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Framework for considering genetics in the workplace[1]

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KEY WORDS

Genetics; workplace; ethics

SUMMARY

There has been a proliferation of genetic information in the last 25 years resulting in a spectrum of existing and potential uses in the workplace. These uses of have different issues and implications which may be more clearly considered in a framework that identifies three distinct uses (research, practice, and regulation/litigation) for inherited genetic factors and acquired genetic effects. Inherited genetic factors pertain to the characteristics of the genes, and acquired genetic effects to the impact on genes and chromosomes of environmental and constitutional factors. Critical in assessing the issues involving genetics in the workplace is attention on the rights of workers, validity and clinical utility of genetic information, cost pressures on employers, and societal implications. Genetic information may provide mechanistic and diagnostic insight into occupational diseases and allow for targeting high-risk groups, improving risk assessments, and providing early indicators of risk. However, these benefits are more likely to be realized and problems avoided when the different uses are considered in a framework that distinguishes them by type and content. The application of such a framework makes it easier to assess whether there is a sufficient evidence base and worker safeguards in place for any particular use of genetic information.

RIASSUNTO

«Schema per considerare la genetica nel posto di lavoro». *L'espansione delle informazioni genetiche durante gli ultimi 25 anni risulta in un'ampia gamma di utilizzi esistenti e potenziali nel posto di lavoro. Questi possono avere diversi problemi e implicazioni, che possono essere considerati più chiaramente in un schema che identifica tre distinti usi (ricerca, pratica e attività di regolamentazione) per fattori genetici ereditari ed effetti genetici acquisiti. I fattori genetici ereditati appartengono a caratteristiche dei geni, e gli effetti genetici acquisiti all'impatto di fattori ambientali e costituzionali sui geni e sui cromosomi. Un fattore critico nel valutare i problemi che coinvolgono la genetica sul luogo di lavoro è l'attenzione ai diritti dei lavoratori, alla validità e all'utilità clinica dell'informazione genetica, il costo che grava sui datori di lavoro, e le implicazioni sociali. L'informazione genetica può contribuire alla comprensione del meccanismo d'azione e alla diagnosi delle malattie occupazionali e permettere di individuare i gruppi ad alto rischio, migliorando la valutazione del rischio e fornendo indicatori di rischio precoci. Comunque si è più vicini a ottenere questi benefici evitando i problemi quando i diversi usi sono inquadrati in una cornice metodologica che li distingua per tipo e contenuto. L'applicazione di questa cornice metodologica rende più facile stabilire se ci sia una base di evidenza sufficiente ed una salvaguardia del lavoratore per ogni particolare uso dell'informazione genetica.*

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[1]The finding and conclusions in this report are those of the author and do not necessarily represent the views of the National Institute for Occupational Safety and Health

Introduction

Genetics has become a core discipline in medicine. That is, that etiology, mechanism, pathogenesis, treatment, and prognosis of disease are influenced by the action of somatic or germ cell genes (22). It is now common to consider genetic components of disease in general medical research and practice (12). It has long been known that there is a range of variability in human response to occupational hazards particularly chemical hazards. Genetic factors contribute to the variability and consequently may be useful to consider in research and control of hazards (27). The growing knowledge about the role of genetic factors provides the promise of sensitive, early-warning indicators of exposure or risk and the characteristics on which to base workplace interventions (11, 29). Most of these promises are yet to be realized. In fact, while genetic information about disease is inherently important, whether it will mean much to pursue genetic factors in the ultimate understanding and control of occupational disease is yet to be demonstrated.

In this paper, genetics related to the workplace will be considered in three categories of use: research, practice, and regulation/litigation (table 1). All of the uses of genetic information in the workplace can be viewed through these three categories. To further explore these categories, they will be considered in terms of inherited genetic factors and acquired genetic factors. This is a common classification scheme for genetic risks. Inherited genetic effects pertain to germ and somatic cell DNA transmitted through meiosis or mitosis. Acquired genetic effects involve modification of genetic material over time and can include genetic damage or genetic expression as a result of workplace and environmental exposures. Either type of genetic information, when it is measured in a biological specimen, can be considered a genetic biomarker (6). However, the line between inherited genetic factors and acquired genetic damage and effects can be blurry in some areas, particularly those related to gene expression status such as transcriptomics, proteomics, toxicogenomics, and metabolomics. The definition of genetic information includes not only the results of genetic tests, but also information about genetic factors in medical records.

Inherited genetic factors-research

Genetic factors are likely to be responsible for some differential distribution of diseases among workers that cannot be accounted for by differ-

Table 1 - *Uses of genetic information in the workplace*

Uses	Types of genetic information	
	Inherited genetic factors	Acquired genetic effects
Research	Gene-environment interactions	Effects of exposure
	Mechanistic insight	Linkage to disease
	Population characterization	Early warning
	Predictive value	Mechanistic insight
Practice	Disease diagnosis	Genetic monitoring
	Preventive services	Intervention evaluation
	Genetic screening	Risk profiling
	Risk management	
Regulation/litigation	Risk assessment	Risk assessment/management
	Workers' compensation	Pre-market testing
	Tort litigation	Workers' compensation
	Standard setting	Tort litigation
		Standard setting

ences in exposures and lifestyle. (27). It is clearly accepted that practically no disease is determined solely by either genes or environment. In the early history of occupational epidemiology, genetic influences were considered only in terms of confounding by race and sex. Today as many occupational exposures are being controlled to lower levels, the importance of genetic factors as sources of variability in risk estimates is increasing. This is not to imply that occupational etiologies will be replaced with genetic etiologies, rather that genetic factors, which might confound exposure-disease associations, are being included as relevant variables in study designs and analyses.

New technologies and approaches now allow researchers to focus more on studies of gene-environment interactions which aim to describe how genetic and environmental occupational factors jointly influence the risk of developing disease (20). The study of gene-environment interactions (3) allows for better estimates of population-attributable risk of genetic and occupational factors, (1) strengthens associations between occupational risk factors and disease, (2) provides insight into mechanisms of action, and (4) provides new opportunities for intervention and prevention (20).

Technological developments, such as DNA and gene microarrays, and automated work stations capable of extracting, amplifying, hybridizing, and detecting DNA sequences will present a number of benefits and issues in studying genetic and environmental variables (11). The benefits include the ability to study large numbers of genes, practically the entire human genome, in one study or experiment and to have access to data banks containing further information on genomic DNA. The primary attendant issue with this technology includes heightened difficulties in analyzing and interpreting such large amounts of data (13).

The underlying rationale of most research involving genetic and occupational risk factors is the extent to which the genetic factors may modify the exposure-effect relationship. That is, will the risk of disease attributable to an occupational exposure be decreased, unchanged, or increased among individuals with a particular genetic characteristic? For the most part, this may be because the gene in question codes for an enzyme or receptor involved in the activation, metabolism, or detoxification of the occupational exposure. This genetic factor generally may not be a risk for disease without the exposure. In contrast, some genes may be risk factors for the same disease that the occupational exposure is and, thus, the two may be additive (43). In addition, there may be variation in genetically coded repair capabilities for mutations or damages.

Ultimately, the focus of occupational genetic research should be conditioned by criteria for the importance of the research to answer questions with workplace relevance. As Millikan (24) noted: "If epidemiologists only direct their efforts toward a comprehensive search for the genetic underpinnings of every discrete health outcome and ignore environmental exposures and attributable risks, they will miss opportunities to prevent disease."

For research on the role of genetics in occupational disease to be useful and informative, the validity of the genetic information needs to be assessed or confirmed. Validity can pertain to the assay used to evaluate genetic polymorphisms and also to the population characteristics that influence the prevalence and distribution of a polymorphism. It is only when the underlying validity questions have been assessed that a genetic assay can be used effectively to study occupational exposure-disease associations. Genetic research that focuses only on one or a few genes may be overly simplistic (39). There are many genes that might affect risk given an exposure. Ultimately, the research needed regarding genes or gene expression will need to take a systems biology approach (41). Such an approach requires much investment and experimentation. However, with the emergence of technologies to enable collection of comprehensive genomic data sets it may be possible obtain system level understanding (23).

Safeguarding rights of participants in research

A broad spectrum of opinion exists about what obtaining informed consent entails and when it is achieved (19, 33-35). Some believe that for genetic data (biomarkers) whose meaning is not known at the time of the study, a subject or worker in an oc-

cupational study cannot give truly informed consent (33). This implies a much higher standard of interpretation for genetic biomarker information than for other information routinely obtained by questionnaires, environmental monitoring, or record linkage. Until there is determination of predictive value and course in the natural history, such genetic biomarkers are clearly only research variables with no clinical meaning, and participants should be made aware of this. The extent to which a biomarker has been validated (i.e., quantitatively linked to risk of disease at the group or individual level) should be clearly described to potential research participants. With regard to informing participants of risks, general practice has been to identify only medical risks; however, it has been argued that truly informed consent should include reference to nonmedical risks that might affect participants. For example, a study subject may be informed that they carry a genetic mutation that puts them at increased risk of subsequently developing cancer given a particular exposure. In the extreme case, the mere acknowledgment on an employment or insurance application that they have had a biological or "genetic test" may result in denial of employment or insurance. Participants in occupational genetic studies consent to provide the specimens and corollary demographic and risk factor information and, hence, cooperate in the specified research. The participant generally does not consent or imply consent to distribution of the data in a way that identifies him or her individually to any other parties, such as employers, unions, insurers, credit agencies, lawyers, family members, public health agencies, etc. (34).

Interpreting and communicating the results of occupational genetic research

Three issues merit consideration in the interpretation and communication of the results of genetic research. These include the realization that: 1) epidemiologic results are group risks and not individual risks; 2) a statistically significant genetic factor may not be biologically significant; and 3) the results of many small studies of genetic polymorphisms have not been replicated (38). Aware of these issues, a Centers for Disease Control and Prevention (CDC) multidisciplinary group (8) using expert opinion, as well as Federal regulation, the National Bioethics Advisory Commission's report on research involving human biological materials (26), and the relevant literature suggested that participants not be told of information that has no direct clinical relevance. However, occupational studies differ from population-based studies in the sampling frame used and the types of intervention available. In occupational settings "clinical relevance" could be defined as whether participants could take reasonable preventive or medical action based on the results. In the workplace, these reasonable actions could include various engineering, administrative, or behavioral controls (46). Clearly, where valid risks to workers are found in studies, notification is warranted.

INHERITED GENETIC FACTORS-PRACTICE

Prevention and diagnosis

Genetic tests have been shown to be useful for various nonoccupational diseases in terms of disease diagnosis and individual risk assessment and provision of preventive services (10, 16). Thus they are becoming a part of general medical practice. The extent to which they will impinge on practice related to the workplace and workers is not known. Whether such approaches will be useful for occupational disease also is not known. If genetic tests are to be useful in occupational health there will need to be a process of evidence based integration of data for the development of guidelines for disease prevention and health services such as been suggested for general clinical and public health practice (http://www.cdc.gov/genomics/gtesting/egapp.htm)

In the future, the practice of occupational medicine may occur against the backdrop of individualized or personal medicine. At the least this may involve the need to consider an individual's genetic profile in the context of occupational exposures in terms of risk and prevention. The pressures to consider genetics and occupational exposures may grow as pharmacogenetic assessments become more common in medical practice (32). The ques-

tion that arises is who actually makes the decisions based on the individual genetic profile, the worker, the employer, or both.

Job actions

The capacity of the human body to respond to chemical exposure and physical agents varies from one individual to another. To some extent this is due to genetic characteristics which, in principle, could become part of employment testing known as genetic screening. Genetic screening is the examination of the genetic makeup of employees or job applicants for certain inherited traits. The actual use of genetic assays or tests of workers in job offering or placement is believed to be rare, but the available data to assess such activity is weak (5).

Four objectives of genetic screening have been identified: (a) to ensure appropriate placement at the job site, (b) to exclude job applicants with increased susceptibility to disease, (c) to set limit values for more susceptible subgroups, and (d) to provide individual health counseling (42). In general, pre- and post-employment nongenetic testing is a relatively common practice in selection and placement in the workplace. Susceptibility, however, is the result of a variety of genetic and nongenetic factors. Despite the profound advances in understanding the human genome, there are still no genetic tests that have been fully validated for use to screen perspective employees for occupational disease risks. Moreover, much controversy surrounds the practice of genetic screening including such issues as the poor predictive value of the tests (18, 42). Genetic polymorphisms may be unevenly distributed in the population among different ethnic groups. Thus, racial or ethnic discrimination could be a consequence of inappropriate use of genetic screening, which might be aimed at excluding workers at employment examination (42). In the practice of occupational medicine, genetic information has been used selectively, mostly as derived from medical history and used in job placement or in diagnosis (5, 39).

Genetic screening has been assessed by the European Group on Ethics in Science and New Technologies (40) which concluded that the use of genetic screening in the context of the medical examination, as well as the disclosure of results of previous genetic tests, is not ethically acceptable. Furthermore, EGE found that, to date, there is no proven evidence that the existing genetic screening tests have relevance or reliability in the context of employment. Generally, genetic screening tests still have uncertain predictive value (40).

Genetic screening information may be useful to inform potential employees of job risks, if that information is not available to employers in individually identifiable form. This was illustrated in a pilot screening program in a company where beryllium was machined.

The employer developed the program for prospective employees because of concern for the debilitating lung condition, chronic beryllium disease, in workers with beryllium exposure. Research had shown that in addition to beryllium exposure, a certain genetic characteristic, HLA-DPB^{E69} was also a risk factor. Moreover, beryllium sensitization could occur regardless of dose and had occurred even in relatively well-controlled areas. The employer established the screening program so that job applicants could receive their individual results. The predictive value of the screening test was poor, and a negative test was not an assurance for lack of risk since other variants on chromosome 6, which were not tested for, also were risk factors (47).

There are no published data on the results of the program or the issues that arose. The program was stopped after a few years. While, in principle, it seems useful that prospective employees would benefit from information about potential risks, the attendant problems are without impact. Using such a test there would be many false positive findings and many people would make employment decisions based on flawed information. Second, it is a slippery slope from voluntary anonymous screening to mandated screening of individually identifiable applicants by prospective employers. In this case with the test for HLA-DPB^{E69} many workers not at increased risk would be discriminated against. In contrast if the test had a high (>90%) predictive value would an employer have an argument for the right to use it in employee selections.

Although currently no genetic tests have been validated for assessing the increased risk of susceptibility to workplace hazards, it is anticipated that such tests will eventually become available. Whether these tests would be socially approved is still in question.

Inherited Genetic Factors –Litigation and Regulation

One of the first workplace areas where genetic information has been used is workers' compensation. In the United States there is no legal prohibition against including any medical or genetic tests in the independent medical examination that is routine in workers' compensation cases (31). In addition, informed consent for such testing is not required. By extension, genetic information may also be used as proof of causation in toxic injury litigation. However, "analysis of the role of genetic factors in multiple cause cases requires statistical and mechanistic data about how the genetic and toxic risks combine to cause disease" (39). One recent example of the use of genetic information in workers compensation type cases involved genetic factors linked to occupational carpal tunnel syndrome (37). However the genetic test had not been validated for this use. Second, unresolved is the question of whether society should use genetic testing for a susceptibility genotype to apportion causation. This question raises the issue of whether immutable traits beyond a worker's control should be factored into a claim of work-relatedness of a disease. Indeed in some jurisdictions (various states such as Iowa, Wisconsin, New York, and New Hampshire), consensual genetic testing is allowed in compensation cases. In the US, most workers' compensation statutes permit medical testing, including genetic testing, to ascertain the medical condition of the claimant and the potential work-relatedness of the claim (38). However, various U.S. organizations do not generally condone genetic testing without informed consent (4).

Regarding the use of genetic information in occupational safety and health regulations, there are no examples of where such information is required. Genetic advances push at the historic boundaries of the U.S. Occupational Safety and Health Act of 1970. The Act mandates standards and rules to assure "that to the extent feasible "employees will not suffer" material impairment of health or functional capacity." This raises the question of whether workers who could be defined by certain genetic polymorphisms as "hypersusceptible" should have special protections. The implementation of these protections raises a host of questions and issues regarding privacy, discrimination, and responsibility (7).

Acquired genetic effects-research

There is an extensive scientific literature assessing the impact of environmental hazards on genetic material (1, 3, 9, 17, 21). For the most part, this has involved assessment of cytogenetic effects (e.g., effects on chromosomes) and changes in various reporter genes such as glycophorin–A (GPA) and hypoxanthine phosphorsibosyltransferase (HPRT), mutations and the formation of DNA and protein adducts following exposure to electrophilic chemicals or ionizing radiation (2, 37). The objectives of much of this research were to determine if genetic damage did occur and if it could lead to harmful health effects (9). Much of the newer DNA and expression technologies including toxicogenomics, transcriptomics, proteomics, and metabolomics are means to assess acquired genetic effects (11, 41, 44, 45). These approaches allow for the assessment of the expression of many thousands of genes before and after exposure. Implicit in these approaches is that effects of xenobiotics can be detected in expression of genes. Critical in using this technology will be the ability to analyze and interpret the vast amounts of data that arises from the studies. Such interpretation is quite difficult because many factors affect gene expression, and there is need to distinguish adaptive or homeostatic responses from pathologic ones.

If a microarray pattern can be validated as a biomarker of effect, it may be used as an independent or dependent variable in etiologic or intervention research, and as evidence of harm in workers' compensation or tort litigation. These patterns could also be used in standards as biological exposure indices.

Acquired genetic effects-practice

The ascertainment of acquired genetic damage information in occupational safety and health practice would generally occur in the form of genetic monitoring. This is the periodic examination of employees to evaluate modification of their genetic material – e.g., chromosomal damage or evidence of increased occurrence of molecular mutation – that might have occurred during the course of employment and exposure to workplace substances (28). In principle, genetic monitoring is similar to other types of health effects or exposure monitoring that is conducted in the workplace (for example, monitoring for lead in blood) (42). However, the fact that it involves preclinical somatic genetic effects often leads to it being considered as a somewhat different form of monitoring. Genetic monitoring is similar to biological monitoring, but instead of merely assessing exposure, it assesses the effects of exposure. At present, the results of genetic monitoring can only be interpreted on a group level; they have not been validated as individual risk predictors (42). If high-throughput expression technologies become candidates for use of genetic monitoring, the issues of standardization, validation, and interpretability will have to be overcome since these will be much greater than with a single test.

Acquired genetic effects-regulation and litigation

Currently, no US regulations require genetic monitoring of workers. In part, this is because questions arise about whether genetic monitoring indicates just exposure or a potential health problem or compensable injury (37). No genetic monitoring test has been fully validated to assess an individual's risk (42). The various expression array technologies also can be applied to human or animal cell cultures that have been exposed to xenobiotics (41, 44, 45). This approach can be used to screen chemicals prior to introduction into commerce.

The gene-expression technologies have been viewed as potentially providing useful data for risk assessment; however, there are numerous interpretive questions, as summarized by Freeman, regarding the use of data from microarray experiments by regulating agencies (15).

In the short-term, transcriptomics and proteomics will probably be of most value for the hazard identification aspect of risk assessment (14, 25). However, if gene expression technology is to enter the mainstream of the risk assessment process, protocols for assays to confirm selected biochemical responses will need to be developed as regulatory requirements (25).

Conclusions

This framework provides the opportunity to compare and contrast different uses of genetics by type of genetic information. The power of genetic information both from inherited factors and acquired indicators of effects must be considered before use in relation to the workplace.

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