Interpretation and Communication of the Results of Medical Field Investigations

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Since the controversy over cytogenetic test results at the Love Canal in New York State, there has been increasing concern about the communication of medical test results to participants in field studies. To identify the range of issues that arise and to present examples of practices that might be useful for consideration, we have drawn from 15 years of experience in interpreting and communicating the results of medical field investigations by the National Institute for Occupational Safety and Health. The investigations were qualitatively characterized according to study type and design, substances involved, language used in the notification of results, and the nature of the efforts to put results in perspective. Based on this evaluation, the following recommendations are made: (1) provide a comprehensible consent form, (2) interpret results for study participants, (3) use clear language, (4) be explicit about uncertainty of findings, (5) where appropriate, indicate the need for medical follow-up, (6) provide results promptly, (7) provide overall study results, (8) evaluate the impact of the notification, (9) train investigators in the practice of communicating results.

In the past decade, the issue of communicating test results to participants in medical field investigations has attracted great attention.[1-3] A dramatic example of the problems that can arise occurred in response to the crisis at Love Canal.[3] Residents were informed that they were found to have chromosomal changes (aberrations), the meaning of which was not clear. Residents were led to believe that they had abnormally high numbers of aberrations and "were at an increased risk of neoplastic disease, of having spontaneous abortions, and of having children with birth defects."[1] Alarm and criticism over the communication of these results were frequent and severe.[1,4,5]

More recently, there has been a series of meetings, workshops, and deliberations in government, academia, business, and labor on how best to express risk.[6-8] The technical aspects of what and how to communicate research results generally have been overshadowed by the larger issue of ensuring that such results are transmitted at all. This concern has been expressed as a manifestation of the principle of "informed consent"[9,10] and the so-called "right-to-know."[11-14] The scope of this "right-to-know" principle encompasses exposures to deleterious, xenobiotic substances, occupational and environmental risks, and, more generally, anything that the medical and public health community knows that will affect the public. While debate continues over these ethical questions, investigators are more frequently confronted with questions of what to tell study participants, how to tell it, and when.

Although some tests provide results that are relatively well understood, such as blood pressure readings (intricacies of interpretation of isolated measurements notwithstanding), many tests used in investigations of occupational and environmental disease are difficult, if not impossible, to interpret. It is not enough merely to communicate results. To avoid misleading or unduly alarming study participants, good practice requires some attempt at a meaningful interpretation of results. For example, on the basis of a pilot cytogenetic study in 1980, some residents of the Love Canal area of Niagara Falls, New York, were informed that they had chromosomal abnormalities.[1] What was not made clear to them at the time was that the prevalence of such abnormalities among the study group was not significantly higher than among other people. Instead they were lead to believe that the study results indicated an increased risk of cancer and adverse reproductive outcomes.[1]

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Some of this alarm is a function of the study design, or failure to provide truly "informed" consent rather than of the process or content of these communication variables. Nevertheless, the communication and dissemination variables are of importance and merit consideration. The objectives of the report are: (1) to provide investigators, public health officials, and clinicians an overview of the range of issues that arise in the notification of test results so that notifications can be more effective; and (2) to present examples of practices that might be useful for consideration. This report raises a number of issues that need further study. It is our intent to identify these, not necessarily to provide specific proposals to evaluate them.

Methods

This paper is a report on an evaluation of the notification issues and communication techniques that have been observed from the 15 years of experience in notifying participants of field studies performed by investigators at the National Institute for Occupational Safety and Health (NIOSH). To identify general practices, we have extracted relevant examples from the records of all field studies contained in the current files of the Human Subjects Review Board (HSRB). The HSRB is charged, among other responsibilities, with consideration of what and how study participants will be notified. In addition, files of the NIOSH Hazard Evaluations and Technical Assistance Branch, which conducts most of NIOSH's medical field studies, were reviewed to evaluate notifications of medical tests that were performed as part of field investigations.

The object of our evaluation was to provide a qualitatively representative sample of various aspects of notification of test results from hundreds of field studies. From 47 studies we have extracted examples of the following characteristics: study type and design, substances involved, language used in the notification, and nature of efforts to put results in perspective. This report is intended as an appraisal of the range of characteristics and issues. It is not intended as a statistically rigorous survey. Rather, it is based on the judgment, evaluation, and "institutional memory" of the authors, and the presentation of that information on a categorical basis. (Each of the authors has been with NIOSH for at least 10 years.)

Generally, the studies reviewed dealt with occupational environments where there was some indication of an "outbreak" or an excess of disease outcomes, or where a priori hypotheses were being tested regarding the association between an exposure and a disease. The studies reviewed are observational, often comparing an "exposed" or "case" group and a comparison group.

The National Institute for Occupational Safety and Health, pursuant to federal regulations requires that all "research" studies involving human subjects be reviewed by the NIOSH HSRB prior to initiation.[15] In recent years, HSRB has required a sample "medical test results notification letter" as part of the HSRB package. The NIOSH procedures require that all participants in medical studies receive written notification of their individual test results. In the past, participants generally have not been notified of overall study results. Typically, individual test results often are communicated prior to the overall study results, since individual test data usually are available before the epidemiologic analysis. Furthermore, the study reports always have been available to anyone on request. Also, employee representatives are always sent reports, and in the case of health hazard evaluations (the most numerous type of field study), copies of final reports are required to be posted in the workplace area where the studied workers are located.

Results

Data Base

Sample "test results" notification letters were available for 36 of the 47 studies considered. The majority of these studies were cross-sectional; that is, assessment of a population of workers for the prevalence of disease or signs of potential adverse health effects and their association with exposure variables. A small percentage of the studies were case-control. A variety of substances or work conditions were identified in the studies. These included specific, well-known hazardous substances such as ethylene oxide, cadmium, lead, methylene chloride, dioxins, asbestos, uranium, and chlorinated hydrocarbon solvents. Less familar substances such as 2-ethoxyethanol and cyanoacrylates; 4,4′-methylenebis(2-chloroaniline, *o*-toluidine, azodicarbonamide, and zeranol; complex substances such as ultraviolet-cured inks, egg dust, soybean dust, antistatic agents, mold (fungi), and welding fumes; and ergonomic risks such as repetitive motions and wrist stress were included as well.

The range of health effects evaluated in these studies and the types of "tests" used are shown in the Table. Most organ systems commonly affected by occupational diseases are represented. The most common health effects involved the respiratory and neurologic systems.

Context

The test results are obviously not the first point of communication between the investigators and the study participants. To perform the study, the participants need to be recruited and told of the purpose, risks, and benefits of the study. This is done through the process of administering the informed consent document. Before a participant is asked to sign the document, an oral explanation is given and any questions the participant has are answered. The document describes the tests to be done, although this may be categorical (for example, "tests of kidney function or damage") rather than a detailed list. Limitations of tests and their meaning for individual participants or for general research also are discussed.

TABLE
Examples of Health Effects and Tests Frequently Found in NIOSH Medical Field Investigations.

Health Effects	Tests
Allergic dermatitis	Physical examination, patch test
Asthma	Spirometry, specific immunoglobulins
Cancer	Urine cytology, urinalysis
Carpal tunnel syndrome	Tactile discrimination
Genotoxic	Sister chromatid exchange, chromosomal aberrations
Hepatic	Serum enzymes
Musculoskeletal	Physical examination
Neurologic	Neurobehavioral tests
Pneumoconiosis	Chest x-ray, spirometry
Renal	Serum creatinine, specific urinary proteins, tubular enzymes
Reproductive	Semen analysis

A statement is included that each person will receive full information about his or her test results and that the results will be sent to a physician of the participant's choice. Many of the issues of notification of medical results discussed throughout this paper also pertain to the informed consent document, particularly the need for this document to be comprehensible to research participants.

Anatomy of a Notification Letter

In the studies reviewed, the medical tests were presented to participants in a letter that usually included the following: an expression of gratitude for participating, object of the study, the tests that were performed, the participant's results, an interpretation, and the name and telephone number of a person to contact if there are further questions. In some cases, results are summarized in the letter and presented in detail on an attached page. Quite often, the presentation of results included a column entitled, "your sample value" or "your results," and a column entitled, "the range of normal," "reference range," or "group results." When relevant, there often was a statement that the overall association between the exposure and the health effects of concern could not be assessed until all of the group data were analyzed.

Letters often contained the recommendation that the participant show and/or discuss the letter with his or her physician and keep it with other personal medical records. In addition, where appropriate, letters might contain recommendations for safe work practices that could help prevent the disease of concern. The "results" letter was sent only to the participants and not to their employers or unions. If the subjects signed a release, the results were sent to their physicians. (Practices varied over the years as to whether participants were required, encouraged, or simply permitted to have a copy of the results sent to a physician.)

Perspective on the Test Results

The participants in a medical study are generally interested in knowing whether they are "all right" or whether there are any problems. This cannot always be determined from medical tests used in the type of studies conducted for occupational and environmental health research (field investigations). This may be due to limitations of the study, the test, or the inflated expectation of the participants. Field investigations usually are confined to examining one or a few organ systems, with reference to a small number of diseases. Furthermore, the tests used may have more epidemiologic than clinical usefulness.

Limitations of the Study. Some studies that were reviewed were designed merely to confirm exposure. Tests that identify a toxin or metabolite in biologic media, while sufficient for the study, do not determine whether a health effect is present or explain the relationship between the exposure and any such effect.

Many of the studies were designed to evaluate the association between an exposure and a biologic effect, which may or may not be part of a disease process. Hence, at best, the conclusions in regard to a participant's results can be expressed only in those terms. Some studies included tests of specific, time-dependent occurrences. For example, in a study of workers who cleaned up a chlordane spill, it was important to caution that: "Since the serum half-life of chlordane is 21 to 88 days, it is possible that exposure you may have had on and/or following May 31st may no longer be detectable in your blood. Since the majority of chlordane is stored in adipose tissue, a fat biopsy would be necessary to provide definite information on your body burden." (Note: Unless otherwise referenced, quotations from notification letters are unpublished.)

Limitations of the Tests—Communicating Uncertainty. Many of the tests that were used (such as spirometry, liver enzymes, and neurobehavioral tests) were nonspecific. Abnormal results of such tests could be due not only to the exposures of concern, but also to other factors. This may not always be apparent when the individual results are presented and will be clear only when the overall study results are available. An example of how the confounding influences on a test were addressed is seen in the following excerpt

> "The type of semen quality changes observed in this study can be found in everyone and happen for a number of reasons. Some of these reasons have been linked with human health problems and some have not. Factors in everyday life, like smoking and the use of certain medications, can also change semen quality measurements. There are also day-to-day changes in measures of semen quality."

On the other hand, some tests may be quite specific, and the task in the notification letter is to caution against overinterpretation. For example, in a study of an allergic, dermatologic reaction to ultraviolet-cured

inks, those participants with abnormal results (that is, a positive patch test) were told, "the tests are designed only to evaluate whether you have a skin allergy to these particular substances or chemicals. A positive reaction does not mean that you are allergic to anything else, or that the chemical or substance has had, or will have, any other effects on you."

Some tests cannot be easily interpreted because they are research tools and have no established "normal" range. This was expressed in one letter in the following manner:

> "We should comment upon the source of the 'normal' or reference range for tests. For some tests the reference range is listed as N.A. (not available). Usually these tests are research tools for which reference ('normal') values have not been well established. Research tests provide useful information about *groups* of workers, but the results are difficult to interpret in *individuals*. Other tests, such as urine creatinine, are used mainly to standardize other tests and are not meaningful themselves. We report the results for your information but do not comment on them."

The inability of a research test to predict disease generally was expressed clearly with no attempt to blur the uncertainty. An example of this may be seen in a study involving exposure to 4,4′-methylenebis(2-chloroaniline) (MBOCA), a suspected bladder carcinogen, where workers were administered both the routine Papanicolaou cytology test and the experimental quantitative fluorescence image analysis test. The letter read:

> "QFIA (Quantitative Fluorescence Image Analysis) measures the amount of genetic material in cells, and may detect cells which have an increased content of genetic material. Increased content of genetic material is one difference between tumor cells and normal cells. QFIA is an experimental test, and we still don't know its value in predicting who is likely to get bladder cancer."

Uncertainty of the meaning of test results was seen also in another study of workers exposed to MBOCA; in this case the meaning of urine levels of MBOCA was addressed:

> "We do not know what level of MBOCA exposure may be considered safe; however, two states have established standards for levels of MBOCA in urine. Michigan, at one time, enforced a standard of 50 μg/L (no longer in effect); California currently enforces a standard of 100 μg/L."

The preceding example concerns a test of *exposure*. In a neurobehavioral study of workers exposed to a solvent, the investigators distinguished between clinical and epidemiologic interpretation of tests of *effect*:

> " · · · these tests were of value only for epidemiologic research · · · · and have little or no neurobehavioral diagnostic power for the individual worker · · · [N]ormal scores on these tests may miss problems that might be found on more complete testing, and conversely, an isolated abnormal score may not really reflect a problem · · · [B]ecause the NIOSH testing battery is designed to look at differences between groups of people, the tests are different than those commonly used in clinical medicine to diagnose neurobehavioral problems. They have not been evaluated for diagnostic accuracy in individuals."

Methods of Presenting Abnormal Findings

Abnormal findings were generally presented by either comparing the participant's results with the expected or normal range, based on general population values, or with the distribution of results from the study group. An example of the population reference value approach, shown in the Figure, is a report of pulmonary function test results, in which one-second forced expiratory volume (FEV_1), forced vital capacity (FVC), and FEV_1/FVC ratio are reported.

	Your result (liters)	Percent predicted	Normal value	Is your result abnormal
FEV_1	2.47	80	80% or greater	NO
FVC	3.26	84	80% or greater	NO
FEV_1/FVC	0.76	--	0.7 or greater	NO

Figure. Example of pulmonary function test results presented in tabular form, using reference value approach.

The other approach, the group comparison approach, is exemplified in a study of the reproductive effects of exposure to 2-ethoxyethanol, and shown in a table with the following headings: Sperm Characteristics, Your Sample, Range of Entire Exposed, and Range of Entire Unexposed.

In some studies large numbers of tests were performed and, in addition to specific test results, the following summary statements were provided:

> "Your test results show some evidence of altered calcium phosphate metabolism. The abnormal tests were ———. As we discussed on the telephone, I suggest that you show this letter and the test results to your personal physician promptly."

Language

The importance of communicating test results is not only to provide information to the study subjects, but to do it in a way that is informative and understandable. In most of the studies reviewed, the language appears to be relatively clear and understandable, at least from the point of view of the authors and the members of the HSRB. The process of letter development, however, involves no field testing of letters, especially among participants or surrogates with similar educational levels. Whether the information is entirely clear to participants who receive such letters has not been studied. However, mailing of the letters, in general, has not resulted in an extensive response by participants, either through the telephone number provided in the letters or by mail. No letter can speak completely to the educational, literacy, or comprehension levels of heterogenous groups of workers. The letters have been written so that they would be generally understood by participants and other nonprofessional persons. The studies reviewed showed a variety of efforts to express technical information.

In a study of workers exposed to *o*-toluidine and *o*-dianisidine, the concentration of these substances in the urine was expressed as parts per billion (ppb). The investigators attempted to clarify the meaning of ppb by stating: "A part per billion is equivalent in proportion to one foot in 189 thousand miles or one second in 1903 years." In a study of workers exposed to azodicarbonamide, pulmonary function tests were described as follows:

> "The breathing tests measure the capability of your lungs to supply air to your body. The forced expiratory volume in one second

(FEV_1) is a measurement of the volume of air you can force out of your lungs during the first second of breathing out after you have taken a full breath in. The forced vital capacity (FVC) is a measurement of the total volume of air that you can force out of your lungs starting from a full breath in."

Medical research must take place in the context that there are widespread public beliefs that medical tests are infallible. In one study the investigators attempted to dispel that notion:

"As you know, we collected urine samples as one means of determining arsenic exposure . . . . The method we used to measure urine arsenic cannot distinguish between the inorganic forms of arsenic found in battery manufacturing plants and the nontoxic forms found in seafood."

In some studies, language still appeared somewhat technical, and possibly difficult to interpret even by an educated lay-person. For example:

"Your x-ray showed the following sign or signs of pneumoconiosis: pleural thickening involving both costophrenic angles, and circumscribed pleural thickening (plaque) involving both sides of the chest."

Recommendations for Medical Follow-up

When abnormal findings were reported, they almost always were accompanied by a recommendation to show the letter to the participant's personal physician. Two examples:

"Your lung function test results show an obstructive pattern, that is, impairment of your ability to blow air out rapidly. This finding may be due to a variety of conditions. If you have not already been evaluated for these findings, you should show this letter to your personal physician in the near future, especially if you are having any respiratory problems or symptoms."

"Your results suggest that your testicles are not responding to the normal stimulation from your pituitary gland. We advise a follow-up visit with your personal physician."

Even when findings of a study are normal, some investigators apparently considered that there still might be residual concern among participants and made recommendations for follow-up, for example, in a study concerned with neurologic and performance effects among fumigators exposed to methyl bromide and sulfuryl fluoride:

"While we see no medical problems in your results, if you are concerned with your test scores, you could consult your personal physician or other medical doctors in whom you have confidence."

In another study, the investigators indicated that a negative test was not a certificate of a disease-free life. In workers exposed to MBOCA, whose tests showed no evidence of bladder cancer, the following recommendation was made:

"We believe that it is important that you continue to receive screening for bladder cancer in the future, even though your test results are normal now."

Discussion

The communication of the results of medical tests in field studies of occupational and environmental hazards has been practiced by NIOSH investigators for more than 15 years. The program described in this report appears to contain most of the elements that are necessary for effective communications. For the effectiveness of communication to be evaluated, it is necessary to know the purpose. Communication of test results is an extension of the informed consent procedures utilized by the Department of Health and Human Services (DHHS), in general, and NIOSH, in particular. These stem conceptually from the principles of the protection of research subjects inherent in the Nuremberg Code and Helsinki Convention, and systematized in the Belmont Report,[9,10] which has become the basis for DHHS procedures and for all federally funded research. In short, the subject of a medical investigation has a right to expect the investigators to disclose his or her individual results.

Beyond the ethical and legal administrative basis, the objectives of communicating results are, from a health viewpoint, to enable the study participant to take action in regard to further exposures, and to enable his or her physician to have pertinent medical information to allow for timely prevention, diagnosis, or treatment of disease.

Notification of test results and overall study results may have an impact on workers' compensation "clocks"; that is, a statute of limitation may be referenced to the time of receipt of such information (L. Rudolph, personal communication). Investigators should be aware of how phrasing of results can have legal implications. In general, investigators should not inadvertently affect the legal rights of participants. The importance of periodically evaluating the impact of research communications on participants and their families, employers, and possibly their physicians has rarely been appreciated. Consequently, investigators and their sponsoring agencies get little or no feedback on the effect of such communications. Hence, efforts to correct communication flaws are not likely to be enhanced. Any efforts by investigators or their sponsoring agencies to address these legal or evaluative issues should be approached in a way that ensures the study participant's confidentiality by not disclosing test results to third parties without the participant's consent.[16]

Important factors in the communication of results are the following:

(1) *Providing a comprehensible consent form.* A recent review of studies (conducted between 1969 and 1987) on comprehension of informed consent for patients showed low levels of comprehension (recall, understanding, knowledge) in patients subsequent to administration of informed consent documents.[17] The reasons for this involved, among other aspects, the way the information was presented; the clarity, language, and formats used. Many of the problems in communicating the results of medical tests might be alleviated by using well-designed informed consent forms that are carefully administered.[16–19] Also, the other recommendations presented here also pertain generally to the informed consent form and should be followed.

(2) *Interpretation of findings.* It is not enough merely to communicate results of specific tests. Investigators need to interpret these results to the extent possible.

This may involve showing the range of normal or the group distribution. Data should be summarized and important aspects stressed. When presenting results, it is necessary to qualify the findings with an indication of how conclusive the test is for indicating exposure or damage.[20] Investigators should caution that interpretations are not clinical and, at the same time, avoid muting diagnostic implications.

(3) *Demystification of technical material and the use of clear language.* Persons who had medical tests may be confused by the language in a "results" letter. Efforts should be made to minimize jargon, clarify terms, and describe tests.[21]

(4) *Communication of uncertainty.* This is an extension of the previous recommendation. Investigators should not attempt to hide their uncertainty about the meaning of results. Rather, it should be made explicit, both when obtaining willingness to participate in the study and when communicating results. It is also important for investigators to communicate the limitations of the research and tests used.

(5) *Indication of the need for medical follow-up.* The communication of the results should provide for recommending follow-up whenever the results indicate a potential health problem. In addition, the notification of results should indicate where the study participant or his or her physician can obtain more information on the study.

(6) *Prompt provision of results.* Test results should be provided to participants at the earliest possible date. Where results of some tests are delayed, the results of others still can be reported.

(7) *Provision of overall study results.* The interpretation of test results, in part, may occur only after the group data have been analyzed. In such a case, the overall study results should be communicated to participants either individually or through some collective means.

(8) *Evaluation of the impact of the notification process.* Those investigators and organizations that routinely perform field studies and notify participants should periodically evaluate the impact of notifications. Results of the research should be used to modify notification procedures.

(9) *Training investigators and use of standard procedures for notifying participants in research.* Organizations that support research should have established programs for training and sensitizing investigators on the need for attention to notifications and adherence to recommendations such as those presented here. Institutional review boards should require sample "results" letters to be included in the review package.

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