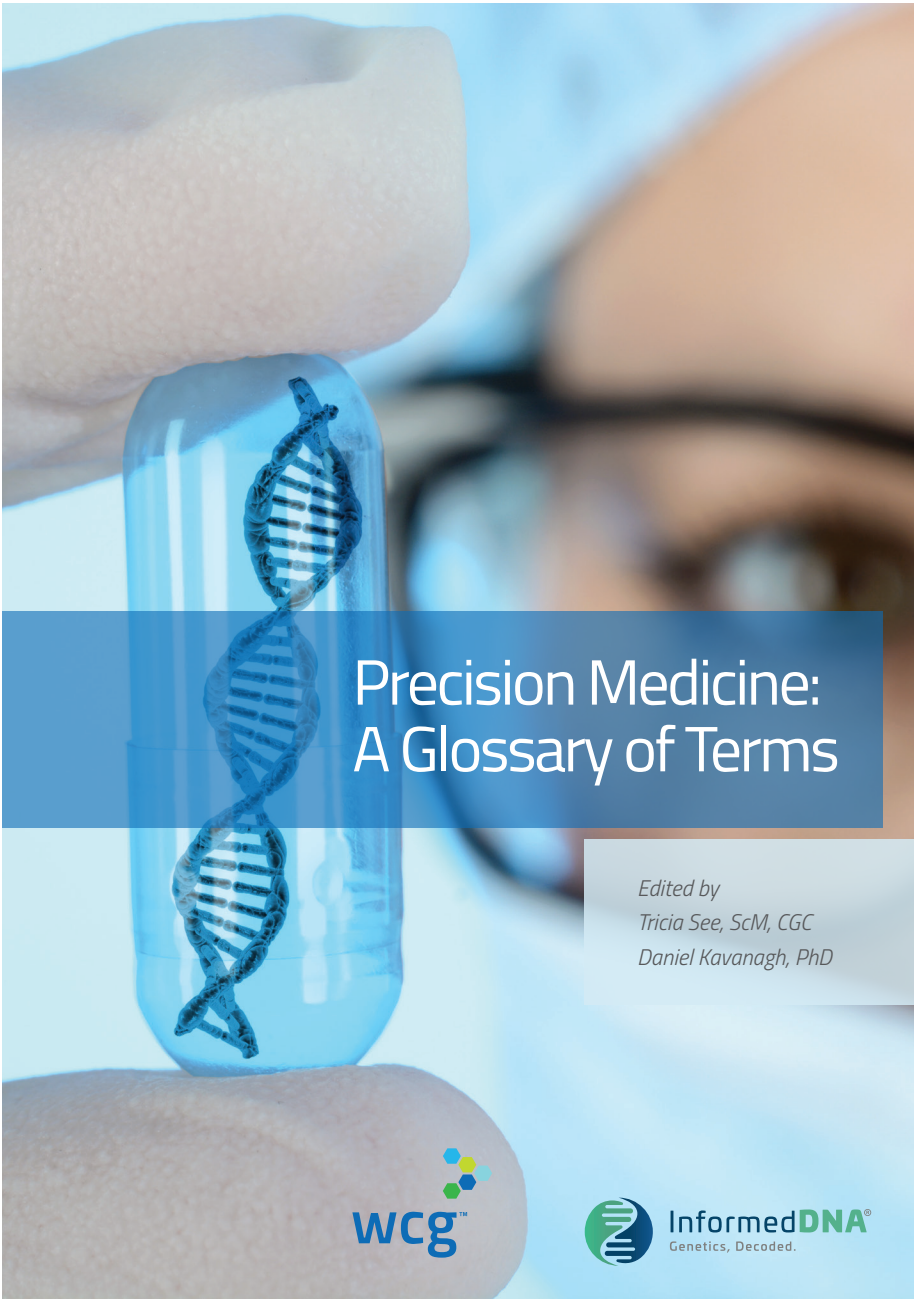

Precision Medicine: A Glossary of Terms

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Genetics, Decoded.

Introduction

The purpose of this glossary is to provide clarification of commonly-used terms in the discussion of genetics, genetic testing, and precision medicine. The terms are provided alphabetically, with illustrations of several of the key concepts. As genetic testing becomes increasingly common as an integral part of clinical development programs, understanding the key terms and definitions is essential for all members of research and clinical development teams.

For more information on precision medicine and related topics, and to access the companion Gene Therapy & Immunotherapy Glossary, please visit https://insights.wcgclinical.com/whitepapers.

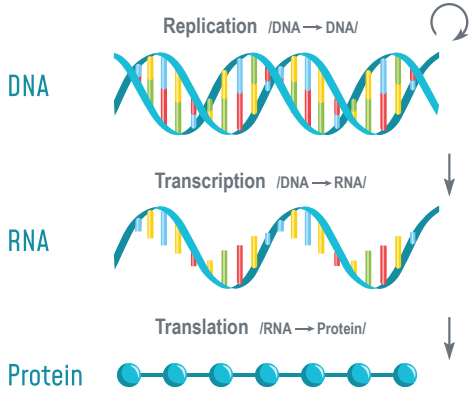
Allele: one of two or more DNA sequences occurring at a particular gene locus, or place on the chromosome.

Autosome/Autosomal: refers to the 22 pairs of chromosomes (in humans) that are not sex chromosomes.

Benign Variants: variation in the DNA that is not disease-causing. Benign variants are common and often not listed on a genetic test report.

Biomarker: characteristic of an individual that can be objectively measured to indicate normal biologic processes, risk for disease, disease progression, or response to treatment. In contrast to medical symptoms, which can be subjective or difficult to define, biomarkers are reproducibly and accurately captured. In medicine, and in clinical trials, biomarkers can be diagnostic, prognostic, or predictive. Biomarkers can be non-genetic (e.g. cholesterol, blood pressure) or genetic.

Central Dogma of Molecular Biology: the "central dogma" of molecular biology refers to the flow of information, encoded in a gene, from DNA to RNA to protein. The transfer of information from DNA to RNA is called transcription, and the transfer of information from RNA to protein is called translation. The term "central dogma" was coined by Francis Crick, who later stated that the religious term dogma was a malapropism—a more correct term would be "central paradigm."[1]



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Chromosomes: thread-like structures located inside the nucleus of human cells containing almost the entire DNA of the cell. Human chromosomes are highly organized structures composed of DNA and proteins. Almost all human cells contain 23 matched pairs of chromosomes. The DNA content includes "coding" DNA (DNA encoding genes), and "noncoding" DNA (all of the DNA not encoding genes). The majority of human chromosomal DNA is noncoding.

Coding DNA: sequence of DNA that provides instructions for a protein; also referred to as functional DNA. Only 1.5% of the human genome is coding DNA. (compare non-coding DNA)

Companion Diagnostics: a medical device offered in conjunction with a therapeutic, which provides essential information for the safe and effective use of the corresponding drug or product. Increasingly, companion diagnostics can involve genetic testing, to identify persons eligible for the therapeutic of interest or at risk for serious side effects, based on specific genetic markers.[2]

CRISPRs (Clustered Regularly-Interspaced Short Palindromic Repeats): originally natural features of bacterial DNA that bacteria use to protect themselves from infection – CRISPR sequences in bacterial DNA provide signals that guide nuclease proteins such as CAS9 (CRISPR-Associated Protein 9) to cleanse genetic material that may be harmful to the bacterium. In modern biotechnology, CRISPRs are used as the basis for an extremely flexible and accurate form of gene editing.

CRISPR-CAS9: one of a number of naturally occurring systems that bacteria use to protect their own DNA and destroy viruses that infect them. Molecular biologists have adapted this system to allow gene editing of DNA in live human cells. Along with Zinc-Finger Nucleases and TALENs, CRISPR-CAS9 is being used to develop gene editing technology.

Deletion/Duplication Testing: genetic testing that evaluates for extra or missing pieces of DNA. DNA sequencing alone will not detect most deletions or duplications, yet these can play an important role in many genetic conditions. For example, deletions/duplications are common in Duchenne Muscular Dystrophy and autism. A number of technologies can be utilized for deletion/duplication testing including array comparative genomic hybridization (aCGH) and multiplex ligation-dependent probe amplification (MLPA).

Direct to Consumer (DTC) Genetic Testing: access to genetic testing offered directly to the general population from a private company, without the aid of an intermediary physician. Direct to consumer testing often employs testing for SNPs (see Single Nucleotide Polymorphism) associated with a trait or condition, which means the DNA variant may be found more frequently in persons with the condition, compared to those without. However, this association does not imply causation, nor does it exclude other genetic and nongenetic factors, which may be playing an important role in a trait or condition. For this reason, and because

DTC testing may not test for all mutations associated with a particular condition, DTC testing results should be interpreted with caution and not be used in medical care and decision-making without consultation from a genetic counselor.

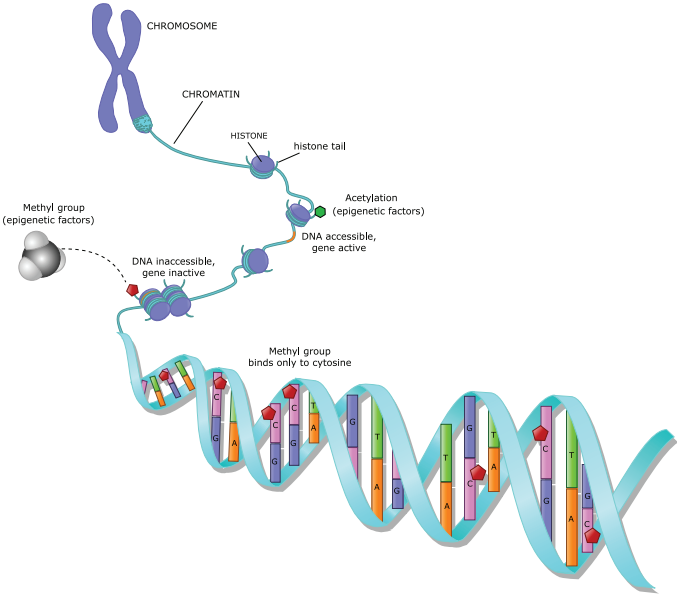
DNA: the long-term storage medium for genetic information that defines the form and function of living cells and some viruses. Many human gene transfer studies involve delivery of recombinant DNA molecules and/or DNA viral vectors. DNA molecules are made of a chain of nucleotides (Adenine, Guanine, Cytosine, or Thymine; represented by A, G, C, and T in genetic notation). The most common form of DNA is double-stranded – composed of two antiparallel strands that form a double helix and where nucleotides from each strand form "base pairs" with the corresponding nucleotides on the other strand. (See RNA).

DNA Sequencing: the process of reading through an entire gene, or set of genes, to identify variants (historically called mutations) in an individual's genetic code. DNA sequencing determines the exact genetic code of an individual for that particular length of DNA. DNA variants identified through genetic testing can be classified as benign, likely benign, pathogenic, likely pathogenic, or unknown significance. The American College of Medical Genetics (ACMG) has published standards and guidelines for the interpretation of sequence variants. This is used by many laboratories to aid in variant classification.

Dominant Inheritance: with respect to human disease, dominant inheritance is when a DNA variant results in disease even if present on only one of the two copies of a gene. Traits and conditions that are dominantly inherited can be passed on through the eggs or sperm to future generations from one parent. (Compare with recessive inheritance)

Enzyme: carries out chemical reactions within the body. Some enzymes also assist in 'reading' the human genome. Most enzymes are proteins.

Epigenetics: the study of how our genes are turned on or off (gene expression) through chemical modifications to the genome. Epigenetic modifications are reversible, and are not permanent alterations to the underlying DNA sequence (compare Mutation). Epigenetics is an emerging area of interest in the study of complex traits and conditions, such as asthma and Alzheimer's disease. Epigenetic modifications will not be detected through traditional clinical genetic testing.



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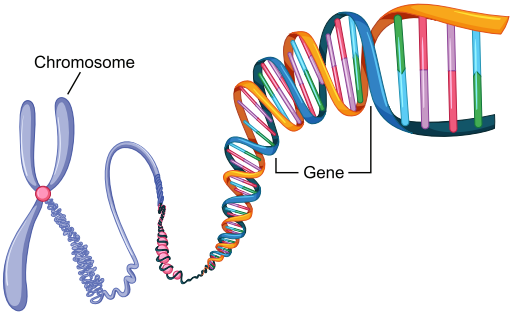
Exon: a portion of DNA sequence within a gene that directly codes for a protein (compare intron).

Exome: the total protein-coding regions of DNA within a cell. The exome comprises only 1.5% of the human genome.

Gene: basic unit of heredity. Some genes code for proteins, while others do not. Human chromosomes contain around 20,000 genes.[3]



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Gene Therapy: any of several techniques to treat or prevent disease by altering the DNA content of some of a person's cells. Traditional approaches to gene therapy generally involve using a vector to introduce DNA into target cells to replace the function of a nonfunctional gene in a subject with a genetic disease. These older approaches do not alter the sequence of the dysfunctional gene in the subject's chromosome. Some authorities limit the term "gene therapy" to interventions intended to treat genetic disease. Others use "gene therapy" to refer to a variety of techniques involving gene transfer, including CAR-T technology. The consensus definition of "gene therapy" is likely to evolve over time. Some people draw a distinction between gene therapy, which introduces DNA into a cell without specifically targeting a particular site on a chromosome, and gene editing or genome editing, which involve specific modifications to targeted sites on a chromosome.

Genetics: the study of how traits or diseases are inherited through DNA subunits called genes. Genetics examines genes, or parts of genes, known to have a biologic function. It focuses on the function of a single gene and the role it plays in traits or disease. Examples of genetic diseases include cystic fibrosis, sickle cell anemia, and Huntington disease. Genetics has a long history and is more limited in scope (compare Genomics).

Genetic Counselors: Genetic counselors are healthcare professionals with specialized education in genetics and counseling. They help people understand and adapt to the medical, psychological, and family implications of inherited diseases. Genetic counselors have advanced training to interpret genetic test results, relay complex information, and assess risk for disease. hrough the genetic counseling process they guide, educate and support individuals and families at risk for, or diagnosed with, inherited conditions. Genetic counselors also provide advice to clinicians and researchers about the most appropriate and effective genetic test panels and testing processes for clinical and research settings.

Genetic Testing (Chromosomal): analyzes entire chromosomes or part of chromosomes to identify variations in the chromosome number, structure, or size. Down syndrome (also called trisomy 21) is caused by an extra copy of chromosome 21.

Genome: the total DNA information within a cell, including the coding DNA within the genes, and all noncoding DNA outside of the genes. The vast majority of the human genome is noncoding.

Genome Editing: the process of "re-writing" small portions of a subject's DNA, frequently to correct a disease-associated defect or to create new functional codes in the DNA. This term is widely used in reference to genetic engineering

mediated by CRISPR-CAS9, TALENs, and Zinc-Finger Nucleases. "Genome editing" is a broad term encompassing gene editing (editing of coding DNA within genes) as well as the editing of noncoding DNA outside of genes. Genome editing may result in addition of DNA, deletion of DNA, or alteration of a DNA sequence without changing length.

Genomics: the study of a complete set of genetic material for an organism (genome), including both coding and noncoding DNA regions. Genomics involves examining how rare DNA changes interact with each other, as well as the environment, to cause disease (compare Genetics). Genomics is employed when studying complex disorders or characteristics, which may not be caused by a single gene or may be influenced by environmental factors. Examples of complex diseases studied through genomics include heart disease, diabetes, and psychiatric illness. Genomics facilitates a deeper understanding of the complex influences to common disorders and allows insight into possible targeted therapeutic interventions.

Genotyping: the process of determining a set of DNA variants processed by an individual. Genotyping does not read through the entire DNA sequence of a gene (see DNA sequencing). Instead, it looks for the presence or absence of specific DNA variants at set locations within the gene. Genotyping is commonly employed when there is a common set of DNA variants inherited together in the population, which are associated with a particular trait or condition. An example is APOE genotyping for Alzheimer's disease risk assessment. The 'e4' APOE genotype has been associated with increased risk for Alzheimer's disease.

Germline Mutation: "germline" is a term used to describe genetic material contained in sperm and ova, or the cells that produce them. Genetic changes in an embryo may affect the germline if the embryo becomes an adult. Germline mutations refer to a permanent DNA change that occurs in a person's sex cells

(i.e. eggs or sperm). Germline mutations can be passed down from generation to generation. Deliberate germline gene transfer in humans is forbidden in the United States using federal funds and in most countries around the world. Because the risk of accidental germline modification exists in human gene transfer, subjects undergoing gene transfer are advised not to become pregnant or to make anyone else pregnant.

GWA Study/GWAS (Genome-wide Association Study): a method for identifying single nucleotide polymorphisms (SNPs) associated with a particular trait or health condition. The general method of completing a GWAS includes gathering DNA samples from a large number of persons with a particular trait/condition of interest and comparing their genomic data to a large number of persons without the trait/condition of interest. Researchers then look for strong DNA "signals," that could indicate a gene, variant, or region associated with the trait/condition. It is important to note that GWAS findings do not imply causation, meaning they cannot say with certainty if, or how, that DNA region directly (or indirectly) contributes to the trait/condition. GWAS studies have been instrumental in the study of common multifactorial diseases, such as cancer, diabetes, psychiatric illness, and heart disease.

Heterozygous: having two distinct DNA sequences (alleles) at a particular gene or genetic locus on each of two paired chromosomes. (Compare to Homozygous).

Homozygous: having identical DNA sequences (alleles) at a particular gene or genetic locus on each of two paired chromosomes. (Compare to Heterozygous).

Human Genome Project: International, collaborative effort to map the entire human genome (see Genome). The Human Genome Project was completed in 2003, and revealed that there are approximately 20,000 human genes. Despite this milestone, our understanding of the function and variation within each of these genes is still relatively limited.

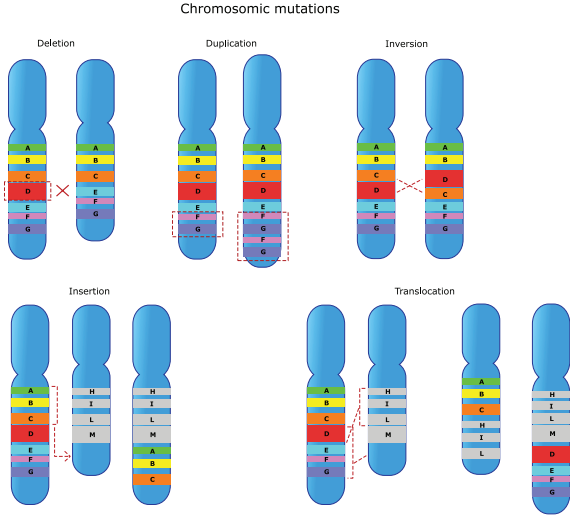
Intron: a portion of DNA sequence within a gene that does not directly code for a protein (compare exon). Introns are spliced out, or removed, from messenger RNA (mRNA). This mRNA sequence is then translated into a specific protein. Sequencing of the exons (see Whole Exome Sequencing) does not include analysis of the introns. However, DNA variants located within the introns can occasionally play an important role in gene expression and, consequently, risk for human disease.

Monogenic Disease: a genetic disease primarily caused by a polymorphism or mutation occurring at a single location in the affected person's DNA on one or both chromosomes. Compared to polygenic diseases, it is much easier to understand the causal relationship between the DNA sequence and the disease state, and thus it is generally easier to design experimental gene therapy to treat a monogenic disease. Although monogenic diseases can be primarily attributed to individual genetic differences, all medical conditions can be affected by multiple genetic factors, and persons affected with monogenic diseases can present with a diversity of severities and symptoms.

Multifactorial: involving both genetic and environmental factors. Multifactorial conditions are collectively more common than single gene disorders (see Monogenic). In fact, most traits or conditions are multifactorial in nature, meaning they are the result of a complex interplay of multiple genetic variants (see Polygenic) and environmental factors. Multifactorial conditions are not inherited in clear-cut patterns within families; however, familial clusters can appear due to the presence of shared genetic and/or environmental influences.[4]

Mutation: a "change" at a specific location in a person's DNA sequence relative to a reference sequence. The term mutation is often used as a synonym for "polymorphism" but it is important to remember that there is no unique "normal" human reference sequence. Disease-associated polymorphisms are often

referred to as “mutations” by default. Some mutations are inherited from a subject’s parents, and some are spontaneous (new in that individual) or somatic mutations that occur at any point in life after conception.



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Noncoding DNA: sequence of DNA that does not provide known instructions for a protein; also referred to as non-functional DNA. Although scientists originally thought that noncoding DNA sections had no function, we are now understanding that some sections of noncoding DNA play a role in turning on and off genes in the coding DNA regions. However, for most other sections of noncoding DNA, the role within the cell and our body is unknown. The majority of the human genome is noncoding.

Pathogenic Variant: rare change in the DNA that alters the gene function in some way, either in changing the protein function, or causing no protein to be produced. Pathogenic variants increase susceptibility or predispose to a disease.

Personalized Medicine: term historically used interchangeably with "precision medicine." In recent years, this term has been used less in reference to specific therapeutics, partly due to a misconception that personalized medicine involves developing unique therapeutics for a single individual. However, the term is still sometimes used in clinical care settings to refer to the concept of making treatment decisions that consider all aspects of a patient's medical condition, social factors, and environment to optimize a therapeutic regimen for each person. (See Precision Medicine).

Pharmacogenomics: the study of how variations in a single gene impacts response to specific drugs. Pharmacogenomics aims to use genetic data to inform choice/avoidance of certain medications, as well as accurate dosing to minimize side effects and maximize therapeutic response.

Polygenic: caused by the combined effects of polymorphisms or mutations occurring at more than one location in the affected person's chromosomes. Compared to monogenic diseases, it is much more difficult to determine the genetic cause of polygenic diseases, and also much more challenging to design experimental gene therapies.

Precision Medicine: a tailored treatment or prevention approach that utilizes patient-specific genomic, lifestyle, and environmental data. Precision medicine accounts for individual and population-wide variability in these factors when designing treatments and contrasts traditional approaches where treatment is "one size fits all." The ultimate goal of a precision medicine approach is to maximize disease prevention efforts or therapeutic response for each individual,

while minimizing harmful side effects. For many common (and rare) diseases, a combination of genomic, lifestyle, and environmental factors play an important role in disease onset, progression, and individual treatment response. Identifying and understanding this complex network allows researchers to develop more targeted therapeutics for subsets of individuals. Contrary to popular belief, precision medicine approaches are not always narrowly focused. Instead, many may be applicable across broad populations.

Polygenic Risk Score: probability of developing a trait or condition, based on a weighted combination of genetic risk factors. A polygenic risk score is increasingly used in the context of complex disorders, such as diabetes and psychiatric illness (see Multifactorial, GWAS). Genome wide association studies (GWAS) have been important in identifying genetic variants associated with traits or conditions, but each individual genetic variant may have only modest impact. Combining genetic variants into a polygenic risk score increases the power of GWAS to explain risk for a trait or condition.

Promoter: sequence of DNA that initiates the process of DNA transcription for a specific gene by defining the 'start.' The promoter is generally directly upstream of a gene, also called the 5' (pronounced "five prime") end. DNA variants in the promoter region can impact whether (or how) a gene is turned on or off. For that reason, pathogenic variants in a gene promoter can influence risk for disease. (Compare suppressor)

Protein: molecule that assists in the biologic function of an organism. Proteins are composed of smaller units called amino acids. There are 20 different amino acids that can combine to make proteins.[5]

Proteomics: the study of all the proteins in an organism or specific tissue.

Rare Disease: in the United States, rare diseases are defined under the Orphan Drug Act of 1983 as those conditions affecting fewer than 200,000 people. There are up to 7,000 different identified conditions that qualify as rare diseases. While some rare diseases are caused by infection or other factors, the majority of rare diseases are believed to be genetic diseases. Many rare diseases are potential indications for gene therapy.

Recessive Inheritance: with respect to human disease, recessive inheritance is when a DNA variant results in disease only if both copies of that gene have DNA variants that are disease-causing (see Pathogenic). A person who has a disease-causing variant on one gene copy often has no symptoms of the disease because of a normal genetic sequence on the paired gene. That person is known as a "carrier" for that disease. However, exceptions to this general rule exist. Occasionally a "carrier" for a recessive condition may be at increased risk to develop symptoms of a different or related medical condition. An example of this is Gaucher disease. Carriers for Gaucher disease are at increased risk to develop Parkinson's disease, when compared with non-carriers.

RNA: a type of nucleic acid molecule similar to DNA and serving various purposes in living cells and some viruses. Notably messenger RNA (mRNA) serves as a short-lived medium for information encoded in the chromosomal DNA of a cell. In contrast to DNA, the most common form of RNA is single-stranded, and does not persist in stable base-paired double-stranded formats. Many human gene transfer studies involve delivery of recombinant mRNA molecules and/or RNA viral vectors.

RNA Interference (RNAi): any of several natural or synthetic mechanisms for controlling gene expression that rely on interactions between RNA molecules. Technology for RNAi therapy includes using synthetic short interfering RNA (siRNA) molecules to block expression of harmful genes. The effects of siRNA

therapy are designed to be much more transient than those of most gene transfer technologies, and siRNA therapies are generally intended to require systematic re-dosing to treat chronic disease. Notably, due to the short length of the molecules, siRNA therapies are generally not classified as human gene transfer under the *NIH Guidelines* and thus do not require IBC review. Nevertheless some siRNA-based approaches to treat disease are referred to as "gene therapy" in popular media.

Single Nucleotide Polymorphism (SNP): DNA variation at a single base pair (nucleotide) in the genome. Single nucleotide polymorphisms, or SNPs (pronounced "snips"), are very common in the general population, with around 10 million SNPs in the human genome. Most SNPs occur in the sequences between genes (see noncoding DNA) and have no impact on biologic health; however, some have been associated with certain traits, drug responses, or diseases. SNPs are generally present in greater than 1% of the population. This contrasts mutations, which are rare and present in less than 1% of the population (see Mutation).[6]

Somatic Mutation: a DNA change that originates in an individual body cell after conception. These can be replicated through cell division in an individual person, but cannot be passed down from one generation to the next (compare Germline mutation). Cancer is generally caused by somatic cell mutations.

Suppressor Mutation: refers to a second DNA variant that reverts the effects of an existing DNA variant, thus negating any impact on health and restoring the original biologic state.

TALENs (Transcription Activator-Like Effector Nucleases): proteins that can be engineered to make specific changes to cellular DNA. As with CRISPR-CAS9 and Zinc-Finger Nucleases, TALENS are used to develop gene editing technology.

Transcription: the process of RNA synthesis in a cell, by which information encoded in chromosomal DNA is transferred to the new RNA molecule (see Central Dogma).

Translation: the process of protein synthesis in a cell, by which information encoded in messenger RNA (mRNA) determines the order of amino acids joined together to form the new protein (see Central Dogma).

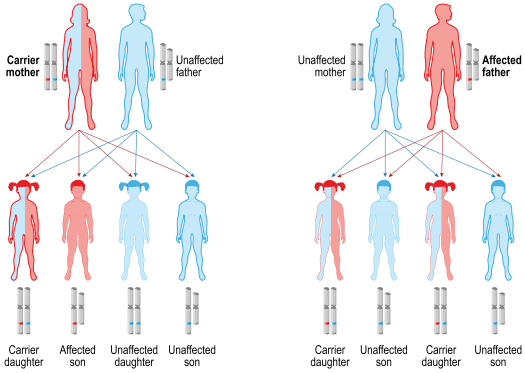
Variant of Unknown Significance (VUS): a change in the DNA sequence, whose role in human disease is unclear. Classifying variation in the human genome is complex, as the DNA spelling across all individuals is not "standard." In fact, there is a great deal of DNA variation within the population, much of which is normal and plays no known role in disease or body function. However, some rare DNA variants do change the function of a gene and are important factors in disease risk. Therefore, when a rare variant is identified that hasn't been either: 1) confirmed through research to be normal (benign, likely benign), or 2) highly likely to increase disease risk (pathogenic, likely pathogenic), it gets classified as "unknown significance." Many times, further studies in the lab or research community eventually result in a better understanding of the variant. If this happens, it may be reclassified. Since the exact role of a VUS in disease or health risk is unknown, strong caution is encouraged when using these findings for medical management purposes or family risk assessment.

WGS/Whole Genome Sequencing: analysis of the entire human DNA genetic code (genome). Whole exome sequencing is comprehensive and captures DNA variants that might be missed with more targeted whole exome sequencing (see WES). Occasionally, disease-causing variants are located in regions outside the exome, such as in the introns or promoter regions.

WES/Whole Exome Sequencing: sequencing of the protein-coding regions of the human genome, called the genome (see exome). Most disease-causing

mutations are located in the exome. Whole exome sequencing can be more cost effective than whole genome sequencing and focuses on the parts of the genome with potential biologic function.

X-linked Inheritance (also called sex-linked): with respect to human disease, X-linked inheritance is when a genetic condition results from a DNA variant present on the X chromosome. X-linked conditions cannot be passed from a father to his son(s), but can be passed from mother to all children and father to daughter. Many, but not all, X-linked conditions are recessive, which means that they result in symptomatic disease predominantly in males. Examples of relatively common X-linked recessive conditions include red-green color blindness and hemophilia A and B.



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About InformedDNA

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