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Law and epidemiology: Misinterpretation of epidemiologic information in claims for asbestos-related diseases

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Abstract

Introduction

The problem of compensating a growing number of people who have contracted lung cancer, as a potential consequence of asbestos exposure, is taxing many legal systems. In most jurisdictions, the victim has to prove all the elements of the liability claim, including the requirement causation. Establishing causation is extremely difficult in asbestos-related cases in which uncertainty arises as to the cause of the damage (multiple causation). In such claims, epidemiologists are appointed to determine causation between the exposure to asbestos and the lung cancer. However, judges and lawyers appear to approach the concept of causation from another perspective when compared to epidemiologists. The multidisciplinary collaboration between judges and epidemiologists can lead and has already led to miscommunication and, more disturbing, legal judgments that are based on different assumptions about causation. Judges and epidemiologists have to work together extensively in order to improve the quality of the court's decisions in specific claims for asbestos-related diseases. The aim of this paper was to discuss the misinterpretation of epidemiologic information in claims for asbestos-related diseases.

Conclusion

Judges and epidemiologists have to work together more extensively in

*Corresponding author Email: sobczak@beeradvocaten.nl order to limit the misinterpretation between the two different disciplines, which will eventually improve the quality of the court's decisions in specific claims for asbestos-related diseases.

Introduction

Mr Karamus was exposed to asbestos in the course of his employment in an asbestos-cement factory in The Netherlands from 1964 till 1979. In 1997, Mr Karamus developed lung cancer and he died from the consequences of that disease in 2000.

The lung cancer was a potential consequence of exposure to asbestos. However, it was also possible that the lung cancer was caused by his 28 years of heavy smoking, his genetic predisposition, or external causes other than asbestos and smoking.

The case of Mr Karamus posed a very difficult question for Dutch Tort Law which will resonate in other legal systems: is it fair to deny all compensation or to award full compensation (through a traditional all-or-nothing scheme) when the actual cause of the lung cancer cannot be specifically determined? In 2006, the Dutch Supreme Court eventually decided to apply proportional liability and awarded damages in line with the Probability of Causation (PoC), which was determined by epidemiologists.

Karamus thus followed Schaier/De Schelde (1999), whereby Prof. T. Smid applied the PoC for the first time in a legal case. Although a number of diseases are linked to asbestos exposure, this paper focuses on the general type of lung cancer, not mesothelioma^{1,2}. This paper aims to inform epidemiologists about the way in which epidemiological data is transferred to legal judgments,

accentuating potential problems of misinterpretation.

Discussion

The authors have referenced some of their own studies in this review. These referenced studies have been conducted in accordance with the Declaration of Helsinki (1964) and the protocols of these studies have been approved by the relevant ethics committees related to the institution in which they were performed.

All human subjects, in these referenced studies, gave informed consent to participate in these studies.

Causation: a fundamental requirement to establish liability

Generally, all legal systems require the victim to prove causation between the defendant's wrongful act or omission and the victim's damage, in order to establish the liability of the defendant and to receive compensation. Applying traditional legal principles, the Dutch asbestos victim must prove to a reasonable degree of certainty that he would not have suffered from lung cancer if the defendant had not exposed him to asbestos (condicio sine qua non). The English legal system has bound a percentage to this notion: the victim must prove that it is on the balance of probabilities more likely than not (> 50%) that asbestos exposure did cause the lung cancer: the claimant must prove that "but-for" the adverse exposure, he would not have suffered from lung cancer. In most claims in Tort law, the assessment of causation results in a simple yes or no answer.

The victim receives full compensation if he is able to prove sufficient causation and leaves empty-handed if he cannot prove sufficient causation between his damage and the act or omission of the

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defendant. However, in specific claims for asbestos-related diseases, the assessment of causation can only be based on a probabilistic basis because lung cancer specialists are unable to determine the cause of the injury in cases in which the lung cancer is a potential consequence of asbestos exposure. In such cases of multiple causation, causation is - in a civil lawsuit - expressed in terms of 'probabilities' and 'percentages'.

All-or-nothing compensation has drawbacks in such cases because the claimant will run the risk of not receiving compensation, even when highly exposed to asbestos.

In addition, (just) one percent can make the difference between being fully compensated or not being compensated at all. In 2006, the Dutch Supreme Court decided to deviate from the all-or-nothing principle and applied the instrument proportional liability in claims for lung cancer that could have been caused by exposure to asbestos. Applying proportional liability, a judge does not simply award or reject the total amount of damages, but awards damages in proportion to the Probability of Causation.

Multidisciplinary collaboration

The establishment of causation in claims for asbestos-related diseases involves a multidisciplinary collaboration between judges and non-legal experts. In these particular cases judges are faced with scientific questions that are at the heart of a legal issue which cannot be resolved without the help of epidemiologists.

Judges do not have the relevant expertise or qualification to assess the probability that asbestos exposure caused the victim's damage. Therefore, the judge calls on expert opinion to assess the likelihood that a given activity (exposure to asbestos) causes a known damage (lung cancer).

It is very clear that judges and epidemiologists do not speak the same 'language' and, as a consequence, this cross-disciplinary discussion can lead and has already led to miscommunication and, more disturbing, incorrect legal judgments.³ In most asbestos-related cases it seems as if judges do not know or do not understand the basic assumption of the research done by the expert.⁴

Work is needed to ensure that the judiciary and lawyers are familiar with which conclusions can and cannot be drawn from the epidemiological evidence.

Cumulative exposure to asbestos

In claims for asbestos-related diseases it is first essential to determine whether there is sufficient evidence for occupational exposure to asbestos in the claimant's work history. This means that a life time job history is necessary to make an adequate assessment of the level of asbestos exposure in a specific claimant's case. The claimant's cumulative exposure is generally expressed in fibre years, which is seen as an important parameter for asbestos exposure.⁵

One fibre year is the exposure to air during one year, which contains one asbestos fibre per cubic centimetre air. A short exposure to high dust concentrations can result in the same cumulative exposure as a long exposure to low dust concentrations: one year of heavy exposure or five to ten years of moderate exposure may increase the risk to develop lung cancer two-fold or more, compared to those who were never exposed to asbestos. This doubling of risk principle is an important standard of causation in English and American Tort law.6

If the claimant is able to prove that the exposure to asbestos doubled the risk of lung cancer, than he will receive full compensation. If the claimant cannot prove that that the exposure to asbestos doubled the risk of lung cancer, than he will not receive any compensation. However, we must acknowledge that historical information on the level of exposure to asbestos is lacking in the

Netherlands (but also across the borders), especially in de period before 1980.8 Less quantitative information will increase uncertainty when establishing the cumulative exposure to asbestos in an individual case.

More disturbing is the fact that the lack of sufficient quantitative exposure data and the large uncertainties in interpreting available historical measurements make the estimation of the cumulative exposure to asbestos for an individual worker less reliable, given his specific work situation and job activities.

Smokers versus non-smokers

It is now widely established that the main cause of lung cancer deaths is tobacco use. Indeed. smoking represents the strongest identifiable risk factor, and accounts for 90 percent of all lung cancer cases.9 However, in the UK it was estimated that asbestos accounted for an estimated 2-3 percent of lung cancer deaths in Britain from 1980 to 2000.10 This reflects both large differences in the proportion of persons in the UK exposed to smoking (80% of respondents had smoked regularly at some time during this period) and asbestos (estimated at approximately 25% of UK population with any exposure during this period) and the associated risks for lung cancer with proportional mortality rates 12.0 and 1.12, respectively.

It must be acknowledged that it is impossible to precisely apportion the relative contributions of asbestos exposure and smoking in an individual case.11 The fact that workers in the asbestos industry tend to have, when compared to the general population, high smoking rates complicates the assessment of the Probability of Causation in claims for lung cancer: is hardly anv reliable epidemiological data on the likelihood of the lung cancer being caused by asbestos exposure among persons who did not smoke.¹² Epidemiological studies show that smoking combination with exposure to asbestos could reinforce each other in the development of lung cancer.13



However, the joint relation is not well-defined and has been subject to much debate in an extensive number of studies. A multiplicative relation between smoking and asbestos exposure has been established in the majority of the studies and has been accepted by many authorities for about the last thirty years. 15

Some recent epidemiological reviews do suggest that the effect of asbestos exposure is not additive multiplicative but submultiplicative: the risk to contract lung cancer is greater than adding up the individual effects (additive model) but the increase in risk of developing lung is, contrary the cancer to multiplicative model, less than multiplying the individual relative risks.16

Due to its complexity, only a few studies have tried to examine the relation between lung cancer risk and more specific smoking habits (intensity and duration of the asbestos worker's smoking history) and smoking cessation in combination with asbestos exposure.¹⁷

For a correct legal judgment, it seems important that epidemiologists not only distinguish smokers from nonsmokers but also heavy smokers from moderate smokers in order to determine the **Probability** Causation in a more adequate and realistic way.¹⁸ A recent (2011) study concludes that the risk of lung cancer mortality increases in situations where asbestos workers have started to smoke at an early age or have smoked many cigarettes for long periods of time.¹⁹

Epidemiologists such as Lee and Rothman underline this, and made it very clear that the term 'smoking' is too imprecise to be used as measurement data: one must specify the type of smoke (i.e., cigarette, cigar, pipe), whether it is filtered or unfiltered, the manner of frequency of inhalation, the onset and duration of smoking, and - presumably - passive

smoking, in order to achieve more reliable results.²⁰

Assessing the Probability of Causation (PoC)

Despite an extensive number of publications, the relationship between asbestos exposure and lung cancer is still subject of controversy, even when asbestosis is present.²¹ In 1999, Burdorf and Swuste suggested to use a probability model that apportions the relative contributions of asbestos exposure amongst other risk factors.²²

The Health Council of the Netherlands²³, who submitted an advisory Report to the State Secretary for Social Affairs and Employment in 2005, also advised to use a specific formula to assess the Probability of Causation in such cases.²⁴ In order to adequately assess the probability that asbestos exposure caused the lung cancer more information is required on the victim's exposure history. smoking history, the chemical nature of the inhaled asbestos fibres, and the (sub)multiplicative relation between smoking and exposure to asbestos. As a consequence of the long latency period of asbestos-related diseases²⁵, information on these factors is not always available for an individual case, which implies that a reasoned assessment of causation, based on population associations, may be too difficult.

An additional problem is that the uncertainty in epidemiological estimates on the relative importance of these factors cannot be translated into uncertainty in probability at individual level.

In spite of the difficulty and sometimes even inability to obtain correct data in claims for lung cancer that could have been asbestos-related, the Health Council of the Netherlands concluded that the 'Probability of Causation', also known as the 'Attributable Risk', to determine the likelihood that the lung cancer was caused by occupational exposure to asbestos, could be assessed by applying the following formula:

The formula could be applied to the previously described case study as follows: Mr Karamus was exposed to asbestos in the course of his employment and developed lung cancer that could have been caused by the wrongful exposure to asbestos. In Mr Karamus' case, the appointed expert concluded that the cumulative exposure (E) was 125 fibre years, that the risk of developing lung cancer increases with one percent per fibre year (K=1%), and thus the Probability of Causation could be assessed as followed:

In this example one could conclude that there is an attributable risk of 55.55 percent that Mr Karamus' lung cancer was caused by the occupational exposure asbestos. **Applying** to proportional liability, 55.55 percent of the damages claimed should be amount awarded as this compensation is exactly in line with the attributable risk that the exposure to asbestos did cause the victim's lung cancer

Transferring epidemiological findings to legal judgments in individual cases

The use of epidemiological findings to determine the Probability of Causation between the wrongful exposure to asbestos and the claimant's lung cancer, has been subject to much discussion and criticism in legal writings. Moreover, there are important distinctions between epidemiological causation and judicial causation. In Tort law, causation deals with a specific level: did the exposure of the defendant

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cause the claimant's damage? This is, however. not the case epidemiology:

the nature of causation is abstract. The question is of whether an act is usually followed by a certain effect?²⁸

Judicial causation, on the other hand, the individual determines responsibility of the tortfeasor in question and his or her share in producing the event.²⁹ The legal perspective of being held accountable for a wrongful exposure is thus not the same as an epidemiological perspective, which mostly focuses on how effects are caused. Furthermore, a legal judgment is a normative judgment, which means that contrary to epidemiological causation - normative elements could influence the court's judgment on judicial causation. Many examples can be found in case law in which the Dutch Supreme Court has, mostly in favour of the claimant, ignored the problems in proving judicial causation between cause and effect on the basis of reasonableness and fairness.30

The court's legal interpretation of epidemiological findings thus can be influenced by normative elements³¹. This so called 'fairness-correction' can be used as a tool to include normative elements in the establishment of judicial causation in order to reach outcomes that have balanced out the interests of the claimants and the interests of the defendants fairly.

information Statistical and epidemiological data is getting more and more individualized. The recent developments in personalised and stratified medicine, for example epigenetic variation in the interaction between dietary patterns and genome subsequent expression and differential risk of type 2 diabetes mellitus and breast cancer³², indicate that these specific combinations of individual characteristics and exposure profiles may guide towards a better prediction for individuals with their own unique and sometimes complex background.

This way, the assessment of the Probability of Causation comes closer to the individual probability that the exposure to asbestos did cause the claimant's lung cancer. But it must be acknowledged that the concrete circumstances of the claimant are not always taken into consideration in epidemiological studies. This can result in unreasonable legal iudgments in cases where epidemiological findings are directly applied in individual claims.33

Should the use of epidemiological data as evidence in court than be rejected? No, but the judge may deviate at his discretion with clearly motivated arguments. The court must whether the consider concrete circumstances of the claimant justify the strict application epidemiological findings on causation in the individual case and should be free to deviate from the expert report stipulated that the decision is motivated clearly. In this respect, the court's decision may follow the classical dilemma in medicine whether it is better to err on the safe side with a false positive decision (type I error) rather than a false negative decision (type II error).

Conclusion

In claims for lung cancer that could have been asbestos-related, uncertainty arises as to the cause of the disease. Lung specialists are unable to determine whether lung cancer is caused solely or primarily by exposure to asbestos or by other factors that could cause or contribute to the development of lung cancer.

In such cases the Dutch Supreme Court deviated from the principle of all-or-nothing compensation and applied the instrument of proportional liability: the judge did not simply award or reject the total amount of damages, rather he awarded damages in proportion to the Probability of Causation.

The establishment of causation in claims for lung cancer involves a

multidisciplinary collaboration between judges and epidemiological experts and, as a consequence, this cross-disciplinary collaboration can lead to miscommunication. Important distinctions have been established between epidemiological causation and judicial causation. Prudence is called for when transferring epidemiological findings to legal judgments.

The findings on epidemiological causation must be considered as a starting point to determine judicial causation because the court's legal interpretation of the epidemiological findings can, contrary to epidemiological causation, be influenced by normative elements. The inclusion of normative elements in the specific claimant's case gives the judge the opportunity to legally interpret the epidemiological evidence in favour of the claimant or in favour of the defendant. Judges and epidemiologists have to work together more extensively in order to limit the misinterpretation between the two different disciplines, which will eventually improve the quality of the court's decisions in specific claims for asbestos-related diseases.

References

- 1. Mesothelioma is a primary tumour of the mesothelium, which covers the serosal cavities of the pleura, the pericardium and the peritoneum.
- 2. See for an assessment of causation in mesothelioma cases that might have been caused by exposure to chrysotile asbestos-containing brake Freeman MD, Kohles SS. Assessing specific causation of mesothelioma following exposure to chrysotile brake asbestos-containing International Journal of Occupational and Environmental Health. 2012, Vol 28/no. 5, p. 329-336.
- 3. Rechtbank Maastricht 13 juli 2005, JA 2006, 44: In this case a man was bitten in his hand by a dog. Instead of cleaning the wound and leave it open, the physician glued and closed the wound. Subsequently, the patient developed dystrophy. In court, the specialist stated that normally (following the correct

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procedure) the chance on dystrophy is 1-2%. Because of the physician following the wrong procedure, the chance on dystrophy had risen to 2-4%. In view of the judge, this means that - at worst - the malpractice caused a 3% (4 minus 1) higher risk on dystrophy. This percentage is too little to assume sufficient causation. However, they should have judged that there is a 50% chance (attributable risk) on a causal relation between the medical malpractice and the dystrophy. Had they applied the instrument of proportional liability, the judge should have awarded 50% of the damages.

- 4. Hoge Raad 31 maart 2006, LJN: AU6093 (Hollink/Eternit) in which the Dutch Supreme Court assumed that smoking was not an important factor in assessing the probability that the claimant's lung cancer (not mesothelioma) was caused asbestos exposure.
- 5. Tossavainen A. Asbestos, asbestosis, and cancer: the Helsinki criteria for and attribution. diagnosis Scandinavian Journal of Work, Environment & Health. 1997 23/4, p. 311-316.
- 6. Sobczak F. Liability for asbestosrelated diseases. Universitaire Pers Maastricht. 2013, p. 122-124.
- 7. See for good examples in English case law: Shortell v Bical Construction Ltd., [2008] QBD Liverpool (16-05-2008); Badger v Ministry of Defence, [2005] EWHC 2941 (QB), [2006] 3 ALL ER 173.
- 8. Burdorf A, Swuste P. An Expert System for the Evaluation of Historical Asbestos Exposure as Diagnostic Asbestos-Related Criterion Diseases. Annals of Occupational Hygiene. 1999 43/1, p. 59.
- 9. Frost G, Darnton A, Harding AH. The effect of smoking on the risk of lung cancer mortality for asbestos workers in Great Britain (1971-2005). Annals of Occupational Hygiene. January 2011, p. 1-19.
- 10. Darnton AJ, McElvenny DM, Hodgson JT. Estimating the number of asbestos-related lung cancer deaths in Great Britain from 1980-2000. Annals of Occupational Hygiene. 2006/50, p. 29-38.

- Tossavainen Asbestos, asbestosis, and cancer: the Helsinki criteria for diagnosis and attribution. Scandinavian Iournal of Work. Environment & Health. 1997 23/4, p. 314.
- 12. Frost G, Darnton A, Harding AH. The effect of smoking on the risk of lung cancer mortality for asbestos workers in Great Britain (1971-2005). Annals of Occupational Hygiene. January 2011, p. 1.
- 13. Frost G, Darnton A, Harding AH. The effect of smoking on the risk of lung cancer mortality for asbestos workers in Great Britain (1971-2005). Annals of Occupational Hygiene. January 2011, p. 8.
- 14. Nelson HH, Kelsey KT. The molecular epidemiology of asbestos and tobacco in lung cancer. Oncogene, 2002/21, p. 7284-7288; Lee PN. Relation between exposure asbestos and smoking jointly and the risk of lung cancer. Journal of Occupational and Environmental Medicine. 2001/58, p. 145-153.
- 15. Wraith D, Mengerson K. A Bayesian approach to assess interaction between known risk factors: the risk of lung cancer from exposure to asbestos and smoking. Statistical Methods in Medical Research, 2008/17, p. 171-189; Erren T, Jacobsen M, Piekarski C. Synergy between asbestos and smoking on lung cancer risks. Epidemiology. 1999, 10/4, p. 405-411.
- 16. Wraith D, Mengerson K. A approach Bayesian to assess known interaction between factors: the risk of lung cancer from exposure to asbestos and smoking. Statistical Methods in Research, 2008/17, p. 182; Berry G, Liddell FDK. The interaction of Asbestos and Smoking in Lung Cancer: A Modified Measure of Effect. Annals of Occupational Hygiene. 2004, 48/5, p. 459-462.
- 17. Liddell FDK, Armstrong BG. The Combination of Effects on Lung Cancer of Cigarette Smoking and Exposure in Quebec Chrysotile Miners and Millers. Annals of Occupational Hygiene, 2002, 46/1, p. 5-13; Reid A, de Klerk NH, Ambrosini GL. The risk of lung cancer with increasing time since

- ceasing exposure to asbestos and quitting smoking. **Iournal Occupational** Environmental and Medicine. 2006/63, p. 509-512; De Klerk NH, Musk AW, Armstrong BK. Smoking, exposure to crocidolite, and the incidence of lung cancer and asbestosis. British Journal of Industrial Medicine. 1991/48, p. 412-417.
- Berry G, Liddell FDK. The 18. Interaction of Asbestos en Smoking in Lung Cancer: A Modified Measure of Effect. Annals of Occupational Hygiene. 2004, 48/5, p. 459.
- 19. Frost G, Darnton A, Harding AH. The effect of smoking on the risk of lung cancer mortality for asbestos workers in Great Britain (1971-2005). Annals of Occupational Hygiene. January 2011, p.
- 20. Lee PN. Relation between exposure to asbestos and smoking jointly and the risk of lung cancer. Journal of Occupational and Environmental Medicine. 2001/58, 145-153: p. S. Basic Rothman Greenland KJ, concepts, 2005.
- 21. Most cases of asbestosis occur after exposure to high dust concentrations over many years. A certain 'dose' or level of exposure is required for the development of asbestosis. Henderson DW, Rodelsperger K, Woitowitz HJ, Leigh J. After Helsinki: a multidisciplinary review the of relationship between asbestos exposure and lung cancer, with emphasis on studies published during 1997-2004, Pathology 2004/36(6), p. 517-550.
- 22. Burdorf A, Swuste P. An Expert System for the Evaluation of Historical Asbestos Exposure as Diagnostic Criterion in Asbestos-Related Diseases. Annals of Occupational Hygiene, 1999 43/1, p. 57-66.
- 23. Official body to inform the Dutch government on health-related issues.
- Protocollen 24. Gezondheidsraad. asbestziekten: longkanker 2005/09.
- 25. 10 to 30 years.
- Gezondheidsraad. Protocollen asbestziekten: longkanker 2005/09. Fibre years (cumulative exposure).
- Gezondheidsraad. Protocollen asbestziekten: longkanker 2005/09. Increased risk of lung cancer per fibre year (risk coefficient).

- 28. Witjens EM. Strafrechtelijke causaliteit: de redelijke toerekening vergeleken met het privaatrecht, Kluwer BV, 2011.
- 29. Haritz MM. An inconvenient deliberation: the precautionary principle's contribution to the uncertainties surrounding climate change liability, Box Press Publishers, 2010.
- 30. Hoge Raad 9 oktober 1999, NJ 1999, 353 (DES).
- 31. For example, the fact that the defendant did not take any precautionary measures to ensure a safe working environment for his employees, or the fact that the defendant has breached a safety norm, or the fact that the legal position of employees should be protected.
- 32. Burdge GC, Hoile SP, Lillycrop KA. Epigenetic: are there implications for personalised nutrition? Curr Opin Clin Nutr Metab Care. 2012; 15(5):442-7.
- Nutr Metab Care. 2012; 15(5):442-7. 33. Van AJ. Bewijs van causaal verband met behulp van epidemiologische gegevens, Boom Juridische Uitgevers, 2000.