EVALUATION OF RESPIRATORY HAZARDS IN THE WORKING ENVIRONMENT THROUGH ENVIRONMENTAL, EPIDEMIOLOGIC AND MEDICAL SURVEYS

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HISTORICAL AND CURRENT CONTEXT

Respiratory disease consequent on work in dusty trades has been recognized since ancient times when man first turned to tools to help him to exploit the riches at the earth's surface. In the past, distinctions have been blurred between various disease processes involved (fibrotic, infectious, malignant), all of which may follow occupational exposures.[1] The term pneumoconiosis was introduced in the 19th century to describe the rather specific nature of the lung's fibrotic reaction to inorganic dusts, such as silica, coal and iron. In keeping with its Greek roots, the term is currently defined by the World Health Organization as the "accumulation of dust in the lung and tissue reactions to its presence."[2] Over the past century, industrialization, the growth of populations, and the increased demands for the raw materials of the earth's crust have led to an increase in the number of workers whose jobs expose them to mineral dusts.

In consequence, the early years of this century saw an increase in the burden of dust diseases in industrialized countries, and post World War II in the newly industrializing countries. There are no global estimates of the number of workers currently at risk; Table I refers to the 1970's[3-5] and is mainly based on information furnished to the International Labour Office by those countries which report on their mining, tunnelling and quarrying operations.[3] The considerable between country differences in rates are no doubt largely due to differences in methods of reporting. Nor is the coverage comprehensive.

Not only the distribution but also the nature of some of the pneumoconioses may be changing. For instance, since the first International Pneumoconiosis Conference held in Johannesburg, in 1930,[6] the profile of diseases such as silicosis appears to have changed, at least in the large controlled industries.[7,8] Whereas in the early decades of this century, these were diseases which disabled young and killed prematurely, they are now increasingly diseases of primarily radiologic manifestation with little morbidity or impact on longevity. Reasons no doubt include improved living standards, better medical care and tuberculosis control in addition to improved environmental controls at the workplace.[8]

However, outbreaks of acute disease continue to appear, usually in new processes or small uncontrolled industries, even in the technologically advanced countries.[1,8-12] The mid-century epidemic of asbestos-related disease is another example of the failure to apply known control technologies to commercial exploitation, in this instance due perhaps in part to the exigencies of World War II.[13]

The perspective envisaged for the VIIth International Pneumoconiosis Conference as reflected in the themes selected for discussion is considerably broader than that of the First Conference, held in Johannesburg in 1930. The players are also different. Clinical, engineering and industrial hygiene scientists were the major contributors at the First Conference, with the major contributing laboratory sciences being pathology and microbiology. Today all branches of the clinical laboratory sciences are represented, in particular, epidemiology. This is a late comer on this scene and has become increasingly important as it adapted the techniques developed for the study of epidemic infectious disease to the study of chronic noninfectious disease of multifactorial etiology. It is well accepted that environmental and medical surveys can be used to evaluate hazards in the working environment. However, today I wish to indicate how they may be combined using the approaches and methods of epidemiology, and statistics which together offers 3 powerful tools: i) a basis for sampling when numbers to be studied exceed resources; ii) a means of estimating power when sample size is limited (workforces are after all finite) and iii) the methods of analysis which enable the simultaneous consideration of more than one factor in these diseases of multifactorial etiology. The examples chosen to illustrate this presentation are from my own field of endeavour.

ROLE OF EPIDEMIOLOGY

Epidemiology is defined as the study of the "distribution and determinants of health related states or events in specified populations and the application of this study to the control of health problems."[14] I agree with those who argue that it is a discipline rather than a science, i.e., a field of learning or practice applicable to the study of natural phenomena (biological, sociologic or other), rather than a science, i.e., a systematized theoretical body of knowledge about a particular category of natural phenomena.[15] As such, it is a

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Table I

Selected Information on Dusty Occupations in Various Countries: Number of Current Workers at Risk, Reported Prevalences of Pneumoconiosis (total cases) and Incidences (new cases each year) per 1000 Exposed Workers

Continent /country	Sources of exposure	Years	Number at risk	Total cases/ 1000	New cases/yr 1000
Europe					
France	mines, pits, quarries	1977	89,391	51.1	5.1
Germany	coal mines,	1977	111,992	228.9	7.5
	other	1977	c.7,000	116.9	2.4
Poland	mines, other	1978	c.90,000	34.4	3.7
UK	coal mines,	1977	252,600	119.1	2.1
	other	1977	5,800	103.4	9.4
America					
US	coal	1973-78	118,579	'20.0	na
Ontario	mining	1970	17,355	na	1.4
Quebec	mining	1967-77	12,556	na	1.8
Mexico*	mining	1973	4,815	8.9	8.9
Peru	not stated	1976	56,819	c.36.0	na
Australia					
NSW	coal	1973-76	15,970	28.8	na
	other	1976-78	4,484	10.6	0.5
Queensland	coal	1968-72	1,387	na	6.4
	other mines	1968-72	3,903	na	8.1
W Australia	mines	1978	6,923	27.0	2.6
India	mines,other	1973-77	c.600,000	c.25.0	
Africa					
Kenya	small mines	1977	3,359	0.0	na
S Africa	hard	1977	19,504	na	11.1
	rock	1977	300,357	na	1.6

Table shows information derived mainly 3 countries reporting to ILO on the number of subjects exposed in dusty occupations as well as pneumoconiosis rates: (ref 3): figures for Ontario, Quebec, and for S Africa were derived from ref 4.

* refers to 1 company only; each company keeps its own statistics

discipline which must be of interest and of use to all participants here today, whatever our branch of science.

Epidemiology can be used to address in populations the same issues which a clinician addresses in the management of a single case: namely, the description and recording of its features (the history, examination and laboratory tests); the explanation contained in the diagnosis and the formulation of prognosis, and in light of the above the planning of the management and the evaluation of its success. Thus population based (epidemiologic) studies may have as their objective, description (prevalence or incidence of disease) and/or explanation (who in a population is affected and why: who is not and why not). These findings can then be used to formulate corrective measures, and once in place, their effectiveness can be evaluated by further studies. The key in the clinical as well as the public health management of occupational disease is how to establish the link between the biologic outcome of interest (abnormality, dysfunction or disease) and the pertinent exposure.

ESSENTIAL ELEMENTS OF AN EPIDEMIOLOGIC SURVEY

These can be summarized in four interrogative adverbs: why (the objectives of the survey), how (its design), who (the target population or workforce(s)) and what is to be studied (referring to the measurements made of dependent and independent study variables).[13] Most important is the first, what McDonald calls the "fundamental ingredient of any scientific endeavour," namely, "an obtainable objective or answerable question ... clearly and unambiguously defined."[16] He also recommends that a subsidiary question be asked: "and what will I do with the answer?" Thus an epidemiologic study is neither "a data gathering exercise with a nebulously defined purpose and no hypothesis to test;" nor is it a study "which misses a truth because it is buried in a mass of data." These are both popular misconceptions which relate to the false belief that the key characteristic in epidemiological study is that it is based on large numbers of subjects.[17] Indeed some of the most effective epidemiologic studies are very economical in this regard.

Design

At the heart of the scientific method is the experimental design. In its complete form it requires that the researcher have control of all aspects of the study including the option of testing the entire target population (or sampling at random from it); control of the assignment of test units to intervention (exposure) or not, as well as the opportunity to examine all test units before and after the intervention with no loss to follow-up.[16] When study units are cells, or plants or animals, this is possible; when the subjects are human, and exposure the result of natural experiment, this is rarely so. Indeed, the definition of a survey (the word used in the title of this presentation) is "an investigation in which information is systematically collected but in which the experimental method is not used."[14]

Other than randomized control trial, for instance, of tuberculosis drug therapy, most occupational health surveys must of necessity use a less-than-complete experimental design. While the strongest designs include measurements before and after exposure (i.e., are longitudinal or cohort in concept), prevalence (i.e., cross-sectional) designs are often all that is feasible, and are most frequently used for chronic non-malignant diseases such as pneumoconiosis whose onset is difficult to pinpoint. Indeed, the prevalence study has been not inappropriately dubbed the "workhorse" of chronic disease epidemiology.[17]

By contrast, the case control design is an elaboration of the traditional clinical case series, in which clinical case experience is described without reference to the population from which they were derived. The case control study also starts with identification cases of the disease under study; persons without the disease (controls) are then selected from as far, as can be determined, the same population as generated the cases, and the past of cases and controls are compared for evidence of exposure. Hybrid designs, using the case-control approach within a cohort, have been creatively exploited in establishing relationships between occupational exposure and malignant diseases,[18] and they are now increasingly being used in the study of non-malignant diseases such as the pneumoconioses.[17] Nor does the case series study necessarily merit the scorn often accorded it by editors and reviewers: it was after all such a clinical case series reported by a missionary doctor, the surgeon to whom his cases were referred, and the pathologist on the surgical pathology service which first drew the attention of the medical community to the link between mesothelioma and asbestos exposure.[19] Indeed, it has been pointed out that shrewd clinical observation remains the most powerful tool in detecting new disease patterns linked to workplace exposure,[20] also in identifying recognized disease patterns in workplaces or associated with exposures not previously thought to be at risk.[17]

Dose Response Relationships

Dose response relationships form the scientific basis of pharmacology (which deals with desired responses) and toxicology (which deals with undesired responses). In both, dose refers to the amount of the agent delivered to the target organ and retained for a period of time sufficient to evoke a response. In occupational surveys of chronic diseases like pneumoconiosis and chronic obstructive pulmonary disease, dose-response relationships are important in establishing causality.[16,17,21] However, estimates of exposure have until recently, been the only available indicator of dose; obviously a very poor substitute given the low deposition rates and highly efficient clearance of so much of what we breathe in. What is surprising, given the impossible task of represent ing exposure over a working lifetime accurately, is that exposure-response relationships are usually demonstrable in workplace surveys even using quite simple indicators of exposure.

The development of new methods, such as the quantitative measurement of lung dust residue represent a quantum advance in the study of the dose variable and these have already contributed to our understanding of why exposure response relationships differ between workforces. For instance, there is now evidence in support of mass rather than fiber number being the determinant of fibrosis scores for asbestosis.[22] This topic is rightly one of the key themes of this Conference.

New technologies of this sort to obtain the most precise estimates of dose possible may not however always be available, and the value of what is surely the simplest estimate of exposure, the worker's personal assessment, should not be overlooked. Thus several recent community-based studies have shown clear evidence of association between indicators of chronic obstructive pulmonary disease (COPD) sucb as FEV_1 and occupational exposure to dusts at work, evaluated subjectively by study participants.[23,24] Subjective estimates of personal exposure have also proved as useful as objective dust exposure measurements in demonstrating exposure response relationships in workforce based studies, an observation of relevance in situations where resources for objective environmental control measurements do not exist, for instance in certain industrializing countries.

Modelling Exposure Profiles

Whether or not lung responses are influenced by exposure profiles (such as the occurrence of peaks or gaps in exposure versus steady level exposure) remains a matter of concern, with implications for setting control levels. However it is not an easy matter to investigate. One approacb is to use mathematical modelling based on biologically plausible models.[26,27] For instance, in Quebec asbestos miners, temporal patterns of exposure appeared to influence the different respiratory responses;[27] thus for asbestosis, the strongest predictor was cumulative exposure; for pleural change exposure, peaks and residence time of dust in the lung; for airway reactivity, both with early and recent exposure, and for airflow limitation and bronchitis, dust level and dust load over time as well as smoking.

MEASUREMENT TOOLS OLD AND NEW: APPLICATIONS AND EXAMPLES

The effect of measurement error, wbether of exposure or response, is attenuation of exposure response relationships. This has led to concerted efforts to improve standardization and reduce measurement error. In the case of the cbest radiograph, the traditional health measurement tool in pneumoconiosis surveys, the ILO has taken the lead in standardizing techniques of film reading.[28] Subsequently, respiratory questionnaires and lung function tests have been included in most workplace surveys,[1,17] originally in support of the diagnosis of pneumoconiosis, but subsequently as outcome measurements in their own right to characterize among other things airway function and standardization procedures for their use in surveys has been developed by various professional bodies.[29,30] Despite its modest status (it is cheap and despised by clinicians as inaccurate), the respiratory questionnaire has proved a surprising but powerful measurement tool. For instance, exposure-response relationships for the complaint of shortness of breath wben hurrying on the flat are readily demonstrated in asbestos exposed workers, consistent with the clinical conviction that shortness of breath is an early, characteristic and essential feature of asbestosis.[8,13] Recently there has been a resurgence of interest in this and other symptoms such as wheezing as response variables coinciding with the increasing appreciation of the fact that acute and chronic airway responses occur following a wide range of occupational exposures.[31]

Pulmonary Function Tests

Obsession with the importance of reproducibility of lung function tests for epidemiology studies often led researchers to exclude subjects whose results failed to meet specified criteria for acceptability.[29] A careful analysis by one research group of subsequent health experience in subjects with and without test failure brought to light a very interesting source of bias, namely, that test failure in itself carries a greater chance of a less unfavourable outcome.[32] This observation has now been confirmed in several cohorts and the underlying mechanism(s) are under investigation.

The "healthy worker effect" is a term originally coined to describe the lower mortality experience of employed workers compared to the general population,[14] presumably due to their better than average health status. There may be a similar explanation for the better than average lung function often seen in workers engaged in physically demanding jobs. For instance, in a survey of Paris workers employed in a number of plants, younger workers with pollutant exposure had consistently better (not worse) values for FEV than those wbose jobs did not involve exposure; in older workers the situation was reversed.[33] Nor is this experience unique.[34] It is also biologically plausible: dusty jobs are traditionally heavy jobs likely to attract those of above average performance. This potential source of bias has implications for analysis as well as for interpretation, and suggests that cross-sectional studies of older workers are likely to underestimate exposure effects on lung function even when external reference values are used to take account of confounders.[35]

Complex Health Measurements as Tools in Epidemiologic Studies

The laboratory measurements now available to characterize pulmonary abnormality, dysfunction and disease are remarkable for their variety and precision, but also for their complexity and cost and their optimal integration into researcb into pneumoconiosis and other diseases of occupation can be challenging. This is often possible through the use of hybrid study designs, such as case-control within a cobort or within a prevalence study. This allows the target population to be described by low-technology measurements (e.g., questionnaire, job, and if necessary lung function or x-ray), and within this framework, stratification by exposure, or response, or both can be done prior to sampling. In this way it is possible to address well formulated objectives by comparison of selected but small groups of subjects using high technology tools. Note the population description should respect basic epidemiologic principles including a complete definition of the target population with an assessment of selection bias into and out of the workforce (respectively the "healthy worker" effect and the "survivor" effect). For example, it was possible to use questionnaire, x-ray and lung function data gathered in a cross-sectional study of the Quebec asbestos miners and millers[36] to select smaller subsets of subjects in whom further measurements were carried out to address additional questions on the early effects of exposure,[37] and whether lung geometry was a risk factor for the development of asbestosis.[38]

UNRESOLVED ISSUES, FUTURE RESEARCH AND DIALOGUE

A conference like this brings to light many unresolved issues, and perceptions vary as to their importance. One which deserves careful scrutiny is how best to evaluate the effectiveness of current pneunoconiosis control measures including health surveillance and environmental control levels. Most current survey research is descriptive (for instance, health hazard identification or evaluation) or etiologic (examining exposure response relationships), little is evaluative (determining the effectiveness of controls). Despite the probably billions of chest radiographs, and the probably millions of spirometric test records carried out in health surveillance programs, it is still not clear whether medical surveillance and/or current environmental control levels for silica[12] and asbestos[35] if respected, do indeed protect human health.

A second and related question concerns the links between pneumoconiosis and tuberculosis, an issue of great importance in those countries of Africa and Asia with both high tuberculosis infection rates, and extensive mining operations.[4] Under such circumstances, mine medical services may be responsible for extensive surveillance and treatment programs which could provide the framework for important research. For instance, a recently completed study in goldminers in the Orange Free State evaluated several short tuberculosis treatment regimens, and in a subset of the data showed that continued mining exposure while on treatment did not affect the outcome unfavourably.[39] This important finding went contrary to the current practice which precluded miners on treatment for tuberculosis from further underground service, in the belief that continued silica dust exposure diminished the chance of treatment success. Nor was outcome unfavourably influenced by the presence of silicosis. As a result of these findings, regulations now permit miners to continue in underground service, while under treatment, without loss of income, an important consideration in a largely migrant and rurally based workforce.

A third issue is how better to exploit the many existing data banks (including case registries and health surveillance data) for research and health control purposes. For instance, the Swedisb silicosis case registry,[40] set up in 1933, has been used to study i) progression (shown to be greater if cases continued in a job with exposure after the earliest radiologic manifestation); ii) the relationship to lung cancer (silicosis cases have a greater risk than non-cases); iii) tuberculosis rates (still a frequent complication in cases of silicosis, even after the introduction of drug therapy in 1951). The PATHAUT data file, another registry containing machine readable autopsy reports on some 33,000 South African miners,[41] has also been used as a data base for a case control study which showed hard rock mining to be a risk factor for emphysema.[41] Other uses of case registries will be reported at this meeting.

Finally there is the issue of dialogue, within and between disciplines, within and between researchers, and within and between professionals. Each of us tends to believe the other is ignorant of what we have to offer. Dialogue is less difficult in the context of a conference such as this, when participants are free of daily tasks; dialogue is also less difficult perhaps in institutes dedicated to a common theme "Dialogue" should also include user-responsiveness: those who are in the workplace on a daily basis are often the first to perceive the unexplained or the unexpected and yet their comments are often not sought or heard. Finally, research into the diseases of occupations (whether it be basic laboratory research, cellular biology, environmental or clinical research) should always and only be driven by hypotheses which have hiologic credibility as well as user plausibility, in the context of good study design. In addition, if there is a sound answer to Dr. McDonald's question: "and what will I do with the information" before starting a survey, then the survey is likely to be one which will furnish a useful evaluation of respiratory hazards in the working environment.

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