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CHAPTER

Methodology

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Methods for Determining Work-Relatedness

Criteria to evaluate scientific evidence for the work-relatedness of various health conditions and effects have been accepted by epidemiologic and public health organizations. Epidemiologic surveillance provides aggregate information about occupational risk and the development of specific medical conditions. Physicians are often asked to provide an opinion for a specific case in which the workplace factors may be the only identifiable cause, one among several contributing causes, or one of several possible causes, each of which could independently produce the condition.

In general, a disease or an injury is considered occupational if the following criteria are met:

1. The medical findings of disease or injury are compatible with the effects of a disease-producing agent or an injury producing event to which the worker has been exposed;
2. Sufficient exposure is present in the worker's occupational environment to have caused the disease; and
3. The weight of evidence supports the disease as having occupational rather than nonoccupational origin.

The need to identify whether the criteria are met led to development of six parts of assessment for the six steps determining work-relatedness by the National Institute for Occupational Safety and Health¹ that were modified by Glass.²

1. Evidence of disease. What is the disease? Is the diagnosis correct? Does the evidence (e.g., history, physical examination findings, and results of diagnostic studies) support or fail to support the diagnosis?
2. Epidemiologic data. What is the epidemiologic evidence for the disease or condition? Do the data support a relationship with work?
3. Evidence of exposure. What evidence, predominantly objective, is there that the level of occupational environmental exposure (e.g., frequency, intensity, and duration) could cause the disease?
4. Other relevant factors. What other relevant factors are present in this case? Are there individual risk factors other than the occupational environmental exposure that could contribute to the development of the disease? For example, if the diagnosis is carpal tunnel syndrome, is the worker pregnant, obese, or diabetic?
5. Validity of evidence. Are there confounding or conflicting data to suggest that information obtained in the assessment is inaccurate?
6. Evaluation and conclusions. Do the data obtained in the preceding assessment support the presence of a work-related disease?

Study Design

One purpose of this book is to describe the literature basis for assertions about the causal relationship between work-related (or putatively work-related) exposures and identifiable anatomic and/or physiologic alterations leading to disease or dysfunction. The literature on industrial causation (occupational exposure) is relatively sparse.

In contrast, there is a large body of literature on causal relationships between non-work-related factors (e.g., genetic, dietary, age-related, anthropomorphic, and environmental) and disease. The evidence basis used to determine causation as it relates to these factors has generally been well-characterized, with the strengths and limitations of available evidence well appreciated by experts in the relevant medical specialties. Therefore, the literature on the causal relationships between nonoccupational factors and diseases was not rated. For each chapter that deals with specific medical diagnoses, determinations as to strength of the association with causation reflects expert opinion on the overall scientific merit based on the scientific validity of the current body of literature. Each conclusion is supported by references.

The literature on the causal relationship between industrial disease and occupational factors was obtained and reviewed in depth. When insufficient literature was available to evaluate factors and exposures to make a determination, the conclusions reflect our opinions. The basis for these conclusions is explicitly described and often reflects extrapolations from available literature, analyzed in the context of the anatomy and physiology of the organ system or body part putatively affected by the exposure. Research activities or study outcomes that allow for further clarification of causation in relation to the conditions discussed are described as well.

When sufficient occupational-exposures literature is available for evaluation, we propose the following five-step method as a guide for analyses. The term, *study* (any published article included in the relevant analysis) may be interchanged with the term *article*.

Quality Scoring for Epidemiologic Studies on Musculoskeletal and Other Occupational Disorders

Step 1

A thorough literature search is performed to collect all peer-reviewed publications on a relevant topic using specific search criteria (Table 4-1). Review articles and meta-analyses are included for a comprehensive literature search.

Step 2

Each original study is submitted to a panel of three raters who are physicians or hold doctoral degrees and have experience in occupational epidemiologic studies (or equivalent). Each article is evaluated by a quality scoring scale, from 0 to 140 points (Table 4-2). The quality score for a given article is submitted to an independent staff member who compiles the quality scores for each of the three raters. If the range of quality scores is more than 20 points, the article will be discussed in a meeting or teleconference. If necessary, the article will be re-rated to obtain the mean rating, which will be the final quality score for the article. If the range of quality scores is less than 20 points, the mean score will be the final quality score for the article.

Step 3

Each article is also reviewed by a panel of at least three raters to identify the most appropriate study design classification. If there is not complete agreement on the study-design classification, the design would be discussed in a meeting or teleconference. If agreement is still not reached, the majority opinion will be used to determine the classification of the study.

Step 4

Each article quality score is multiplied by a weight factor (Table 4-3) to obtain the final impact rating (Table 4-4).

Step 5

To determine the strength of evidence for causation for a specific topic or diagnosis, the final impact ratings for all relevant studies are summed. It is unrealistic to expect that every possible occupational exposure risk will have been studied. Therefore, there might be no scientific evidence for some medical conditions and their causation. When possible, the conclusion of causal associations and determination of work-relatedness are based on multiple, high-quality studies, making it necessary to combine the quality ratings of individual studies into an aggregated rating that characterizes the body of evidence on which the conclusion is based. The evidence in the literature for a relationship between workplace factors and the development of a specific medical condition is classified into the categories shown in Table 4-5.

TABLE 4-1 Search Criteria

Database	Terms of Search	No. Found	No. Reviewed in Detail	No. Accepted
PubMed				
AHRQ				
CINAHL				
Cochrane Register				
EMBASE				
EMB Online				
MEDLARS				

Abbreviations: AHRQ, Agency for Healthcare Research and Quality; CINAHL, Cumulative Index of Nursing and Allied Health Literature; EMB, EMB is an evidence-based medicine database; EMBASE, EMBASE is a biomedical and pharmacological database; MEDLARS, MEDLARS is used for preparing publications like Index Medicus®.

TABLE 4-2 Quality Scoring Scale*

Criteria	Range of Scores	Rating Anchor	Explanation of Rating Anchors
Clearly defined groups	0-10	0	Study lacks clearly defined groups or reports such groups, but subsequent analyses of data suggest groups were not clearly defined
		5	Clearly defined groups mentioned, but descriptions incomplete; or other questions about adequacy of study group identification cannot be adequately addressed
		10	Clearly defined groups specifically stated; reported data show well-defined groups
Exposure measurements	0-10	0	No mention of how exposures were measured
		2.5	Exposure measurement by job classification or questionnaires given to subjects; or assessment methods unclear
		5	Mixture of objective and subjective measures and lack of clarity and completeness about how measures were done; individualized assessment required for rating of 5 or higher
		7.5	Measures mostly objective and individualized; few questions about how exposure assessments were accomplished
		10	Exposures objectively measured and individualized; exposure assessments well described
Participation and dropout rates	0-10	0	Participation rate less than 50% or not mentioned (for cohort studies, annual dropout rate of 40% or higher)

TABLE 4-2 Quality Scoring Scale* (continued)

Criteria	Range of Scores	Rating Anchor	Explanation of Rating Anchors
		2.5	Participation rate of 50% to 59% (for cohort studies, annual dropout rate of above 30%)
		5	Participation rate of 60% to 69% (for cohort studies, annual dropout rate of 20%-29%)
		7.5	Participation rate of 70% to 79% (for cohort studies, annual dropout rate of 10%-19%)
		10	Participation rate of 80% or more (for cohort studies, annual dropout rate of less than 10%)
Blinding of exposure measurements	0-10	0	No mention of how measurements were blinded; measurement methods unlikely to result in blinding; or measurement relied on subjects' perceptions of exposure
		2.5	Some mention of blinding, but significant questions remain; complete blinding unlikely
		5	Mention of blinding; questions remain about adequacy of blinding
		7.5	Blinding procedures carried out; minor questions remain about adequacy of procedures
		10	Blinding procedures described that would result in exposure assessments being blinded
Health outcomes measurements	0-10	0	No mention of how health outcomes were assessed
		2.5	Measurement by administrative databases; or methods unclear or would result in substantial misclassifications

TABLE 4-2 Quality Scoring Scale* (continued)

Criteria	Range of Scores	Rating Anchor	Explanation of Rating Anchors
		5	Measurement by individualized assessments of complete population; questions remain about adequacy of assessments or objective measures not used
		7.5	Measurement mostly objective; few questions about how outcome assessments were accomplished
		10	Health outcomes individually measured on all subjects; the most objective methods used; health outcomes assessments well described
Frequency of health outcomes assessments	0-10	0	Only one assessment
		2.5	More than one assessment but annually or less frequently; or more frequent assessments that do not include entire study population
		5	Health outcomes assessments of population at least every 6 months
		7.5	Health outcomes assessment of population at least quarterly
		10	Health outcomes assessments of population at least monthly
Blinding of health outcomes assessments	0-10	0	No mention of how health outcomes assessments were blinded; or methods unlikely to result in blinding
		2.5	Some mention of blinding; significant questions remain; complete blinding unlikely
		5	Mention of blinding; questions remain about adequacy of blinding

TABLE 4-2 Quality Scoring Scale* (continued)

Criteria	Range of Scores	Rating Anchor	Explanation of Rating Anchors
		7.5	Blinding procedures carried out; minor questions remain about adequacy of procedures
		10	Blinding procedures described that would result in health outcomes assessments being blinded
Comparable groups adjustment for confounders	0-20	0	Major confounders (individual risk factors, e.g., age, sex, obesity, diabetes mellitus, tobacco, or trauma) unaddressed; or statistical control procedures inadequate to control for confounders
		5	Some control for major confounders; significant questions remain; complete control for confounders unlikely
		10	Confounders addressed; attempts made to control for confounders; questions remain about adequacy of control for confounders
		15	Confounders addressed; adequate control procedures likely used; minor questions remain about adequacy of procedures used or minor confounders uncontrolled
		20	All major and minor confounders addressed; control procedures used; no remaining questions about adequacy of control for confounders; confounders measured objectively when possible
Bias	0-10	0	Significant biases (not coded elsewhere) possible that are uncontrolled and may have influenced the study's results

TABLE 4-2 Quality Scoring Scale* (continued)

Criteria	Range of Scores	Rating Anchor	Explanation of Rating Anchors
		5	Some biases present and reported but not controlled for; therefore results less likely to have been influenced by the biases in section 0.
		10	Only minor biases or biases that are well controlled methodologically and unlikely to have influenced the study's results
Temporality	0-10	0	No description of how exposure preceded outcomes; or methods used could not address temporality
		5	Mention of exposure preceding outcomes; questions about whether methods could adequately address temporality
		10	Exposure preceded outcome; prospective cohort study; methods would result in assurance of temporality for inclusion in the study
Dose-response gradient	0-10	0	Dose-response assessment not possible (e.g., only two categories of exposure); or no gradient across categories
		5	Dose-response gradient assessed but not statistically significant
		10	Statistically significant dose-response gradient identified
Strength of association	0-10	0	No association between exposure and disease
		2.5	Non-statistically significant positive association
		5	Some strength of association with a statistically significant association of 2.0- to 3.9-fold risk

TABLE 4-2 Quality Scoring Scale* (continued)

Criteria	Range of Scores	Rating Anchor	Explanation of Rating Anchors
		7.5	Strong association with measure of effect of 4.0- to 7.9-fold risk
		10	Very strong evidence of association with a measure of effect (relative risk or odds ratio) of at least 8-fold risk
Psychosocial factors	0-10	0	No mention of psychosocial factors
		3	Some evaluation and control in one of the two domains (occupational and nonoccupational factors)
		5	Moderate evaluation and control in each of the two aforementioned domains
		7	Advanced evaluation and control methods in at least one domain and moderate evaluation and control methods in the other
		10	In-depth evaluation and control in both domains and few minor questions about adequacy of control

* Raters may select any integers (positive whole numbers) between 0 and 10 or 0 and 20 for the rating anchors. The integers provided should be used as guides and not absolutes for determining the appropriate value within the available range.

TABLE 4-3 Study Design Weighting Factors*

Study Design	Weighting Factor
Prospective cohort	1.0
Retrospective cohort	0.60
Case-control	0.30
Cross-sectional	0.15
Ecologic	0.05

*Each study design will be reviewed regardless of original author's statements about the design and will be assigned a weighting factor by the panel member rating the study.

TABLE 4-4 Final Study Impact Rating*

Article Title	Final Study Impact Rating
Sum	

*For each article, the average quality score as determined by using the quality scoring scale (Table 4-2) is multiplied by the weighting factor (Table 4-3) to obtain the final study impact rating. The final study impact ratings for all accepted articles are summed to determine the strength of evidence for a specific topic or diagnosis.

TABLE 4-5 Strength of Evidence of Causation in Epidemiologic Studies

Evidence	Point Value
Very strong	>500
Strong	300-500
Some	100-299
Insufficient	<100

Limitations and Other Considerations

Epidemiologic surveillance studies and aggregate information about occupational risk and the development of specific medical conditions are commonly confounded by psychosocial factors. Strength of evidence (determined by the quality score multiplied by the weighting factor) is used to rate the quality of the body of evidence. The body of evidence (the sum of the strength of evidence values for all studies reviewed) is determined by using the strength of evidence values shown in Table 4-5, providing a final conclusion for a causation relationship. Furthermore, study outcomes should be consistent with each other or the conclusions should be similar (implying minimal variance) and the study data groups should be similar (implying minimal variance, that is comparing apples to apples).

Psychosocial factors are addressed separately in Table 4-2. Unlike the more finite (and generally more familiar) range of physical factors (e.g., force, repetition, and posture), psychosocial factors includes a vast array of conditions that usually fall within two separate domains:

1. Factors associated with the job and work environment (occupational factors), and
2. Factors associated with the non-job environment, including the characteristics of individual workers (nonoccupational factors).

Interactions among factors within each of these domains constitute as a “stress process,” the results of which are thought to affect health status and job performance.³⁻⁶

Included in the occupational domain are a host of environments, sometimes referred to as “work organization factors,” that include various aspects of job content (e.g., repetition, force, posture, vibration, job control, mental demands, and job clarity); organizational characteristics (e.g., tall vs. flat organizational structures and communications issues); interpersonal relationships at work (e.g., supervisor-employee relationships and social support); temporal aspects of the work and task (e.g., cycle time and shift work); financial and economic aspects (e.g., pay, benefit, and equity issues); and community aspects (e.g., occupational prestige and status).^{3,7-9} These occupational factors are often thought of as demands, or “risk factors,” that may pose a threat to health.

Non-occupational factors typically include factors associated with demands arising from roles outside of work, such as responsibilities associated with a parent, spouse, children, hobbies, and/or interests. Individual worker factors correspond to three types of factors: genetic (e.g., sex and intelligence); acquired (e.g., social class, culture, and educational status); and dispositional (e.g., personality traits and characteristics and attitudes such as life and job satisfaction).³

Employees who are committed to remain at work will try to overcome limitations (physical or mental) resulting from (real or perceived) work intolerance by adapting or changing work tasks to fit their physical and mental abilities. Employees who experience job-related dissatisfaction are less likely to look for ways to match their physical abilities to the physical and mental demands of the job.

Summary

This chapter provides the framework for determining causation for specific activities, conditions, or events. This approach can be applied to a specific case or to groups of workers. By using this scientific method, reasonable decisions about work-relatedness of various health conditions can be obtained from the current epidemiologic surveillance literature.

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References

1. National Institute for Occupational Safety and Health. *A Guide to the Work Relatedness of Disease (Revised)*. Washington, DC: US Department of Health, Education, and Welfare; 1979.
2. Glass LS. *Occupational Medicine Practice Guidelines ACOEM: Evaluation and Management of Common Health Problems and Functional Recovery in Workers*. 2nd ed. Beverly Farms, MA: OEM Press; 2004.
3. Melhorn JM. Epidemiology of musculoskeletal disorders and workplace factors. In: Mayer TG, Gatchel RJ, Polatin PB, eds. *Occupational Musculoskeletal Disorders Function, Outcomes, and Evidence*. Philadelphia, PA: Lippincott Williams & Wilkins; 1999:225-266.
4. Bongers PM, de Winter CR, Kompier MAJ, Hildebrandt VH. Psychosocial factors at work and musculoskeletal disease. *Scand J Work Environ Health*. 1993;19.
5. The Joint International Labour Organization / World Health Organization on Occupational Health. *Psychosocial Factors at Work: Recognition and Control*. Geneva, Switzerland: International Labour Office; 1986.
6. Sauter SL, Swanson NG. Psychological aspects of musculoskeletal disorders in office work. In: Moon S, Sauter SL, eds. *Psychosocial Factors and Musculoskeletal Disorders*. London, England: Taylor and Francis; 1998.
7. US Department of Health and Human Services. *Musculoskeletal Disorders and Workplace Factors: A Critical Review of Epidemiologic Evidence for Work-Related Musculoskeletal Disorders of the Neck, Upper Extremity, and Low Back*. Cincinnati, OH: National Institute for Occupational Safety and Health; 1997; Bernard, BP, editor. National Institute for Occupational Safety and Health Cincinnati, OH: 1-500.
8. World Health Organization. Work with visual display terminals: psychosocial aspects of health. *J Occup Environ Med*. 1989;31:957-968.
9. J. J. Hurrell and L. R. Murphy. Psychological job stress. In: Environment and occupational medicine, edited by W. N. Rom, New York: Little, Brown and Company, 1992: 675-684.