

Chapter 9

**Application of Ethical Principles
to Genetic Testing**

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Application of Ethical Principles to Genetic Testing

The use of genetic testing in the workplace touches on areas of basic concern to most people: opportunity for employment, job security, health, self-esteem, and privacy. Genetic screening may enable workers to have greater control over their health by providing medical information on which to base job site selection and use of personal protection devices. It could be used by management to better match employees to their jobs or to reduce levels of exposure to hazardous substances. It also could be used to exclude or transfer people from jobs and conceivably could result in classes of people being stigmatized. While genetic monitoring might permit employees or management to take preventive health measures, it may simply create unjustified fears of nonexistent hazards. Moreover, both techniques result in the collection of information of an extremely personal nature. Thus, the technology has both risks and benefits, depending on how it is used.

Because genetic testing procedures are relatively new and have not been widely used, there is little direct experience on which to make judgments regarding their use. Nor are there direct legal precedents. Under those circumstances, it is appropriate for policy makers and others involved in decisions concerning genetic testing to look to ethical principles for guidance. These principles can assist decisionmakers in ensuring that the technology is used justly and with the greatest regard for human values.

Ethics is the study of moral principles governing human action. These principles, or general prescriptive judgments, create moral duties that guide action in particular circumstances. Sometimes, however, the principles conflict in their application and provide no clear guidance. Then dif-

ficult choices must be made. Such is the case with genetic testing in the workplace.

This technology raises a number of questions that can be put in a framework suitable for ethical analysis:

1. Do employers, occupational health specialists, or society in general have any particular obligations toward workers who may be at increased risk for disease because of their genetic constitution or because of exposure to hazardous substances? If so, what are they?
2. Are genetic screening and monitoring for genetic damage compatible with ethical principles?
3. Does the answer to the second question depend on the particular circumstances involved? If so, the following must be examined:
 - a. What moral rights and duties exist between the worker and company medical personnel?
 - b. Must participation in genetic testing programs be voluntary, and if so, how is that to be guaranteed?
 - c. What rights and obligations exist regarding the use of medical information?
 - d. What ethically permissible actions may be taken on the basis of information gained through genetic testing programs?
 - e. Do the answers to these questions depend on whether the testing is being done for research purposes or as part of a medical program?

To address these questions, it is first necessary to consider some basic ethical principles. Their application to the various ethical questions raised by genetic testing then will be discussed.

Ethical principles

Four ethical principles are most relevant to an assessment of this technology: autonomy, nonmaleficence, beneficence, and justice.

Autonomy

The principle of autonomy has two aspects. The first relates to the ability of a person to make considered judgments and decisions that lead to acts that foster self-reliance or independence. In this sense, autonomy depends on being able to plan and act deliberately, based on one's own judgment about the consequences of certain behaviors and their value or utility to oneself or others. This leads to the notion that individuals should be free to act as they wish, regardless of how foolish their actions may appear to be and without interference by others, so long as their actions do not harm others or interfere with their liberty (2). The second aspect of autonomy derives from the belief that people should be treated as ends rather than means, a principle known as respect for persons. In other words, in evaluating the actions of others, one should respect them as persons with the same right to their judgments as one has to his or her own (2). Thus, the principle of autonomy imposes the dual moral obligation not to interfere with the autonomous actions of others and to respect their personhood and beliefs.

A corollary of the principle of autonomy is the requirement to secure informed consent from persons before taking actions that may put them at risk. The rule of informed consent requires full disclosure of all important information, comprehension of the information, the ability to choose freely, and the mental competence to make decisions (7). Thus, the rule serves to protect individual autonomy.

Not everyone is capable of full self-determination. This capacity develops during a person's life, and some individuals lose it in whole or part because of illness, mental disability, or circumstances that severely restrict their liberty. For example, children, prisoners, or those who are in institutional settings may be less capable of autonomous actions (7).

Autonomy may be compromised in other ways. These include situations where behavioral options are limited, where direct or implied coercion is used toward actions favored by others, or where circumstances limit the ability to act knowledgeably in one's own interest.

Workers as a group may be situated in ways that limit their full expression of autonomy. Preordained rules of behavior, job requirements, limited resources or information, and concern over job security can limit autonomy. Whether or not particular limitations are justified will depend on a determination of the validity of reasons for overriding the principles of autonomy.

Respect for persons gives rise to the obligation to protect those with diminished autonomy (7). The extent of protection generally would depend on the degree to which their autonomy is diminished. Some persons require little protection beyond ensuring that they undertake activities voluntarily and with an awareness of possible adverse consequences; others may have to be excluded from activities that harm them.

The principle of autonomy is not absolute. Where the prospect of severe harm is evident, some commentators have argued that intervening in order to protect the individual is justified (3,6). Thus, it may be justified to intervene where persons are otherwise competent to exercise autonomous thought and action (as is the case for the great majority of workers), but who may be unable to do so because of their ignorance of the risks or their inability to understand those risks due to their complex technological nature.

Genetic testing has the potential to be used in a way that restricts the autonomy of prospective employees or workers already on the job. For instance, preemployment tests that presumably identify genetically susceptible individuals may be used to restrict the type of job an employee is permitted to undertake or to ban the worker from employment in the industry altogether. Similarly, testing done during employment, which detects early warning indicators of possible future disease, might be used preemptively to remove

employees from a given station or set of job duties. Each of these steps, if taken unilaterally by an employer, could be seen as a restriction of the autonomy or liberty of the individual worker to elect a suitable job and/or to accept the attendant risks.

Nonmaleficence and beneficence

Nonmaleficence is the obligation not to harm others (2). Beneficence is the obligation to help others further their important and legitimate interests when we can do so at minimal risk to ourselves (2). In practice, it is difficult to separate the two principles, because avoiding harms and producing benefits exist along a continuum. However, one philosopher, William Frankena, separated this continuum into the following duties:

1. One ought not to inflict harm.
2. One ought to prevent harm.
3. One ought to remove harm.
4. One ought to do good.

Frankena stated that each of these duties should take precedence over the next, so that nonmaleficence is the strongest duty, and doing good is the weakest (5). Beneficence is usually considered to encompass the second, third, and fourth elements; it is distinguished from nonmaleficence in that it requires positive steps to help others and not merely restraint from harming them (2).

In a workplace setting, this priority listing could correspond to an employer's duty to: 1) not knowingly subject workers to conditions that are likely to cause injury or ill health, 2) take steps to prevent the likelihood of workers becoming injured or diseased, 3) remove harmful substances, and 4) take affirmative actions to improve worker health.

our society generally accepts the proposition, as reflected in our legal system, that we cannot legitimately impose an affirmative duty to do good, but may impose negative injunctions to avoid harm. However, in certain cases, usually involving special relationships such as that of employer-employee or doctor-patient, society imposes a duty to prevent or to remove harm. For example, the policy embodied in the Occupational Safety and Health Act of 1970 that all workplaces

be safe and healthy can be interpreted as the legal imposition on employers of at least a duty to prevent harm and remove potentially harmful conditions.

Arguments in favor of genetic testing rely on the principles of beneficence. If the tests are able to identify individuals or populations at increased risk, the employer has the duty to prevent harm by preventing exposure to harmful substances or to remove the harm by reducing the level of exposure.

Such action may conflict with the principle of autonomy, however, where it overrides a person's own informed choice. An example would be where a job was denied to a susceptible person who was willing to accept the risk. Whether or not such paternalistic actions are justified depends on whether one places beneficence above autonomy. Generally, ethicists favor autonomy over beneficence (2), a choice also widely reflected in judicial decisions and legislation.

The concept of beneficence embodies the notion of maximizing possible benefits and minimizing possible harms (2). This leads to the requirement for a risk/benefit assessment whenever a technology is claimed to provide benefits, such as prevention of illness. As applied to genetic testing, this would require at a minimum that the claimed benefits in fact exist. In other words, the association between one's genetic makeup and disease or between damage to one's chromosomes or DNA and disease must be scientifically demonstrated.

Justice

Justice is a broad and elusive concept. Different moral philosophers have explained it in terms of freedom, fairness, equality, or entitlement. Most would agree, however, that an injustice occurs when a benefit to which a person is entitled is denied without good reason or when a burden is improperly imposed. A more positive and often quoted statement of the principle of justice is that equals should be treated equally, and unequals should be treated unequally (2). But what does this tautology really mean? Who is equal and who is unequal?

A somewhat more useful formulation of the principle of justice says that individuals who are equal in relevant respects should be treated equally, and individuals who are unequal in relevant respects should be treated differently in proportion to the differences (2). The problem then becomes to determine relevant differences. Most commentators would allow distinctions based on ability, experience, need, and merit to justify differential treatment, depending on the circumstances. In addition, the other moral principles already discussed provide some guidance in determining whether particular differences are relevant (2).

A slightly more restricted notion of justice is the concept of distributive justice, which refers to the proper distribution of social benefits and

burdens among different classes of people. There are several widely accepted formulations of just ways to distribute benefits and burdens on the basis of relevant differences. These are: to each person an equal share; to each person according to individual need; to each person according to individual effort; to each person according to societal contribution; and to each person according to merit. These principles may give conflicting results in particular cases (2).

Thus, it is clear that a precise statement of the requirements of the principle of justice is best left to a case-by-case analysis. Its application to genetic testing will be discussed in the context of the particular ethical issues raised in the following section.

Applications to genetic testing

Ethical principles can provide some guidance to policymakers and others who must decide whether or not genetic testing should be done in the workplace and, if so, under what circumstances. This section first considers the routine use of genetic tests for clinical purposes at their current level of development, where there is low correlation between the endpoints and risk of disease. It then considers the use of genetic testing at its current level of development for purposes of medical research. Next, because the technology is developing, it considers the issues raised by the clinical use of these tests, where there is an assumed high correlation between genetic endpoints and risk of disease. Finally, two particular problems that arise in all three of these situations are considered: What should an employee be told about test results? What are the obligations of the employer and company medical personnel to maintain confidentiality of medical data?

Routine use of tests of doubtful clinical value

GENETIC SCREENING

The use of genetic screening to identify individuals who might be at an increased risk of

disease in a workplace environment could not be justified by the principle of beneficence where there was a low correlation between the genetic endpoints and disease. There would be great uncertainty over whether or not that individual would be at increased risk of harm. Thus, it would be uncertain whether the employer could prevent harm. At the same time, there would be some risks to the workers. First, there would be some physical risks associated with the medical procedures. Second, there would be risks to the worker from the use of the information. These include adverse job actions, loss of self-esteem, and possible stigmatization from being labeled "genetically inferior." Such a label conceivably could result in the person being barred from certain jobs in an entire industry. In addition, it would be particularly troublesome if placed on historically disadvantaged groups because it could help continue that status. In view of the substantial risks and uncertain benefits, one could not argue that poorly predictive tests could be used to prevent harm.

If the person labeled as susceptible were fired or excluded from a desirable job, such action would not comport with the principle of justice. It would be difficult to argue that genetic makeup

was a relevant characteristic for treating one group of workers differently from another, when the scientific data at best show only a weak association between genetic makeup and susceptibility to disease.

GENETIC MONITORING

Under circumstances where there is only a weak association between cytogenetic or noncytogenetic endpoints and disease, the use of genetic monitoring in the course of clinical practice would also raise ethical concerns; however, monitoring may be somewhat less at variance with accepted ethical principles than genetic screening. Arguably, there could be a small benefit to an entire group of people if the tests indicated they might be at an increased risk of disease. Moreover, the risks would be minimal; they include the physical risks of drawing blood and the possibility that some anxiety about future illness would be created unnecessarily. Presumably, there would be less of a risk of adverse job actions than for screening because monitoring cannot identify individuals who might be at increased risk. Assuming the workers were not subject to job discrimination or other adverse action, there would not be problems with respect to the principle of justice.

The strongest ethical argument against such testing, whether screening or monitoring, would be based on autonomy. The concept of respect for persons requires people to be treated as ends, not means. Using medical procedures of questionable value on people could only be justified by the voluntary and informed consent of those subject to the procedure.

Medical research

The use of techniques of low or uncertain clinical value for purposes of research can be ethically justified when certain conditions are met (7). The underlying purpose would be beneficent; if the research showed the techniques to be useful or led to their further development, society would benefit. Those workers participating in the research also might benefit at some future time. The risks to them would be similar to those discussed previously, except that there would presumably be less of a risk of adverse job actions being taken.

However, there would still be the psychological risk of a person gaining information about himself that he might prefer not to know.

Under these circumstances, where participants in medical research are not likely to benefit directly from the medical interventions, the principle of autonomy becomes paramount. This principle usually requires that the subjects enter into the research voluntarily and with adequate information (7). In practice, this means that the subjects must give informed consent to the procedures.

The elements of informed consent are disclosure of information, comprehension of information, and voluntariness (7). Competence to consent is sometimes viewed as an element of informed consent and sometimes as a precondition. In any event, it would not be relevant here because it refers to the mental capacity to make decisions on a rational basis. Workers actually on the job are presumably competent.

The type of information disclosed usually includes the research procedure, its purpose, the risks and possible benefits, the fact that the subjects may ask questions, and the fact that they may withdraw at any time. Generally, the subjects should be told what a "reasonable person" or perhaps a "reasonable volunteer" would want to know about the experiment (7).

Information must be presented in a way that is understandable to potential subjects. Moreover, the investigators are generally considered to have an obligation to determine that the information was understood. (7).

Voluntariness requires conditions free of coercion or undue influence (7). This maybe especially problematical in an occupational setting where workers may perceive their job security or potential for promotion to be affected by their willingness to participate in the research.

High correlation between genetic endpoints and risk of disease

GENETIC SCREENING

In the hypothetical case where particular genetic traits correlated with an increased risk of disease, genetic screening could be supported by

the principle of beneficence, depending on how the results were used. Clearly, the data generated by the tests would identify a potential harm, and given this information, steps could be taken to prevent the harm or to remove it. How the information is used then becomes the paramount question.

One action that the employer could take would be to bar genetically predisposed workers from certain jobs, by not hiring them, by placing them in other jobs when hired, or by transferring them. This action might be considered beneficent because harm to the employee would be averted. However, another action, also consistent with beneficence, would be to lower exposures to the point where these people would not be at increased risk. Still another action might be to devise personal protective equipment for them. The principle of beneficence provides little guidance in choosing among these alternatives.

The principle of justice provides some guidance. One way of considering the problem would be to ask if genetic makeup is a relevant characteristic on which to treat a small part of the work force differently. One could argue that genetic makeup is relevant because, in our hypothetical case, these people are more prone to illness. This illness would result in additional costs to themselves, the employer, and society. It may be unfair for society or the employer to bear these costs for the benefit of these few individuals. On the other hand, these people are not responsible for their genetic makeup. Therefore, it is arguably unfair to single them out for special treatment. In addition, their genetic makeup may be irrelevant because it is not related to their ability to do the job efficiently and without risk to others.

Another way to address the problem is to ask who, if anyone, has the obligation to compensate genetically disadvantaged workers? Three schools of thought on distributive justice are relevant: the libertarian school; the utilitarian school; and the needs-based school,

The libertarian school emphasizes merit and contribution. Under this theory, a worker or group is entitled to get back exactly that proportion of the national wealth that he or they created (4). If genetically disadvantaged workers were not

contributing to the national wealth, even if the reason was because they had been denied jobs, they would not be entitled to compensation, according to this school.

The utilitarian school emphasizes consideration of all of the various principles of distributive justice with the goal of maximizing public and private benefits (2). Under this theory, one could argue that compensation could materially help these individuals at little cost to society, which would bear the costs directly through government compensation plans or indirectly, when the employer passed on the costs in the price of the product. On the other hand, if the costs of compensation were large and the number of workers were small or if employers were forced out of business by having to install extremely expensive engineering controls, one could argue against compensation.

The needs-based school emphasizes fundamental needs; that is, something without which a person will be harmed or at least detrimentally affected. If genetically disadvantaged workers faced at least moderate difficulty in finding any job or a job at an adequate wage level, this theory would require compensation.

The principle of autonomy is also important in this hypothetical situation. Respect for persons would probably require that genetically susceptible workers be informed of their condition. At the same time, autonomy would appear to require that such workers be given the right voluntarily to assume the risk, if given adequate information in a comprehensible way. In situations of conflict between autonomy and beneficence, most ethicists generally favor choosing autonomy. Thus, paternalistic behavior on the part of the employer to exclude the employee for the latter's benefit but without his consent generally would be viewed as unethical. However, society sometimes accepts paternalistic actions when they benefit affected groups, such as compulsory vaccination or fluoridation of the water. If genetically susceptible workers were given alternative jobs at equivalent pay and benefits, the paternalistic behavior of excluding them from certain jobs probably would be ethical.

GENETIC MONITORING

If there were a high correlation between cytogenetic or noncytogenetic endpoints and risk of disease, genetic monitoring could be justified by the principle of beneficence. The reasons would be essentially the same as those discussed for screening.

The actions that an employer may take on the results of monitoring are somewhat different, however. Unless the monitoring tests were so predictive that high-risk individuals could be identified, a situation that would be the same as screening, monitoring would only identify a high-risk group already on the job. The most likely courses of action open to the employer would be to do nothing, to lower exposure levels, or perhaps to take some intermediate action such as providing personal protection devices,

Doing nothing to alleviate a known risk would be unethical. Since the employer actually created the risk, inaction would amount to inflicting harm. Moreover, autonomy would appear to require informing the workers of their increased risk, arising from being members of the group.

Lowering exposure levels or providing protection devices would be consistent with the principle of justice. No discrimination would be involved, and employees would not unfairly bear the burden of the actions.

Special problems

Two problems deserve special attention because they arise regardless of the predictiveness of the various tests: What information should be given to workers about testing procedures and the results? Who besides the employees should have ac-

cess to medical data and under what circumstances?

The principle of autonomy implies a duty to provide employees with information about their health, even where the significance of the information might be uncertain. This duty would be even stronger when the information was highly predictive of a risk of disease.

Autonomy would also appear to require that workers be fully informed of the nature of medical procedures to which they are subjected. While the concept of informed consent would be most crucial in a medical research situation, it is also applicable to clinical interventions. In the latter case, even though the procedures are clearly beneficent, their application to the worker without his informed consent is a paternalistic action,

Once medical data have been collected, the issue of who has access to the data arises. As a general rule, medical data are considered confidential on the grounds that respect for a person's autonomy requires respect for his or her privacy. The stringency of this rule, however, is a matter of much debate, particularly in the work environment where the employer is viewed as having some rights to that information. The Code of Ethical Conduct for Physicians Providing Occupational Medical Services states that employers are entitled to be informed of the medical fitness of individuals for work but are not entitled to diagnoses or details of a specific nature (I). One potential consequence, however, might be that workers determined to be genetically unfit could be stigmatized and have difficulty finding other employment for similar jobs.

Conclusions

Genetic screening and monitoring are not inherently unethical. The tests are morally justified to the extent they enhance worker health in a manner consistent with the principles of auton-

omy, nonmaleficence, beneficence, and justice. Whether or not they are consistent with these principles will depend on how the tests are done and how the information is used.

Ethicists generally agree that autonomy requires that no medical procedure, especially those of unestablished clinical validity, be done on a person without his informed consent. This principle would also require that the person be told the results and what they mean and that medical data be held confidential.

Ethical principles constrain how the results of genetic testing may be used. With a low correlation between genetic endpoints and disease, it would be unethical for the employer to act adversely to the employee's interests, such as by denying him or her a job. In the hypothetical case of a high correlation between genetic endpoints

and disease, the morally correct course of action is significantly less clear. An employer may be justified in allowing a susceptible person to assume the risks on the basis of informed consent. On the other hand, the most ethically feasible course of action for an employer once genetic monitoring identifies a group at increased risk would be to inform the workers and to reduce workplace exposure. Failure to do so would be inflicting harm, and it is unlikely that the group would consent to assuming this risk. Finally, whether or not genetically susceptible people are entitled to compensation depends on which theory of distributive justice is chosen.

Chapter 9 references

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