

Information about occupational exposure to asbestos given to cases in an etiological study: Ethical aspects

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Abstract. The aim of the study is to consider some ethical aspects of the provision of information, to the cases or their families, about the assessment of occupational asbestos exposure obtained in a case-control study of malignant mesothelioma of the pleura. An informative letter with the result of the evaluation of their occupational exposure to asbestos was sent to the participating cases (and/or their family). Those whose exposure was classified as certain/probable were also informed of the legislation regarding occupational diseases. Of the 132 cases, 32.6% of subjects and/or their families made telephone calls expressing interest in the content of the informative letter. Among the 63 cases classified as certain/probable exposure, this proportion was

47.6%. Out of 43 cases in which the age at diagnosis was ≤ 65 years and the exposure to asbestos was certain/probable, only two (4.6%) were signed off work owing to occupational disease. Only one of the mesothelioma cases was recognized by the Spanish National Institute for Social Security (INSS) as having an occupational disease. The process of communication of the results of an epidemiological research should include the provision of information on the exposure data to each one of the subjects, and/or their families. There is a great disparity between the number of cases of certain/probable exposure to asbestos identified in our study, and the number registered as an occupational disease by the INSS.

Key words: Asbestos, Ethics, Occupational exposure, Patient information

Introduction

For a biomedical research study of any kind to be considered ethically correct, its objective must be scientifically relevant; i.e. the results should represent an increase in our knowledge regarding health, the illness being studied, and the correct way of dealing with it. Furthermore, the study must be correctly designed and those who are going to conduct it must be capable of doing so [1, 2].

Epidemiologists who conduct research on human subjects must abide by the same rules as other biomedical scientists. These rules, promulgated in codes of conduct such as the Helsinki Declaration [3, 4], should be consistent with basic ethical principles in biomedicine, i.e. autonomy, non-maleficence, beneficence and justice [5, 6].

Worries about the ethical principles applied to epidemiological practice and, above all, to research, have been reflected in debates and reflections promoted by epidemiologists themselves [7] and their scientific associations [1, 8], and have led to the drafting of ethical guides [9]. The recent extension of

epidemiology into the area of genetic research has intensified the debate on the relationship between ethics and epidemiology [10].

Our obligations and responsibilities in relation to subjects studied in epidemiological research include the provision of information to the population of the study about the risk factors revealed by the research, and the guarantee that the possible political and economic consequences will not be detrimental to them [6].

As part of the responsibilities cited, consideration should also be given to those relating to the transmission of individual information concerning relevant exposures to which the study subject may have referred in an interview or concerning the results determined by relevant analyses performed on the subject. Exposure data, normally analyzed in aggregate, may have implications for the subject when presenting claims based on civil and/or penal rights to the appropriate administrative and/or judicial authorities.

The specific aim of this article is to recount the experience of information transmission to a group

of patients and/or to their families, diagnosed with malignant mesothelioma of the pleura, concerning exposure to asbestos of occupational origin, within the framework of a multi-centre case-control study [11] and puts forward various ethical reflections. Furthermore, it presents data enabling a comparison to be made between the malignant mesothelioma cases with certain occupational exposure to asbestos identified in the study and those obtained from the official institutions responsible for its legal recognition and registration as an occupational disease.

Methods

The case-control study on which the present article is based, was planned to identify occupational and environmental risk factors of malignant mesothelioma of the pleura [11, 12]. It included all the new cases of this disease diagnosed between 1993 and 1996 in residents of the province of Barcelona, and in 1995–1996 in residents of the province of Cadiz (Spain). The cases were identified by an active search in the Services of Pathology, Respiratory Diseases and Oncology of the hospitals collaborating in the study.

Each of the cases, or a first-degree relative if the patient had died, and an appropriate set of controls were interviewed in the hospital or in their home, by specially-trained professionals. The questionnaires used in the interviews reconstructed the occupational history, together with environmental and domestic type information. Once the data had been checked, the study subjects were classified according to the assessment of their exposure to asbestos made by a group of industrial hygienists who were unaware of the case-control status of the questionnaire to be reviewed. This assessment, based on criteria developed by the research group, classified the probability of occupational exposure into the categories of certain, probable, possible and improbable, together with the categories of no exposure and exposure unknown.

To each of the addresses provided by the case subjects or their family, one of two models of informative letter were sent. For those cases classified as certain/probable exposure, the letter model 1 was sent, and for the remaining cases, letter model 2 (Annex 1). In both letters, recipients were informed of the conduct of the study and the results of the classification of probability of exposure made by the industrial hygienists. In letter model 1, details were given of the legal regulations under which they could request recognition as suffering an occupational disease for the purpose of claiming their right to any financial compensation which might be awarded to them; the address of the institution (the Spanish National Institute for Social Security, the INSS)

through which this procedure could be initiated was also given in the letter. Recipients were also provided with the telephone number and name of a member of the research team, from whom they could request any complementary clarification of the content of the letter. Informative letters were not sent to the controls.

The number of employees signed off work due to the occupational disease of malignant mesothelioma of the pleura during the period of the study was counted from the reports of the Centers for Health and Safety at Work of Barcelona and Cadiz.

To obtain the number of benefits allowed for malignant mesothelioma between the years 1993 and 1998, both inclusive, data were requested from the provincial offices of the INSS.

Results

Of the total of 132 cases included in the study, 63 (47.7%) were classified in the certain/probable category of probability of exposure to asbestos (Table 1). Of these recipients of the letter model 1, 47.6% made a telephone call requesting complementary information.

Of the 69 cases classified under the remaining probabilities of exposure, who had been sent letter model 2, 18.8% made a telephone call asking for more information.

The next-of-kin group making the most calls were the subject's son and/or daughter (or son/daughter-in-law), accounting for 55.8%, followed by the subject's spouse, with 16.3%. Three cases personally telephoned for further information. Only 2 calls were made by lawyers. Overall, we did not find any difference in the proportions telephoning for clarification between the provinces of Barcelona and Cadiz (32.5 and 33.3%, respectively). However, for the group of cases in the certain or probable exposure category, there were more requests for clarification in

Table 1. Informative letters sent and telephone calls received, by category of probability of exposure to asbestos

Probability of exposure to asbestos	Letters sent	Telephone calls received (%) [*]
Letter model 1		
Certain	54	24 (44.4)
Probable	9	6 (66.6)
Letter model 2		
Possible	20	10 (50.0)
Improbable	17	1 (5.8)
No exposure	29	2 (6.9)
Exposure unknown	3	0
Total	132	43 (32.6)

^{*} % response, by level of probability.

Table 2. Cases of malignant mesothelioma of the pleura recognized as an occupational disease, during 1993–1998, by province

Cases in the study, classified as certain/probable probability of exposure	Total no. of cases recognized as an occupational disease ^a and no. signed off work ^b
Province of Barcelona 55 (38) ^c	Signed off work due to occupational disease: 1 Occupational diseases: no information
Province of Cadiz 8 (5) ^c	Signed off work due to occupational disease: 1 Occupational diseases: 1

^a INSS.

^b Health and safety at work centers.

^c Number (in brackets) diagnosed before retirement (i.e. 65 years).

Barcelona than in Cadiz (49.1 and 37.5% respectively).

Of a total of 43 cases with certain/probable exposure to asbestos, and below retirement age (i.e. 65 years) at the time of diagnosis, only 2 (4.6%) were signed off from work due to the occupational disease of malignant mesothelioma of the pleura, in the period of the study – one in each province (Table 2). The case in the province of Cadiz was finally accepted by the INSS as an occupational disease; it has not proved possible to confirm whether the case in Barcelona was so recognized or not.

Discussion

The causal relationship between asbestos and malignant mesothelioma of the pleura has been accepted for several decades [13]. Since the first declaration in Germany in 1943 of cancer of the lung as an occupational disease when it is associated with exposure to asbestos, but with delays of varying lengths of time, legislation in most European and some other countries has incorporated this causal relationship for the purposes of recognizing certain rights, mostly to financial compensation, derived from the harm produced by occupational exposure to this substance [14, 15]. Spain included pleural mesothelioma due to asbestos in the official List of Occupational Diseases in 1978 [16].

Although situations exist in which our ethical position as epidemiologists is simply to admit our lack of scientific evidence and to resist pressure from politicians, the communications media and the public health authorities [17], we cannot adopt an identical attitude with respect to causal relationships that have been proved beyond scientific dispute, such as that between asbestos and malignant mesothelioma of the pleura. Use of asbestos is dangerous, and past and current evidence is sufficient to argue against any relaxation of public health control on asbestos [18]. Furthermore the authors believe that an active position on the transfer of information on the results

of studies such as the one discussed here is a correct way to practice the ethics of epidemiological knowledge [19]. Although it has been stated that scientific research data should not be divulged generally before its results have been subjected to professional peer review and published in a recognized scientific journal [20], one has to ask oneself what is the more appropriate ethical attitude in the face of the typical current situation when 2 years or more may elapse between the presentation of an article and its publication.

Among the negative elements characterizing the framework in which occupational health is developing in our country there are: the lack of knowledge of the risks deriving from exposure to carcinogenic substances such as asbestos, among subjects exposed; the ignorance of legal rights resulting from illnesses related to occupational exposure, both in the patients and in the doctors treating them; the diagnosis of these illnesses generally after the retirement of the subject; and the sparse data on occupational history included in subjects' clinical records. In the case of asbestos, the latency of 20, 30 or even 40 years between exposure and the appearance of the cancer makes it even more difficult to establish a clear relationship between the exposure and the disease. Those who most suffer the consequences of this unsatisfactory situation are the exposed workers themselves and their families.

An indirect measure of the attitude of the affected cases and their families towards taking action to claim the rights recognized by our legislation can be obtained from our analysis of the telephone calls made to members of the research group after the informative letters had been sent. We consider the response has been scarce: it was less than half in the group of cases with greater probability of exposure to asbestos. We do not have a clear explanation of this reality. However, from personal contact maintained with some of these families, we deduce that they do not believe it is worth the trouble to initiate juridical-administrative procedures that will probably be very expensive and very slow, and from

which they have serious doubts of seeing positive results in terms of either compensation or justice. Other families asserted their wish not to suffer a more prolonged period of grieving their deceased relative because of the authorities, given the foreseeable long-drawn-out judicial processes typical of our country.

Although a complete follow-up of the series of cases has not been carried out to check the number of claims presented before judicial institutions, it is notable that only two calls requesting information were received from lawyers, both in the province of Barcelona. This may also be taken as another indication of the remiss attitude of these families towards the exercise of their theoretical legal rights.

Controls were not informed about the results of the evaluation of their occupational exposure to asbestos. We considered that if they were not able to claim for compensation in respect of occupational disease, this information could be a source of anxiety to the subjects, with no relevant benefit. Furthermore, in most controls the exposure occurred in the past, and no effective method exists for early detection of pleural mesothelioma that could increase chances of survival. However there are ethical reasons for considering that controls have the same rights as cases to receive this information.

From our contact with the administrative bodies responsible for the classification of the damage to health consequent upon the exposure studied, and for the subsequent award of financial compensation, we have been able to confirm the difficulties still existing in quantifying the scale of occupational diseases. We are also acutely aware of the contradiction between the reality reflected by our data and the picture deduced from the scarce references available from the official institutions. In our country, the system of declaration is based more on an insurance-type logic, that seeks compensation for damage, rather than being oriented towards a function of knowledge of the problem in all its aspects, and of all the factors associated with the occurrence of diseases and accidents at work [21, 22].

In Spain, applications for the recognition of occupational disease must be presented to the Provincial Offices of the INSS. These authorities retain medical teams charged with assessing the medical information on the patient and his or her occupational history. On the basis of these assessments it is decided whether or not to accept the claim. Appeals

may be presented against these decisions before magistrates in the so-called 'Social Courts'. Independently of this procedure, it is possible to present claims in the penal courts, normally directed towards obtaining compensation or indemnity from the employing company.

Although it is necessary to prove the existence of exposure to asbestos, the lawyers who are involved in the corresponding administrative and judicial procedures acknowledge that it is helpful to the interests of the affected or their family to have the assessment of the exposure undertaken from an epidemiological perspective.

The publication in a scientific journal is not the end point of the process of communication of the results of an epidemiological research study. This process should include the prior provision of information, at an individual level, to all those who have participated in the research as subjects of study so that, wherever it may be relevant, they can know their own data and the corresponding classification of risk. Apart from the clinical, pathological and other diagnoses, epidemiologists should increasingly give attention in their research activity to the communication, from valid measures, of the data and individual exposure diagnoses. These diagnoses may have immediate importance or else may assume significance later when causal relationships have been acknowledged that had not been proved conclusively at the time of completion of a particular study. We consider that the protocols of epidemiological research should incorporate specific recommendations in this respect.

Informed consent in epidemiology, and more specifically in its occupational side, should contemplate the inclusion, in the oral and written undertakings that are established between researcher and subject of study, of reversion clauses and individualized access to the data collected and the information produced on the subjects [23]. The purpose of all this is to ensure that, in accordance with the legal regulations of each country, the rights of the persons who participate in epidemiological research may be better protected and exercised.

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Annex 1

Contents of the informative letters sent to the cases or their families

Common contents of model 1 and model 2 letters	<p>To Mr/Mrs:..... Or next-of-kin of subject.</p> <p>Dear,</p> <p>Our Research Group has conducted a study on Pleural Mesothelioma and exposure to asbestos, in the provinces of Barcelona and Cadiz. This group consists of researchers from the Centre de Seguretat i Condicions de Salut en el Treball (CSCST) of Barcelona, from the Institut de Recerca Epidemiològica i Clínica (IREC) of Mataró, from the Servei d'Anatomia Patològica of the Hospital Clínic (Barcelona) and from the Servicio de Medicina Preventiva of the Hospital "Puerta del Mar" (Cadiz).</p> <p style="text-align: center;">[Specific Contents]</p> <p>Please contact Dr....., of for any clarification you may require of this letter, on telephone no., between the hours ofam andpm.</p> <p>Yours faithfully,</p> <p>Director of the CSCST Barcelona</p>
Specific contents of letter model 1	<p>As part of this study, a comprehensive assessment has been made of the personal and occupational history of Mr/Mrs:..... as a result of which, his/her case has been classified as: (Certain/Probable) in respect of possible occupational exposure to asbestos, in accordance with the assessment criteria developed by the group.</p> <p>For this reason, we are hereby informing you that:</p> <ul style="list-style-type: none"> <input type="checkbox"/> In accordance with the Royal Decree 1995/78 of 12 May concerning the official "List of Occupational Diseases in the system of Social Security", Pleural Mesothelioma, and the activities that can produce it, is recognized as an Occupational Disease (Section F., point 2). <input type="checkbox"/> Any person officially recognized as suffering from this disease is entitled to the corresponding social and financial benefits under this legislation. <input type="checkbox"/> You may, if you wish, initiate the corresponding application procedures in the INSS (Instituto Nacional de la Seguridad Social), at the following address
Specific contents of letter model 2	<p>As part of this study, a comprehensive assessment has been made of the personal and occupation history of Mr/Mrs:..... as a result of which his/her case has been classified as (possible/improbable/no exposure/exposure unknown), in respect of possible occupational exposure to asbestos, in accordance with the assessment criteria developed by the group.</p> <p>This assessment has been made by a group of expert hygienists of the CSCST, based on information on the working history and occupational exposures of the subject. We are grateful for your valuable collaboration in this study.</p>

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