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Genetic Testing
Genetic testing is a type of medical test that looks for changes in genes, chromosomes, or proteins. Genetic testing can be done for many reasons, including to find out if someone has a genetic condition, to see if someone is a carrier for a genetic condition, to see if someone is at risk for developing a genetic condition, to see how a person's body will react to a medicine, or to see how a person's cancer is growing or responding to treatment. Genetic testing can be done on a person's blood, tissue, or other bodily fluids.
Genetic testing is a rapidly evolving field. Many genetic tests are available now, and many more are being developed. Genetic testing can be very helpful for people who have a genetic condition or who are at risk for a genetic condition. However, it can also be complicated and raise many ethical, legal, and social issues. For example, genetic testing can reveal information about a person's health that he or she may not want to know. Genetic testing can also affect a person's relatives, insurance status, and ability to get a job.
This page provides an overview of genetic testing. It includes information on why people may get genetic testing, how it is done, what it can tell people about their health, and what the potential risks and benefits are. It also includes information on how genetic testing is regulated and how it is covered by health insurance. It also includes information on how to find a genetic test and how to find a genetic counselor.
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Why Do People Get Genetic Testing?

People may get genetic testing for many reasons. For example, they may want to know if they have a genetic condition that runs in their family, or they may want to know if they are a carrier for a genetic condition that they could pass on to their children. People may also want to know if they are at risk for developing a genetic condition, or they may want to know how their body will react to a medicine. People may also want to know how their cancer is growing or responding to treatment.

Genetic testing can be done for many reasons, including:

- To find out if someone has a genetic condition that runs in his or her family
- To see if someone is a carrier for a genetic condition that he or she could pass on to his or her children
- To see if someone is at risk for developing a genetic condition
- To see how someone's body will react to a medicine
- To see how a person's cancer is growing or responding to treatment

Genetic testing can be done on a person's blood, tissue, or other bodily fluids. It can be done on people of any age, including children, adults, and pregnant women. It can also be done on people who are healthy or who have a medical condition.

Genetic testing can be very helpful for people who have a genetic condition or who are at risk for a genetic condition. It can help them know what their future may be like, and it can help them make decisions about their health care and their lives. For example, it can help people decide what kind of medical care they need, what kind of jobs they want to have, and whether they want to have children.

However, genetic testing can also be complicated and raise many ethical, legal, and social issues. For example, genetic testing can reveal information about a person's health that he or she may not want to know. Genetic testing can also affect a person's relatives, insurance status, and ability to get a job.

How Genetic Testing Is Done

Genetic testing can be done on a person's blood, tissue, or other bodily fluids. It can be done on people of any age, including children, adults, and pregnant women. It can also be done on people who are healthy or who have a medical condition.

The most common way to do genetic testing is to take a blood sample. The blood sample is then sent to a laboratory where it is tested for changes in genes, chromosomes, or proteins. The results of the test are then sent back to the person who ordered the test, which may be a doctor, a genetic counselor, or a genetic testing company.

Genetic testing can also be done on other bodily fluids, such as saliva, urine, or amniotic fluid. It can also be done on tissue samples, such as a piece of skin or a piece of a tumor. The type of genetic test that is done depends on what the person is looking for.

What Does Genetic Testing Tell People?

Genetic testing can tell people many things about their health. It can tell people if they have a genetic condition that runs in their family, if they are a carrier for a genetic condition that they could pass on to their children, if they are at risk for developing a genetic condition, how their body will react to a medicine, and how their cancer is growing or responding to treatment.

Genetic testing can also tell people if they are at risk for developing a genetic condition that they could pass on to their children. For example, if a person has a genetic condition that runs in his or her family, he or she may want to know if he or she is a carrier for that condition. If he or she is a carrier, he or she may want to know if his or her children are at risk for developing that condition.

Genetic testing can also tell people how their body will react to a medicine. For example, some people may have a genetic condition that makes them more likely to have a bad reaction to a medicine. Genetic testing can tell them if they have that condition, so they can avoid taking that medicine.

Genetic testing can also tell people how their cancer is growing or responding to treatment. For example, if a person has cancer, genetic testing can tell him or her if the cancer is growing or if it is responding to treatment. This information can help the person and his or her doctor decide what kind of treatment to use.

What Are the Risks and Benefits of Genetic Testing?

Genetic testing can be very helpful for people who have a genetic condition or who are at risk for a genetic condition. It can help them know what their future may be like, and it can help them make decisions about their health care and their lives. For example, it can help people decide what kind of medical care they need, what kind of jobs they want to have, and whether they want to have children.

However, genetic testing can also be complicated and raise many ethical, legal, and social issues. For example, genetic testing can reveal information about a person's health that he or she may not want to know. Genetic testing can also affect a person's relatives, insurance status, and ability to get a job.

Some of the risks of genetic testing include:

- Genetic testing can reveal information about a person's health that he or she may not want to know.
- Genetic testing can affect a person's relatives, insurance status, and ability to get a job.
- Genetic testing can be expensive.
- Genetic testing can be inaccurate.
- Genetic testing can be misleading.
- Genetic testing can be used to discriminate against people.

Some of the benefits of genetic testing include:

- Genetic testing can help people know what their future may be like.
- Genetic testing can help people make decisions about their health care and their lives.
- Genetic testing can help people avoid taking medicines that they may have a bad reaction to.
- Genetic testing can help people decide what kind of treatment to use for cancer.

How Is Genetic Testing Regulated?

Genetic testing is regulated by the Food and Drug Administration (FDA). The FDA regulates genetic tests that are used to diagnose, treat, or prevent a disease or condition. The FDA also regulates genetic tests that are used to see how a person's body will react to a medicine.

The FDA has not approved most genetic tests. However, it has approved some genetic tests that are used to diagnose, treat, or prevent a disease or condition. The FDA has also approved some genetic tests that are used to see how a person's body will react to a medicine.

The FDA has not approved most genetic tests because it has not been able to review them. The FDA is currently reviewing a number of genetic tests that are being developed. The FDA is also reviewing a number of genetic tests that are being used in clinical trials.

How Is Genetic Testing Covered by Health Insurance?

Genetic testing is covered by health insurance in some cases. For example, genetic testing is covered by health insurance if it is used to diagnose a person's disease or condition. Genetic testing is also covered by health insurance if it is used to see how a person's body will react to a medicine.

However, genetic testing is not always covered by health insurance. For example, genetic testing is not always covered by health insurance if it is used to see if someone is a carrier for a genetic condition that he or she could pass on to his or her children. Genetic testing is also not always covered by health insurance if it is used to see if someone is at risk for developing a genetic condition.

How Do I Find a Genetic Test?

There are many genetic tests available. The Genetic Testing Registry (GTR) is a database that lists many genetic tests. The GTR also lists many genetic testing laboratories. You can use the GTR to find a genetic test that is right for you.

How Do I Find a Genetic Counselor?

A genetic counselor is a person who has been trained to help people understand and cope with the medical, psychological, and family implications of genetic testing. Genetic counselors can help people decide if genetic testing is right for them, they can help people understand the results of genetic testing, and they can help people cope with the emotional and family issues that may come up after genetic testing.

There are many genetic counselors. You can find a genetic counselor by asking your doctor, or you can search for a genetic counselor online.

Genetic Information and Nondiscrimination Act

Genetic information is information about a person's genes, genetic tests, or genetic disorders. It can also be information about a person's family's genes, genetic tests, or genetic disorders. For example, it can be information about a person's parents, siblings, or children.

The Genetic Information Nondiscrimination Act (GINA) of 2008 explicitly prohibited employers and health insurers from discriminating against individuals on the basis of their genetic information. This ruling protects people from GINA's privacy protections.

Signed into law in 2008, the Genetic Information Nondiscrimination Act (GINA) ensures that people who are healthy or have a genetic condition cannot be denied health insurance or be discriminated against in the workplace because of their genetic information. The law also protects people from discriminatory genetic testing practices. For example, it prohibits employers from using genetic information from their employees' family members to make employment decisions. It also prohibits health insurance companies from using genetic information from their family members to make decisions about their health insurance coverage.

GINA's protections are limited, however, in several ways. For example, there are no protections for people who are self-employed or who work for companies with fewer than 15 employees. There are also no protections for people who have a genetic condition that causes them to have a bad reaction to a medicine. There are also no protections for people who have a genetic condition that causes them to have a bad reaction to a medicine.

Genetic Testing and Insurance

Genetic testing can affect a person's health insurance in several ways. For example, it can affect a person's ability to get health insurance, the cost of health insurance, and the type of health insurance that is available to him or her.

Genetic testing can affect a person's ability to get health insurance because some health insurance companies may refuse to sell health insurance to people who have a genetic condition that is likely to cause them to have a bad reaction to a medicine. Genetic testing can also affect a person's ability to get health insurance because some health insurance companies may charge more for health insurance to people who have a genetic condition that is likely to cause them to have a bad reaction to a medicine.

Genetic testing can affect the cost of health insurance because some health insurance companies may charge more for health insurance to people who have a genetic condition that is likely to cause them to have a bad reaction to a medicine. Genetic testing can also affect the type of health insurance that is available to him or her because some health insurance companies may only sell health insurance to people who have a genetic condition that is likely to cause them to have a bad reaction to a medicine.

Genetic Testing and Employment

Genetic testing can affect a person's ability to get a job because some companies may refuse to hire people who have a genetic condition that is likely to cause them to have a bad reaction to a medicine. Genetic testing can also affect a person's ability to get a job because some companies may fire people who have a genetic condition that is likely to cause them to have a bad reaction to a medicine.

Genetic testing can also affect a person's ability to get a job because some companies may require their employees to take genetic tests. For example, some companies may require their employees to take genetic tests to see if they are carriers for a genetic condition that they could pass on to their children. Genetic testing can also affect a person's ability to get a job because some companies may require their employees to take genetic tests to see if they are at risk for developing a genetic condition.

Genetic Testing and Privacy

Genetic testing can affect a person's privacy because it can reveal information about a person's health that he or she may not want to know. Genetic testing can also affect a person's privacy because it can reveal information about a person's relatives' health that they may not want to know.

Genetic testing can affect a person's privacy because it can be used to discriminate against people who have a genetic condition that is likely to cause them to have a bad reaction to a medicine. Genetic testing can also affect a person's privacy because it can be used to discriminate against people who have a genetic condition that is likely to cause them to have a bad reaction to a medicine.

Genetic Testing and Ethics

Genetic testing can raise many ethical issues. For example, genetic testing can reveal information about a person's health that he or she may not want to know. Genetic testing can also affect a person's relatives, insurance status, and ability to get a job.

Genetic testing can also affect a person's privacy because it can be used to discriminate against people who have a genetic condition that is likely to cause them to have a bad reaction to a medicine. Genetic testing can also affect a person's privacy because it can be used to discriminate against people who have a genetic condition that is likely to cause them to have a bad reaction to a medicine.

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Genetic Testing and Research

Genetic testing can be used in research to study genes and their effects on health. For example, genetic testing can be used to study how genes affect a person's risk for developing a disease or condition. Genetic testing can also be used to study how genes affect a person's ability to respond to a medicine.

Genetic testing can be used in research to study how genes affect a person's ability to respond to a medicine. For example, genetic testing can be used to study how genes affect a person's ability to respond to a medicine for cancer. Genetic testing can also be used to study how genes affect a person's ability to respond to a medicine for other diseases or conditions.

Genetic testing can be used in research to study how genes affect a person's risk for developing a disease or condition. For example, genetic testing can be used to study how genes affect a person's risk for developing cancer. Genetic testing can also be used to study how genes affect a person's risk for developing other diseases or conditions.

Genetic Testing and Pharmacogenomics

Dr. Hamburg emphasized that in order to ensure the safety and effectiveness of these new personalized technologies, the FDA must adopt an approach to monitoring the entire life cycle of a product, which necessitates postmarket follow-up research. The FDA plans to devise postmarket research protocols; when they are established, regulators and businesses will become more confident about the preapproval process.

2. **The FDA is forming crucial collaborations with other agencies.** The day before her address to the Personalized Medicine Coalition, Dr. Hamburg joined NIH Director Francis Collins and DHHS Secretary Sebelius to announce a new collaborative effort between the NIH and the FDA, designed to advance regulatory science. She also explained that the FDA and the AHRQ have discussed some research topics. More controversial, an audience member questioned her about the possibility of collaboration between the FDA and the CMS, which determines payments. We regard this as an important way for the FDA to gather information about the real-world usage of drugs and medical devices and for companies to have a better idea of the economic viability of their products, as has been done with the genetic tests surrounding warfarin, which are paid for only if the patient is part of a clinical trial.

3. **The FDA is making its procedures more transparent.** Dr. Hamburg acknowledges that coordination between the CMS and the FDA might raise concerns because the reimbursement rates determined by the CMS heavily influence the profitability of drugs and diagnostics. However, she said that the FDA would need to clearly explain to the public the scientific evidence and administrative rationale behind the decisions that these agencies make. Along with greater flexibility and collaboration, she considers the transparent sharing of evidence and explanation of policy rationales as one of the major components of the FDA's modernization.

One of the more logistically complex issues for the future of PM is the need for coordination between makers of genetic tests, drug manufacturers, and health care providers. For instance, Dr. Hamburg described the FDA's "scenario-based" approach to "companion technologies," such as a genetic test that is coupled with a drug whose effectiveness on a patient can be determined by the test results. Although some drugs and diagnostics will be developed in tandem, others will follow separate paths through different companies. She acknowledged that this would require a procedure by which various companies can be made aware of all the data coming into the FDA from different sources that may be relevant to each specific product.

CONCLUSION

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In this 2nd part of our series, we have explored several key ethical, legal, and regulatory issues facing the future of personalized medicine (PM). Specifically, there are a variety of ethical issues that remain unresolved regarding the use of PM diagnostic or treatment products. This area becomes further clouded by the companion use of PM products in addition to new technologies that have not been seen in the marketplace before by consumers or clinicians. As we move out of the basic and early stage research environment with an ever increasing array of PM products, there will be a greater societal interest in debating and resolving these ethical concerns.

Along with the 2010 health reform legislation, there have been other key pieces of federal legislation that will have broad-reaching implications on the future of PM along with their use in the marketplace by clinicians. Both legislative and regulatory expansions to HIPAA, along with HITECH, will require clinical practice as well as health system adjustments to maintain information privacy or face stiffer penalties for failing to do so. Similarly, GINA expands the coverage of patient testing in a variety of marketplace applications beyond clinical medicine to include the workplace. Benefit managers, along with insurance and health plans, are now more directly at risk for inappropriate business practices related to consumer health testing or information.

Finally, a trend toward coordination among federal agencies beyond past cooperative practices may further complicate the marketplace dynamics for PM manufacturers as well as for clinicians. While it may still be too early in the evolution of health reform regulation now, given the number of high-level agencies and their regulatory bodies in addition to approximately 150 oversight groups in the health reform legislation, it is probably safe to say that following this trend among agencies will be important for all health care stakeholders in order to determine safe harbors for research and daily business practices.

Footnotes

Go to:

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