies companies, trade groups, unions, the Occupational Safety and Health Administration, the Mine Safety and Health Administration, and state health and labor departments of the results of such studies, and the results are typically published in the scientific literature and reported in the media. However, it has not been common for NIOSH to notify individual cohort members of study results.

Many questions impinge on the issue of notification of subjects of the results of epidemiologic studies.[1-6] These issues range from ethical considerations subsumed under the rubric, "the right to know," to technical considerations concerning the limitations of the epidemiologic method to discern individual risk. Although many of these issues are unresolved, there is an emerging consensus that individuals have a right to be informed of risk information about themselves when such information is held by an institution such as a government, corporation, university, or labor union.[1-3]

The cohort selected for notification in this study had not (prior to the notification) actually been found to be at increased risk in a previously conducted retrospective cohort mortality study. That study is in progress. However, based on the fact that the cohort was known to have had heavy exposure to proved human carcinogens, the investigators believed that an excess risk was likely to be present and that the cohort would be found to have an excess incidence of bladder cancer.

Although various groups, such as asbestos workers[7] and vinyl choride workers,[8] have previously been notified of excess risks, the study reported herein is believed to be the first actual evaluation of the procedures and impacts of notification. It was designed to identify practical problems associated with notification and to develop a model for future use in similar situations. Also a concomitant effort

was made to assess the risk for bladder cancer in this cohort; the results of that epidemiologic risk assessment will be discussed in a companion article.

Methods and Materials

Cohort Ascertainment – As a prerequisite to notification, it was necessary for NIOSH to acquire the names, addresses, and current vital status for all members of the cohort. In 1972, NIOSH researchers had microfilmed all pertinent personnel records from the company. The records consisted of a card on each worker containing the following information: name, address, date of birth, department, jobs worked, date of work, wage, Social Security number, spouse's name and address, and name and address of a person to notify in event of emergency. Not all records were complete, and the degree of incompleteness was quite variable. The information from these personnel records was coded, keypunched, and stored in a computer file and served as a basis for notification.

The cohort at risk was defined to include all hourly employees who ever worked at the company between Jan. 1, 1940, and Dec. 31, 1972. From review of the personnel records, a total of 1,385 individuals were included in the cohort. The sex and race distribution of the cohort is presented in Table 1; 32% of the males were identified as white, 66% as black, and 2% were of unknown race.

In 1979, the cohort list was sent to the Social Security Administration (SSA) and to the Internal Revenue Service for determination of vital status for each worker; address information was sought for those alive, and state of residency or of SSA claim-filing for those deceased. Additionally, the list was sent to the state bureaus of motor vehicle registration in Georgia and South Carolina for further address information. In some cases, address confirmation was requested from the main post office in Augusta. After completion of those efforts, 269 (24%) members of the cohort were still of unknown vital status or apparently deceased, but with no indication as to why they had died or where their death certificates were located. These files were referred to a commercial firm with experience in tracing subjects for epidemiologic studies.

Table 1 – Sex and Race Distribution of the Augusta Cohort as Derived From Personnel Records

Sex	No.	% of Cohort
Male	1,313	94.8
Female*	72	5.2
Total	**1,385**	**100.0**
Race (Males)	**No.**	**% of Males**
White	415	31.6
Black	871	66.3
Oriental	1	0.1
Unknown	26	2.0
Total	**1,313**	**100.0**

* Of 72 female workers, 68 were white, two were black, and two were of unknown race

On Jan. 20, 1981, it was established that of 1,385 individuals in the cohort, 272 were deceased, and 19 had no address available. Consequently, we assumed that the number who could potentially be notified was 1,094. The geographical distribution of these surviving members of the cohort is shown in the Figure: 789 (73%) had addresses in or within a 50-mile radius of Augusta. These were designated as the "in-town" group. Those with addresses at more distant locations were designated the "out-of-town" group. This stratification by distance was a necessary prerequisite for developing the notification and medical screening strategies.

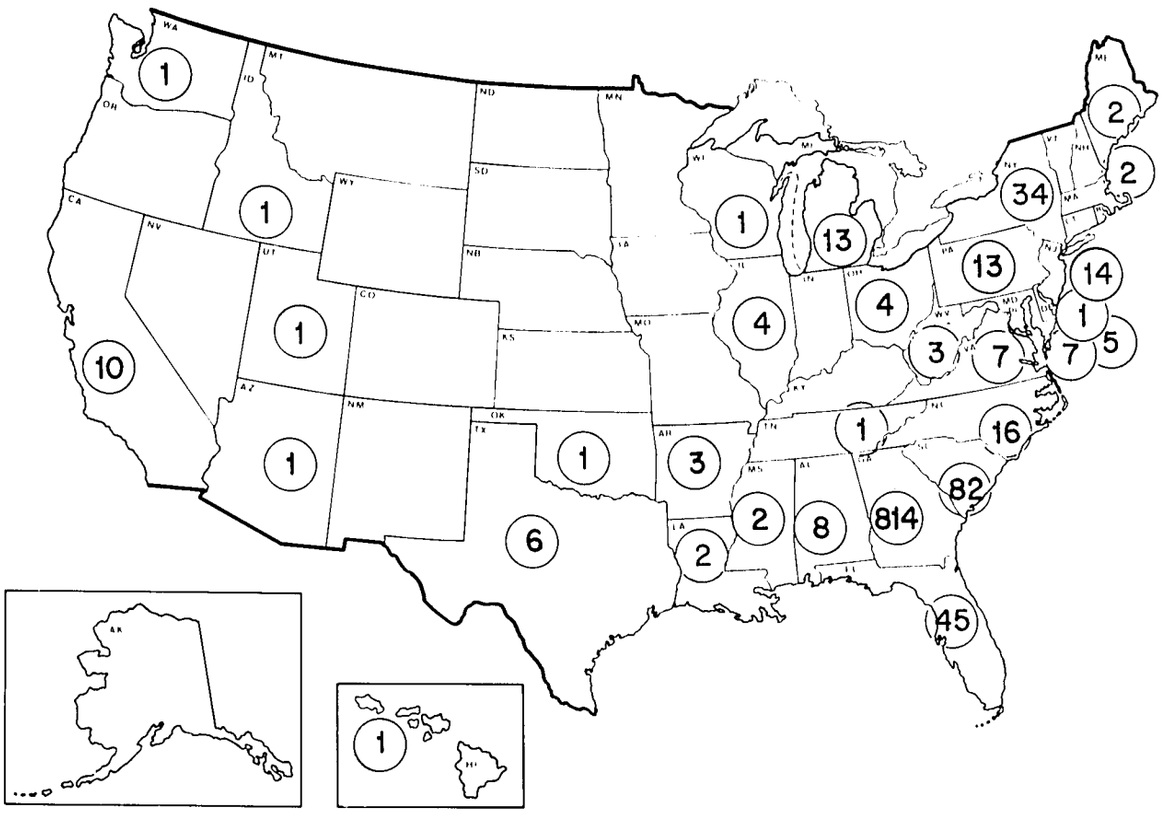
Development of the Notification – From the outset, we considered notification to be a multistage process rather than a single act. The effort would be triggered by NIOSH. However, we envisioned that media, community groups, local agencies, and individuals within the cohort would serve as additional sources of notification. Therefore, we determined from the outset of this study that assessment of the efforts of these groups must be included in the evaluation of the effectiveness of notification.

Personal notification by first class U.S. mail was the approach selected for initial contact. This approach was considered to be a method of notification most likely to be used by NIOSH in future notifications, and therefore it was appropriate to evaluate this approach in this demonstration project.

Although the degree of risk among cohort members was not considered to be homogeneous, three factors led us to make a decision that the same initial notification message should be sent to all members of the cohort. First, because of the amount of missing information on job assignment and because of the multiplicity of chemical exposures among workers in the plant, the personnel records were not an adequate basis for identification of the extent of exposure. Second, reports from the NIOSH investigators who first evaluated the plant in 1972 indicated that the plant historically had been dusty and dirty and that all employees had potential exposure to aromatic amines. Third, since BNA is an extremely potent carcinogen that has been shown to cause cancer with apparently minimal exposure, we were concerned that a decision not to notify some members of the cohort might represent a breach of ethics.

The initial notification letter was developed with the assistance of appropriate members of the Augusta community. An effort was made to include in the letter the point that risk is a probabalistic concept and not deterministic. The primary letter was designed merely to notify a person of his risk and to indicate that something could be done to try to manage this risk. The letter did not try to answer all possible questions, but rather was intended to give enough information so that a person would be motivated to enter a program of medical surveillance. Contained in the letter was a telephone number for clinic appointments or general information. Although there was concern that a substantial proportion of the cohort might be functionally illiterate, we nevertheless believed that a letter would be the most effective medium for initial notification. The initial letters were mailed on Aug. 28, 1981.

Those members of the cohort who failed to respond and



Geographic distribution of the Augusta cohort, 1980.

whose initial letters were not returned by the post office as undeliverable by the end of three months were sent a second notification letter. This letter was designed to emphasize that an asymptomatic state was no proof that a person would remain free of disease. Those members who still did not respond to the second letter were telephoned six months later. The following information was sought in these telephone contacts: (1) whether the person had received the notification letter, (2) whether the person had understood it, (3) and what the person intended to do about it. Further information was supplied if requested. If a person indicated that no further contact was desired, that request was acknowledged.

The "out-of-town" cohort members had an opportunity to respond to notification in two ways: either by returning an enclosed postage-paid form (including their telephone number) indicating their desire to participate in screening (to be arranged with a physician in their own community), or by calling (collect) a number specified in the notification letter. Nonresponse for this group was followed by a second and third letter and then, if necessary, by telephone, where telephone numbers could be obtained.

A staff member in the Richmond County Health Department was charged with the task of locating valid addresses for those Augusta-area subjects whose letters were returned as undeliverable. He traced cohort members using such sources of information as city directories, voting rolls, and telephone books, as well as through direct contact and extensive discussion with members of the cohort and with various relatives and friends of missing cohort members.

Related Program Components – Simultaneous with planning of the notification itself, we developed several related program activities. In particular, a medical surveillance program focusing on screening, early detection, and treatment for bladder cancer was organized as a special clinical activity in the Department of Family Medicine of the Medical College of Georgia (located in Augusta). An initial screening of all cohort members was funded by NIOSH as a part of this project.

We recognized that for two reasons it would be most important to enlist the help of the County Health Department and of local physicians in this effort: (1) for support of the project during its initial stage (at the medical college) and (2) for provision of future care and medical surveillance after withdrawl of the federal presence. Hence, we held three meetings with the local medical societies to encourage cooperation of their members. Subsequently, we sent a detailed letter giving an overview of the project to approximately 900 physicians in the region. A key feature of the letter was the statement that the County Health Commissioner would serve as the registrar of cases identified in the future. The Richmond County Health Department was, therefore, to serve as the focal point of an ongoing surveillance system.

Also, in this connection, an ad hoc committee of the Richmond County Board of Health, the Hazardous Sub-

stances Committee, was created to serve as a community-based group that would maintain ongoing concern and advocacy for the needs of the cohort. The committee consisted of a member of organized labor, a member of the business community, a member of the community-at-large, and a representative from the company and was chaired by the Commissioner of Health. The charge to the committee was to support the project and to encourage the development of ongoing programs.

Prior to the mailing of the initial notification letter, we held meetings with the regional and local chapters of the American Cancer Society, the general community, the Richmond County Health Department, Medical College of Georgia, legal aid services, and the media. Experienced field workers were engaged to assess the community. They identified and enlisted the assistance of many people (particularly in the black community) who were concerned about the problem and who expressed a willingness to participate in the development of the project.

From both a research and a service perspective, these community programs were considered to be important; they were intended to enhance participation in the screening program and to provide supplementary information to the cohort. Moreover, we were of the opinion that this strong community participation would assist cohort members and their families in dealing with the immediate and subsequent psychological and social impacts of notification.

To further involve the cohort, a second committee, the Committee of Concerned Citizens (CCC), was formed under a grant from the National Cancer Institute and was incorporated as a nonprofit organization. This committee consisted of people from the cohort and others who knew members of the cohort personally or were similar to them in socioeconomic status. This committee indicated that it intended to work closely with the cohort to encourage participation in the screening and to achieve financial support for members of the cohort. A staffed office of the CCC was established so that the CCC could respond to inquires from the cohort, promote participation in the screening, and serve as advocate for the workers.

An important component of the notification effort was the mobilization of the print and television media. The goal of the media contact was to furnish general information, to encourage participation in the project, and to minimize fear and anxiety. The media contacts were usually accomplished by means of interviews and press conferences.

We expected that the relationship between the notification effort and these other activities would be sequential in that:

1. The notification letter would initiate the program and would make reference to the other program components.
2. The activities of th CCC and the media would reinforce the impact of the notification letter and promote participation in the available services.
3. The medical surveillance (and other services) would serve as an inducement to participate in the project by providing benefits of value to the subjects.

We recognized that there was no way in which we could separately examine the effects of these various components in our evaluation of the project.

Tracking of Responses to Notification – Tracking of the notification and monitoring of the response was performed by means of a series of master logs. These logs maintained information on the status of each cohort member vis-à-vis response to the initial or subsequent letters, progress through the phases of the screening program, and diagnosis. Regular contact, in person and by mail and telephone, allowed for coordination of the logs. The logs and their eventual tabulation served as the basis for extracting lists of nonrespondents who would then receive further letters. Items of interest and concerns of the cohort members or of the contractors were also recorded in the logs.

Evaluation of Response – To assess the impact of notification, we (1) tabulated the sources of notifications as reported by cohort members, (2) computed rates of participation of the cohort in screening programs, (3) described the reaction of selected portions of the community to the program, and (4) conducted a content analysis of the local print media. Subsequent articles will discuss in further detail the psychosocial effects of notification.

For the in-town group, the principal anticipated response was the setting and keeping of an appointment at the screening clinic. An equally valid but, from the investigational point of view, less desirable response was an indication from the person that he/she was already seeing a physician for assessment of urinary function. A questionnaire was administered to each participant in the screening program. It contained questions about source of notification and about the participant's awareness of the risks of BNA exposure. Responses to these questions were tabulated and evaluated.

Two approaches were used to evaluate the role of the media. The first approach was descriptive. We compiled the chronology of media involvement and related it to parallel events. Second, we conducted a content analysis of the local newspaper coverage based on all BNA-related articles that had appeared in the *Augusta Chronicle* between 1968 and Aug. 1, 1982. This analysis included an enumeration of article topics and an evaluation of the frequency with which these articles amplified or supplemented the notification. A semantic content analysis, following the method described by Andren,[9] was used in this study and focused on the following variables: (1) specification of exposure to a carcinogen, (2) distinction between a probable and an absolute occurrence of disease, (3) identification of the asymptomatic period or the latency period, (4) presentation of information on the screening clinic, (5) discussion of the possible responsiveness of bladder cancer to treatment, (6) identification of the symptoms, (7) identification of other risk factors, and (8) expression of the need for ongoing surveillance.

Results

In the initial notification mailing to the Augusta cohort, 1,094 letters were sent (Table 2). Between August, 1981 and December, 1981, five hundred fifteen (64%) of the in-town recipients and 181 (61%) of the out-of-town recipients responded to this mailing in some manner. This response included making an appointment at the screening clinic, calling to declare no interest, or indicating intention to be screened privately. For the out-of-town group a response involved mailing to NIOSH a postage-paid card that was included with the notification. For the entire cohort, 364 (33%) letters were returned as undeliverable.

Table 2 – Notification and Response Rates for the Augusta Cohort

Total No. in cohort	1,385		
No. assumed deceased prior to notification	272		
No. with no address available	19		
No. assumed alive and sent first letters (8/27/81)	1,094		
Geographic Distribution	**In-Town**	**Out-of-Town**	**Total**
No. actually eligible to receive notification letters	798	296	**1,094**
No. of letters returned as undeliverable	277	87	**364**
(% of eligible)	(35%)	(29%)	(33%)
No. who responded in any manner between 8/27/81 and 12/3/81	515	181	**696**
(% of eligible)	(64%)	(61%)	(64%)
No. of second letters sent (12/3/81)	283	115	**398**
No. of second letters returned as undeliverable	187	58	**245**
(% of eligible)	(22%)	(20%)	(22%)
No. assumed to be notified directly	611	238	**849**
(% of eligible)	(77%)	(80%)	(78%)
No. screened or in process at sponsored clinics by 9/1/82*	433	153	**586**
(% of those notified)	(71%)	(64%)	(69%)
No. who indicated they were seeing their own physician	39	22	**61**
	(6%)	(9%)	(7%)
No. who were out-of-town but screened in-town	...	8	**8**
Total No. screened	472	183	**655**
(% of those notified)	(77%)	(77%)	(77%)

* Excludes an additional 47 persons, who worked for contractors, serviced the plant, or worked for the adjacent railroad and were also screened

By September, 1982, four hundred thirty-three (71%) of the in-town and 153 (14%) of the out-of-town workers, who were assumed to have been notified, had been screened or were in the process. Another 61 (39 in-town and 22 out-of-town) individuals indicated that they were already seeing a physician for screening or treatment related to their urinary system.

For the in-town cohort, of those who received the letter, 556 (91%) had read it and said they understood it, and 458 (75%) said that they had discussed it with another person. Similarly for the out-of-town cohort, of those who reported receiving the letter, 231 (97%) said they had read it, 226 (95%) said they had understood it, and 188 (79%) said they had discussed it.

Several reasons were identified for the failure of letters to be delivered: invalid address, moved with forwarding address expired, moved with no forwarding address extant, no such address, or residence burned. The in-town screened subjects consisted almost entirely of males, and two thirds were black (Table 3). Most had little formal education and relatively low incomes. Twenty-seven percent said that they had other family members who worked at the company.

Demographically the out-of-town cohort was similar to the in-town cohort only in sex distribution. It had fewer blacks, more education, slightly different distribution of marital status, and generally higher incomes.

Awareness of BNA – Of the in-town cohort who attended the screening clinic, approximately 245 (65%) said

Table 3 – Demographic Characteristics of In-Town and Out-of-Town Workers Who Participated in the Screening Clinic

Variable	% In-Town (n = 379)	% Out-of-Town (n = 137)
Sex		
Male	94.0	97.1
Female	6.1	2.9
Age, yr	Male / Female	Male
25-29	3.7 / 4.8	...
30-34	15.6 / 0.0	8.7
35-39	13.1 / 4.8	11.3
40-44	10.5 / 4.8	14.0
45-49	14.2 / 19.1	12.7
50-54	14.2 / 19.1	21.3
55-59	13.6 / 33.3	14.7
60-64	6.5 / 14.3	10.0
65+	8.5 / 0.0	7.3
	Male and Female	
Race		
White	32.4	52.6
Black	67.5	47.4
Education, yr		
≤8	30.9	25.9
9-12	55.3	45.1
>12	13.8	28.9
Marital status		
Married	64.9	84.1
Divorced	12.9	9.4
Separated	10.0	4.3
Widowed	5.0	1.5
Never	7.1	0.7
Income, $		
<5,000	12.1	13.7
5,000-10,000	23.9	16.3
10,000-15,000	19.9	22.9
15,000-25,000	18.4	23.5
25,000-30,000	4.9	6.5
>30,000	3.5	13.1
Chose not to answer	18.4	3.9

Table 4–Knowledge of BNA and Associated Risks for Workers Screened In-Town and Out-of-Town

Variable	% In-Town (n = 379)	% Out-of-Town (n = 137)
Ever heard of BNA prior to notification	64.7	38.4
Date of first knowledge of BNA		
1949-1967	43.8	60.4
1968-1972	20.5	18.9
1973-1980	3.2	1.9
1981	27.7	17.0
Cannot remember	4.8	1.9
Source of first knowledge		
Employment at Augusta chemical company	59.8	66.0
Reading newspaper	15.1	7.5
Talking with someone	10.6	9.4
NIOSH letter	6.5	3.7
Other	7.7	13.2
Ever worked with BNA		
Yes	51.3	75.7
No	16.1	24.3
Do not know	32.6	...
Worked in grinding room	49.4	32.1
Reason to believe BNA was harmful		
Yes	25.1	19.2
No	71.9	80.8
Don not know	3.0	...

that they had previously heard of BNA (Table 4). Overall, the majority, 227 (60%), said that they had first heard about BNA while working at the company. Fifty-seven (15%) indicated they had first learned of BNA from the newspaper, 27 (11%) from talking with someone, and 25 (6.5%) from the NIOSH notification letter. Sixty-nine (28 (28%) said that they had heard of BNA for the first time in 1981. The largest percentage, 167 (44%), had heard about it in the period 1949 through 1967. Of the 69 who first had heard of BNA in 1981, 49% learned by newspaper, 22% by NIOSH letter, 20% by other means, and 9% by conversation. Of those who indicated that they had ever heard of BNA, 51% indicated that they had worked with it, and 32% said they did not know whether they had. Prior experience in the grinding room (a putatively high-risk work area) was indicated by 49%, and another 10% indicated they did not know if they had worked there.

When asked if they had any reason to believe that BNA might be dangerous or harmful to them in some way, approximately 72% said "no," and 3% said they did not know. Of the 25% that did have reason to believe that BNA was dangerous, 8% learned of this danger from a plant official; 15% from a co-worker; 17% from a label; and 61% from past health complaints such as skin discoloration, burns, bumps, sneezing, or urinating blood.

Approximately 52 (38%) of the out-of-town cohort said that they had previously heard of BNA. Table 4 shows when and how the workers first learned this information. Seventeen percent said they they had first heard of BNA in 1981, 19% between 1968 and 1972, and 60% between 1949 and 1967. The majority (66%) said that they had heard about it while working at the company, 7.5% said that they had first learned of it in the newspaper, 9% by talking with someone, 4% by NIOSH letter, and 13% by other means, which most frequently included television. Of

those who indicated that they had ever heard of BNA, 78% indicated that they had worked with it, and 32% said that they had worked in the grinding room. When asked if they had any reason to believe that BNA might be dangerous, 81% said "no."

Evaluation of the Role of the Media – The media played a dual role in this notification. They were both a part of the notification process and a register of its impact. For those people whose addresses were unknown, media coverage was the primary route of notification. For others, media served to amplify or supplement the information conveyed. Fifteen percent of the in-town cohort indicated that they first learned of BNA from the newspaper, and 20% said that the media were the most convincing sources of information that motivated them to participate in the screening.

Most of the local newspaper coverage was by the *Augusta Chronicle,* the larger of the two major local newspapers. It ranked "β-naphthylamine" the fourth most important news story in 1981. The newspaper's series on BNA was submitted for a regional Pulitzer Prize.

Two facets of the *Augusta Chronicle* coverage were controversial. During the preparatory phase of the project, we made an effort to apprise representative members of the community of the nature of the project and to solicit their participation. At the same time, we were strongly of the opinion that widespred publicity should be avoided until a response capability was in place. We were concerned that publicity constituted de facto notification and that premature publicity would trigger unnecessary fear and anxiety among people who had worked at the company as well as in other members of the community. We were concerned also that preliminary publicity would stimulate a demand for medical services before these services were available. Despite our repeated requests for prudence, the *Augusta Chronicle* "broke" the story of the notification effort on Jan. 30, 1981.

To accommodate the reaction of concerned cohort members to that premature announcement, we established a hotline at the Richmond County Health Department three days after the initial article appeared. In the month subsequent to the publication of the article, 27 calls were received on this line. Most callers inquired as to the date of the clinic opening or if certain individuals had been exposed to BNA.

The second controversial newspaper article was a story published on July 13, 1982, in the *Augusta Chronicle* entitled "Ex-Chemical Workers Sought." The article listed the names of 121 former company employees who had not received notification letters due to unknown address. Such publication of the names of individuals potentially invades the privacy of the cohort members and may have been a violation of the Privacy Act of 1974 (5 U.SC. 522a). The information was supplied to the *Augusta Chronicle* by the CCC after they had received it from the Richmond County Health Department, which in turn had received it from NIOSH. No authorization was given by NIOSH for the Health Department to provide this information via the CCC to the *Chronicle.* However, the actions of the Health Department and more specifically of the CCC were consistent with the task of locating cohort members and were motivated by concern that people be screened. Subsequent to the publication of the article, approximately 40 additional people were located. None indicated displeasure with the publication of their names. We believe, however, that, in general, this "leak" substantiates the point made in the publication *A Study of the Issues in Locating Assessing and Treating Individuals Exposed to Hazardous Substances* (National Center for Health Statistics, 1981) that "a balance must be struck between the protection of individual privacy and confidentiality on the one hand and the health of the individual on the other."[10]

Content Analysis of Local Newspaper Coverage – A total of 52 articles on BNA appeared in the *Augusta Chronicle* between 1968 and Aug. 1, 1982. The first article, in 1968, was the earliest public mention in Augusta of the use and risk of BNA.[11] The article included the statements that BNA is "extremely hazardous . . . and . . . produces bladder cancer."

The next article appeared approximately 13 years later on Jan. 30, 1981. It was entitled, "Program to Inform Chemical Workers of Cancer-Causing Chemical." This article was the first of a series. Subsequent articles in the series dealt with seven major topics: (1) prenotification delay, (2) notification, (3) the screening clinic, (4) funding for the future, (5) locating cohort members, (6) results of the study, and (7) litigation. A total of 31 articles on BNA were published in Augusta in 1981, and 20 in 1982.

As would be expected, 92% of the articles specified the exposure, chemical, and company. In descending order of frequency, the following additional topics were mentioned: the screening program, 68%; the asymptomatic nature of the early disease and its latent period, 34%; the probabilistic nature of the risk, 16%; the responsiveness of bladder cancer to treatment, 16%; the need for ongoing surveillance, 14%; and other risk factors for bladder cancer, 4%.

The *Chronicle* coverage was also evaluated for its description of the extent and magnitude of the social, political, and legal problems associated with notification of the cohort. The major concerns expressed were for personal financial plight (16% of the articles) and funding for future surveillance (14%). Fear and anger on the part of cohort members were mentioned (8% of the articles); 6% made reference to occupational disease in the community. Two percent of the articles mentioned each of the following: the potential of the community to be exposed to BNA from the plant; concern about whether other family members of cohort members were at risk; family disruption; and current job-related problems of cohort members. Blame for creating this problem or for failing to respond promptly to it was directed at the company in 12% of the articles and toward government (local, state, federal) in 10% of the articles.

Television Coverage – One of the three major television network affiliates provided especially extensive coverage of this project. A total of 29 different reports were broadcast two times each on either the 6 or 11 o'clock news or the "Midday" report. The television ratings showed that the news reports reached 117,000 viewers and that the "Midday" report reached 150,000 viewers in Georgia and adjacent South Carolina.

Additionally, on Monday, Nov. 17, 1982, the station broadcast a 30-minute prime-time documentary entitled "Lethal Labor." This documentary provided an overview of the entire situation and presented coverage of the seven aspects previously discussed in newspapers.

Other Impacts of the Notification – Various anecdotes provide further evidence of the impact of the notification. One worker was temporarily suspended by his current employer (not the company that owned the plant in question) until he had been screened at the Medical College Clinic. Another worker, attempting to borrow money at a bank, was told that his credit rating had been lowered due to his membership in the high-risk cohort.

More than 80 lawsuits have been filed against either a supplier of BNA or the company that owned the plant in question. Many of the lawsuits appear to have been initiated by people with no evidence of bladder cancer but who had concern about their risk and about the funding of future surveillance.

Discussion

The notification of cohorts at high risk of disease involves interrelated scientific and social issues. Notification is a social action triggered by scientific information and research. Following a notification, there are needs for further social actions and additional scientific information. For discussion purposes, it is useful to examine these issues separately.

Scientific Issues – *Basis for Notification* – The ethical basis for individual worker notification is the possession by an investigator of both the names (and often the addresses) of cohort members and risk information about the cohort.[1,3,5,6] The quality of the risk information is critical to deciding whether or not to notify. Notification projects should not be undertaken in the absence of a solid scientific foundation. Epidemiologic data in particular, but also toxicologic and industrial hygiene information, provide the basis for demonstrating exposure-disease associations or excess risks that are topics for potential notifications.

Epidemiologic information by definition, however, pertains to groups of people rather than individuals and is therefore probabilistic. While all scientific determinations are probabilistic, the demonstration of association or causality in epidemiologic studies is notably so, owing to the multifactorial etiologies, individual variation, and the inability of the investigator to achieve totally controlled study conditions. Therefore, it may be possible to be fairly precise in concluding that the findings of an epidemiologic study are not due to chance, but such precision may not be available to document the web of causation or the degree of confounding and interaction as it applied to an individual cohort member. Nevertheless, using generally recognized scientific criteria, epidemiologic studies have demonstrated disease-exposure relationships with enough specificity, especially in occupational situations, to identify causal agents, subsequent risks, and related diseases. For these reasons, the epidemiologic data guided the development of the project and now provide the basis for planning its future. In the course of the project, it has become possible to go from general data to more highly specific data concerning who is at risk.

Because the exposure history of the cohort was poorly characterized, it was decided to treat all members of the cohort equally in terms of notification methods. Subsequent to the notification and attendant case finding, history taking, and medical screening, it has been possible to characterize the cohort in greater detail. Consequently, the cohort is now being stratified based on risk estimates, and a more differentiated screening program is being designed to target the frequency and content of future medical surveillance.[12]

Criteria for a Notifiable Risk – Critiera for what constitutes a notifiable risk need to be developed. The need for such criteria is particularly evident when a study yields results where the risks are interpreted as being very small. Here it is important to distinguish between the small probability of a common disease from the large probability of a rare disease. In these cases the criteria should include evaluation of the magnitude of both absolute and relative risk. Failure to utilize explicit criteria in the evaluation of study results for notification may result in large numbers of people being notified when they are not at risk.

Social Issues – *Communitywide Efforts* – The results of this study corroborate our contention that notification is not a single act but rather the first stage in a long process that involves not only the cohort, but also their families and community. The Augusta project has demonstrated that, initally, precise individual notification was not always achieved and that a subsequent message was needed to explain specifically who was at risk and what kind of surveillance was recommended. The community activities that surrounded the notification stimulated interest in the project and reinforced the interest of the media. The combined effect, in terms of amplifying and supplementing the notification, was much greater than initially anticipated.

Additionally the CCC performed a vital function in maintaining communication with the cohort. One independent reviewer of the project, who was retained by NIOSH for evaluation, described the CCC as "one of the most positive aspects of this project" because it represented an effort to involve the target population in the planning and implementation of a program that would impact upon it.[13]

Nonnotification – In the Augusta project, a relatively large number of people could not be located (approximately 22% of the target population) despite rigorous search efforts. Other ways to find former workers need to be developed. The risk characteristics of these lost people are not known and need to be evaluated. Also, further characterization is needed of those workers assumed to have been notified (because their letters were not returned by the post office), but who have not responded. Efforts are underway now to find and talk with these people, but the process is slow and difficult. The balance between the individual's right to privacy and the investigator's responsibility for protecting public health will always be delicate and require judgment. However, if notification programs are to be truly effective, the interpretation of the Privacy Act may have to be broadened to allow appropriate groups to assist in locating "hard-to-find" individuals.

Local Agencies – This project demonstrated the utility of involving local agencies in dealing with a high-risk occupational cohort. In this case, the Richmond County Health Department performed invaluable service in helping to locate cohort members, stabilize a potentially volatile situation, and provide a focus for seeking long-term funding and continuity of the program.

Community Education – A notification program should be considered a health education program for the entire

community. It involves not only the cohort at risk, but their families, their company and union, their current employers, and the community at large, as well as physicians, lawyers, the media, religious groups, social services agencies, and local and regional government. The Augusta project demonstrated that, eventually, all of these groups will become involved as a result of notification. These groups have wide-ranging concerns and need information and education. Table 5 shows the types of information needed in the Augusta project.

The thrust of the educational component concerns not merely the plight of an individual cohort, but occupational disease in general. Indeed, because of the concern that is raised by such projects, they offer the opportunity for widespread and effective health education about toxic substances and chronic diseases. Moreover, the process of notification demonstrates the depth and magnitude of the impact of occupational disease on the human as well as the abstract statistical level.

The Establishment and Funding of Services — Many lessons learned from this project appear applicable to notifications in general. Subsequent to a notification, a cohort will have a variety of sociomedical needs, such as medical screening, treatment, counseling, and ongoing follow-up. The funding of these services will be a primary need of many cohorts. It is unclear who is responsible for providing these services and under what conditions. It would seem that the courts or Congress will have to resolve this issue. Under any circumstances, the initiator of a notification should be responsible for at least interacting in the planning and development of screening and surveillance services by providing the relevant information that it has about a particular cohort. This may include demographic, epidemiologic, or therapeutic information.

Litigation — Until more appropriate mechanisms are found, initiators of worker notification projects can expect to become involved in litigation and, in particular, to be called on to provide epidemiologic and medical information in litigious proceedings. In the Augusta study, the various investigators have testified in legal proceedings and have had their records subpoenaed.

Conclusions

This project represents an example of a program designed to meet the needs of a group identified as being at high risk of occupational disease. There are many such groups that will need this type of program. The control of occupational diseases such as cancer induced by aromatic amines requires not only primary but secondary prevention. Notification is the first step in secondary prevention. Unfortunately there is only a patchwork of programs to meet the needs of high-risk groups. A more systematic approach is needed and until it is initiated, there will be no recourse for workers other than litigation.

The potential implications of the Augusta project for agencies and institutions that perform epidemiologic studies are striking. At the present, individual notification of former employees who were subjects of epidemiologic record studies is not customarily done, nor are there criteria for doing it. If, however, this study is seen as a precedent, there may be increased pressure on investigators to notify individual subjects. This effort would ultimately involve hundreds of thousands of people.

Future notification efforts will require the following: (1) a resolution of the technical matters relating to individual notification, (2) development of criteria as to what constitutes a notifiable risk, and (3)development of societal

Table 5 – Type of Information Necessary for a Notification Program

Aspect	Information Needed
1. Identification of cohort	a. Personnel records b. Epidemiologic findings from retrospective mortality studies
2. Location of cohort addresses	a. Community contacts b. Social Security Administration, Internal Revenue Service, Bureau of Motor Vehicles, subject tracing, and social services
3. Development of message	a. Differential risk information b. Screening availability c. Therapeutic potential d. Socioeconomic status characteristics of cohort
4. Notification of community physicians	a. Address information b. Epidemiologic and animal data on exposure-disease association c. Plans for case finding d. Recommendations for follow-up
5. Notification of community and media gatekeepers	a. Extent of risk, i.e., to family and to the adjacent community b. Other target organs c. Information from 3*a, b, c* d. Surveillance requirement e. Symptomatology and risk history
6. Supplementary cohort education	a. 5 *a-e* b. Risk factors
7. Screening	a. Evaluation of approach b. Inclusion criteria
8. Results dissemination	a. Evaluation of ascertained cases b. Screening results
9. Surveillance recommendation	a. 1*a*, 8*b*
10. Monitoring impact	a. Psychosocial information b. Research data
11. Participation in legal process	a. All of the above

solutions for the problem of compensation and funding for ongoing medical surveillance. This study has begun to address the first two of these needs.

If notification of subjects becomes part of epidemiologic studies, both the notifiers and the subjects need to become more sophisticated in handling risk information. Epidemiologic information needs to be presented in such a manner that nonscientists can make some sense of it. The classic admonition that epidemiologic information pertains to groups and not to individuals must be reflected in notifications.

Finally, as new research allows for the exploration of disease markers, genetic predispositions, or indicators of previous exposures, it will be likely that the issues raised in this study will again need consideration. The Augusta project may provide useful guidelines for future notification efforts.

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Medical Care Costs for the Dying

No one disputes the alarming increase in consumption of costly medical services by the elderly. An especially difficult question is how much society should spend on care for the dying. In the United States, we spend one percent of the gross national product on the 1.3 million elderly in their last year of life, a figure that exceeds *all* monies spent in the country on the institutionalized mentally ill and mentally retarded and on *all* basic and applied medical research.

As Stanford economist Victor R. Fuchs has pointed out, a free-market approach is no solution to the problem of high medical costs for the elderly; in medicine, we rarely find knowledgeable buyers paying directly for services rendered by competitive suppliers. The sick and their relatives are in no shape to deal calmly, logically, or effectively with the complex technical and ethical choices to be made. Private insurance and income redistribution provide no easy solutions either. Striking a just balance between care for the dying and health services for everybody else is an enormous challenge; a wrong decision may rend the very fabric of our society.

—From "A Duty To Die?" by Louis Lasagna in *The Sciences*, published by the New York Academy of Sciences, July/August, 1984.