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Knowledge of Precision Medicine and Health Care: An Essential Nursing Competency

How to incorporate 'omics' sciences into practice.

ABSTRACT: Advances in genetic and genomic research, combined with the rapid development of new technologies, have reshaped our understanding of health and disease processes, generating what have collectively become known as "omics" sciences. These sciences are now an integral part of health care delivery, with nurses and nurse scientists at the forefront, implementing and adapting genomic technologies in the clinical setting while advancing knowledge in these areas. With the increasing focus on precision medicine and health care, integrating genetic and genomic knowledge has become an essential competency in nursing care, research, and education, as it enables nurses to collaborate effectively with patients in improving their health and well-being.

Keywords: genetics, genomics, nursing practice, nursing science, omics, pharmaco-omics, precision health care, precision medicine, Precision Medicine Initiative

Since the late 1970s, there have been calls for nurses to enhance their knowledge of genetics in order to improve patient care.[1,2] The Human Genome Project, which was completed in 2003,[3] sparked the development of faster and less expensive DNA sequencing, giving rise to technologies that advanced various "omics" sciences—those that use genomic technologies to investigate all types of molecules that exist in an organism's cells—and prompting further efforts to improve the genetic and genomic knowledge of nurses.[4] Rapid advances in the various omics sciences and the development of new technologies in data analytics were highlighted in President Barack Obama's 2015 State of the Union address, in which he announced the launch of the Precision Medicine Initiative, the goal of which is to deliver "the right treatments, at the right time, every time to the right person."[5] Nurses, who are consistently ranked the most trusted health care professionals in the United States,[6] are vital in advancing the goals of the Precision Medicine Initiative through

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their day-to-day assessment and monitoring of patients, health history taking, and patient teaching.

This article provides a foundational background in omics sciences and precision health care. After describing the Human Genome Project and the omics sciences it generated, we review the Precision Medicine Initiative; describe the roles pharmacogenetics and pharmaco-omics play in achieving its goals; and discuss the implications for nursing practice, research, and education.

THE HUMAN GENOME PROJECT

The completion of the Human Genome Project, which sequenced the entire human genome, mapping all genes (about 20,500) on the 46 chromosomes and revealing information about their structure, function, and organization,[3] provided insight into both mutations (genetic variations that occur in less than 1% of the population) and polymorphisms (genetic variations that are sufficiently common to be considered normal). Genetic variations confer not only such unique individual characteristics as eye color and blood group, but also susceptibility to such diseases as sickle cell and Tay–Sachs as well as response to treatment. In human populations throughout the world, scientists have identified more than 100 million of the most common type of genetic variation: single nucleotide polymorphisms (SNPs, pronounced "snips"), which result from the substitution of one nucleotide for another in a DNA sequence.[7] When SNPs lie close to each other within a chromosomal segment, they are frequently inherited as clusters, referred to as *haplotypes*. SNPs and haplotypes can increase the level of risk in such complex diseases as Alzheimer's disease and type 1 diabetes but also provide protection against the insulin resistance seen in type 2 diabetes. In addition, they can affect patients' responses to medications developed to treat these diseases.

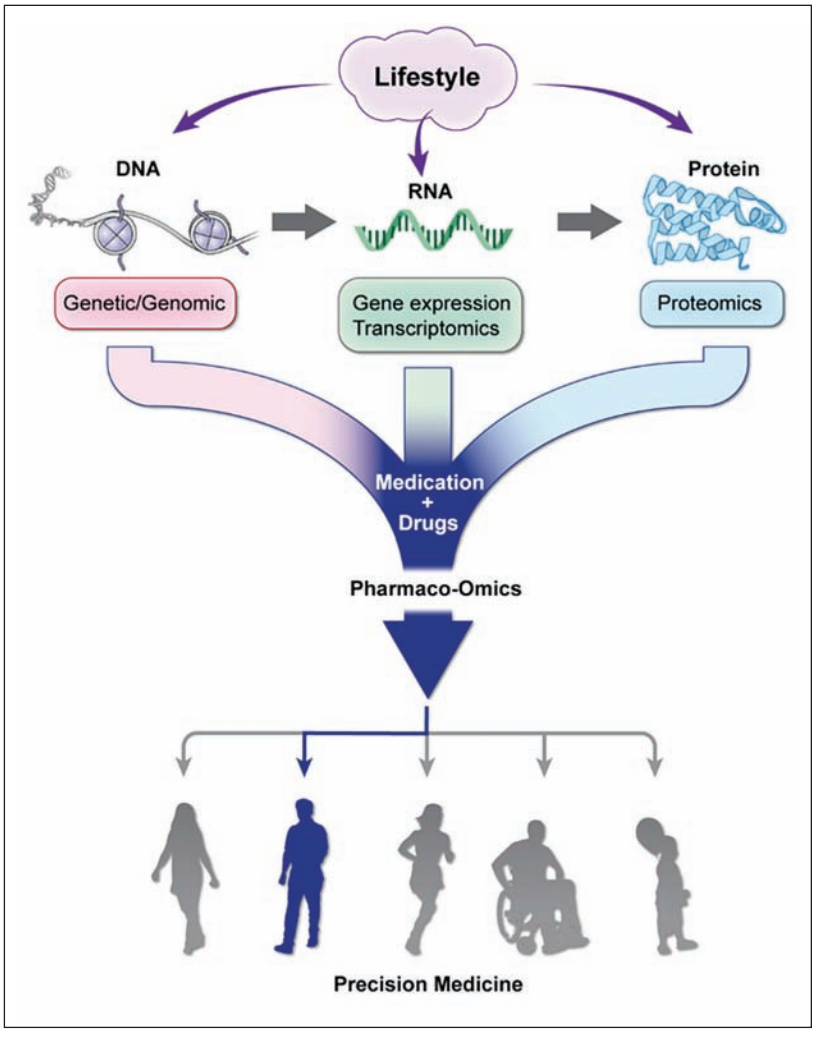

Figure 1. This conceptual framework for precision medicine illustrates that, while genetic information flows from DNA through RNA to proteins, lifestyle influences its expression, which can predict a patient's response to medications (pharmaco-omics). While a large number of patients (signified by the figures in gray) may respond similarly to a particular therapeutic intervention, a small number (signified by the figure in blue) may have a completely different response under apparently similar circumstances. Illustration by Erina He, MS, Medical Illustration, NIH Medical Arts Branch, based on a sketch by Edwin N. Aroke.

OMICS SCIENCES

In the omics sciences, molecules are categorized and studied as groups. The terminology associated with these new sciences is still being refined (see Table 1), but collectively, the sciences are named for the suffix (-omics) attached to the object of their study. For example, sciences investigating the roles, relationships, and actions of the following cellular components are named accordingly:

- genes, *genomics*
- messenger ribonucleic acid (mRNA), *transcriptomics*
- proteins, *proteomics*
- metabolites, *metabolomics*

Table 1. The Terminology of the Omics Sciences and Precision Medicine

Term	What It Means
Alleles	Alternative forms of a gene that occur at a given point (or "locus") on a chromosome. Examples include the alleles A, B, and O, which determine blood type. The term also refers to variation among non-coding DNA sequences.
Biomarker	A characteristic of an organism that can be measured (usually in tissue, blood, or another bodily fluid) as an indicator of normal or pathogenic biological processes or as a response to an exposure or intervention. Examples include a blood pressure measurement, cholesterol level, cortisol level, or SNP.
Clinical genomics	The use of genomic information to direct diagnosis and care.
DNA	The hereditary code found in each human cell. DNA is made up of four chemical bases: adenine, guanine, cytosine, and thymine, the sequence of which determines a person's biological instructions. When genetic code sequences are described, they are written as A, G, C, and T. These bases form specific pairs, A with T and C with G, forming ladder-like rungs that attach to long, vertical side pieces consisting of sugar and phosphate molecules; together, they create the DNA double helix. DNA contains the code required to produce all the proteins an organism needs to function.
Exon	A section of DNA or RNA that codes for amino acids (that is, that tells the cell how to make the protein).
Gene/Genotype	A gene is the sequence of bases in a DNA molecule that contains the instructions to create one or more proteins or other functional molecules. A genotype is an organism's specific collection of genes, inherited from the parents, which contributes to the phenotype.
Genetic signature	The genetic expression associated with a cell, tissue, disease, or tumor type. Well-known examples include those associated with breast cancer: HER2, luminal A, luminal B, or basal-like tumors. Each responds to type-specific, targeted treatments.
Genome/ Genomics/Genetics	The genome is the complete hereditary code found in each of an organism's cells, which includes all of the organism's genes. Genomics is the study of an organism's entire genome. Genetics is the study of specific genes and their functions.
Haplotype	A set of DNA variations on a chromosome that tend to be inherited in a cluster. Haplotypes may include clusters of SNPs or a combination of alleles in a single gene or in multiple genes.
Intron	A section of DNA or RNA that does not code for amino acids. Introns provide the "brakes" in the code that tell the cell where to start and stop the creation of a specific protein.
Metabolomics	The study of metabolites, the small molecules (as opposed to large molecules like proteins) within an organism that have metabolic functions. Metabolomics provides insight into environmental influences on genetic expression.
Next-generation sequencing	High-throughput DNA sequencing technologies that followed first-generation Sanger DNA sequencing. NGS sequences DNA and RNA much more rapidly and at a lower cost.
Nutrigenomics	The study of the interactions of nutrition and genes—how diet affects genes and how genetic variations influence response to nutrients—especially as these interactions are related to disease.
Omics	Sciences that use technologies to investigate the molecules that exist in an organism's cells. Also, the technologies used to study the roles and relationships of various cells in the body.
Personalized medicine	A term formerly used to describe what is now referred to as precision medicine. The term is rarely used today, out of concern that it connotes the development of a unique treatment for every patient.

Table 1. Continued

Term	What It Means
Pharmacogenomics	A science that combines the fields of pharmacology and genomics to study the interaction of drugs and genomes and how genetic variation influences a person's response to certain drugs.
Phenotype	The observable characteristics of an organism. The expression of a person's genotype after interaction with the environment.
Precision health	A proactive approach to health care that aims to predict, prevent, and treat or slow the progression of disease by precisely defining the genetic, developmental, behavioral, and environmental factors that promote health. The concept can be extended to include precision public health, the goal of which is to promote health and reduce health disparities within populations.
Precision medicine	An approach to health care that considers genetic variability, as well as environmental and lifestyle factors.
Proteins	A class of molecules composed of one or more long chains of amino acids sequenced to correspond to the DNA sequence of the encoding gene. Proteins include enzymes, antibodies, and structural proteins like actin, which are essential for the structure, function, and regulation of tissues and organs. The instructions for building each protein are found within the gene.
Proteome/ Proteomics	The proteome is the set of all proteins produced by an organism or a cellular system, including the modifications made to the proteins. Proteomics is the study of the proteome, protein expression, function, and structure. Researchers in this area locate, identify, and compare the proteins that occur in a cell, quantifying their amount and size, and determining how they function. Proteomics allows investigators to study how protein expression within a cell is affected by specific pathophysiologic conditions, such as cancer or immune deficiency, and in response to various stimuli, such as drugs and physiologic or environmental stressors.
RNA/mRNA	RNA is a biomolecule essential to determining how the data in our genes influence cell function. The term mRNA refers to a single-stranded RNA molecule that complements one of the DNA strands of the gene, copies its genetic code, and carries that code from the cell nucleus to the cytoplasm, where an organelle called a ribosome reads the base sequence and uses it to translate the instructions so that amino acids can be joined to create a specific protein chain.
Single nucleotide polymorphism	SNPs (pronounced "snips") are differences in a single nucleotide within a gene (such as an A replaced by a G), resulting in a genetic variation.

HER2 = human epidermal growth factor receptor 2; mRNA = messenger RNA; NGS = next-generation sequencing; RNA = ribonucleic acid; SNP = single nucleotide polymorphism.

These biomarkers—and others—can be used to study both normal physiologic function and pathophysiologic states. Findings from such studies are being incorporated into clinical decision making for the prevention, screening, diagnosis, prognosis, treatment, and monitoring of disease and to predict responses to environmental exposures or medical interventions.[8,9]

Predictive biomarkers. In humans, for example, a number of drugs are metabolized by the cytochrome P-450 (CYP) 2D6 enzyme, which is encoded by the CYP2D6 gene. More than 100 CYP2D6 alleles (alternative forms of the gene) have been defined by the Cytochrome P450 Nomenclature Committee and can be used—some now and some in the future—to predict which patients are more likely to have desired or adverse responses to various drugs, including codeine, a prodrug that the CYP2D6 enzyme converts to morphine (the active drug) for pain relief.[10] This knowledge has been used to create a scoring tool that classifies people by likely codeine metabolism phenotype into poor, intermediate, extensive, or ultrarapid metabolizers.[10]

Normally, people have copies of two functional alleles of the CYP2D6 gene (one from each parent), but as many as 2% of the population inherit more than two functional copies. Such people are referred to as ultrarapid metabolizers because their CYP2D6 enzyme system processes codeine at a much faster rate than that of those who have copies of only two

functional alleles.[10] On the other end of the spectrum, as many as 10% of the population are poor metabolizers of codeine because they have no functional alleles of the gene. Whereas ultrarapid metabolizers quickly convert codeine into morphine, potentially leading to morphine toxicity, poor metabolizers receive little to no analgesia from the administration of the drug. The CYP2D6 genotype is thus a useful biomarker for predicting which patients might have adverse or inadequate responses to codeine and other drugs.

Tailoring patient care based on genomic biomarkers requires highly competent practicing physicians, advanced practice nurses, RNs, LPNs, and pharmacists who understand the omics sciences.[11]

THE PRECISION MEDICINE INITIATIVE

The idea underlying precision medicine isn't new. Prescription eyeglasses and blood typing have been in use for more than a century. Just as ophthalmology and blood typing reveal people's unique characteristics, the technologies used in precision medicine uncover distinctive biomarkers, such as gene variants and altered levels of certain hormones or metabolites, which may be used in conjunction with lifestyle and environmental information to prevent, diagnose, treat, and monitor disease. The National Institutes of Health notes, however, that "while some advances in precision medicine have been made, the practice is not currently in use for most diseases."[12]

Concerns about the initiative. Many have expressed concerns that despite precision medicine helping only a small proportion of the population, its funding may come at the expense of other initiatives with much broader applicability.[13] Although precision medicine holds much hope for some patients, many groups, including lower-income populations, the uninsured, and racial and ethnic minorities, have not been well represented in research studies, in part because of lack of access and the high cost of health care.[13] There are thus fears that the findings of precision medicine studies may be inherently biased. Furthermore, precision medicine studies often require participants to allow significant amounts of biological data and specimens to be stored for use in future research whose specific purpose is not yet known, a practice that may breed mistrust and fears of stigmatization or loss of privacy, further limiting the diversity of the populations studied.[13-15]

'All of Us.' An important component of the Precision Medicine Initiative is the creation of a research cohort comprising at least 1 million volunteer participants who represent the diversity of the U.S. population with regard to age, health status, race, socioeconomic background, and environmental exposures. This cohort, referred to as "All of Us" (see https://allofus.nih.gov), lays the groundwork for a new way of conducting research. The underlying idea is that response to therapy, which varies among patients from highly effective to ineffective to detrimental, is often rooted in unrecognized pathophysiologic, environmental, behavioral, and genetic factors.[16] But a diverse cohort, 1 million strong, could enable researchers to identify many of the unknown circumstances that influence both disease risk and response to treatment, allowing them to develop better targeted preventive and therapeutic strategies. Just as lung, breast, and colon cancers are treated based on tumor genotype rather than disease site, it's now possible to treat chronic myeloid leukemia, in which the *BCR-ABL* fusion gene is a driving force, with imatinib (Gleevec), a tyrosine kinase inhibitor that targets BCR-ABL.[17] The hope is that the data obtained from the All of Us cohort will reveal more about drug–gene (pharmacogenomic) and gene–gene associations, lead to the discovery of new biomarkers and drug therapies, and illuminate the effects of lifestyle and environment on patients' responses to numerous therapies.[16] (See *How to Be a Part of 'All of Us.'*)

Pharmacogenomics, which combines pharmacologic and genomic data to predict a patient's response to medications, underlies the basic premise of the Precision Medicine Initiative. Through pharmacogenomics, we have learned that alterations in DNA sequences can change the expression or function of proteins that are targeted by drugs or involved in drug metabolism or absorption, possibly affecting the patient's response. Genomic variations affecting drug metabolism are explored using targeted single-gene techniques (pharmacogenetics) or global techniques that consider the entire genome (pharmacogenomics).

Pharmaco-omics, which grew out of pharmacogenomics, is the study of how data from the various omics sciences can be used to individualize and optimize drug therapy.[18] Each year, adverse drug effects are responsible for more than 1 million ED visits in the United States.[19] In fact, approximately 7% of the medications approved by the U.S. Food and Drug Administration (FDA), which represent

How to Be a Part of 'All of Us'

- People interested in joining the "All of Us" cohort can enroll through participating health care organizations throughout the country or directly online (visit www.joinallofus.org/en).
- Nurses can participate in this initiative as researchers, participants, or recruiters (by referring potential participants who represent the diversity of their community).

18% of U.S. outpatient prescriptions, are affected by "actionable pharmacogenes"—that is, genetic variants for which there is clear evidence of a clinical effect.[20]

Lifestyle and environmental exposures must also be considered in precision medicine, because while genetic information flows from DNA through mRNA to proteins, lifestyle and environmental exposures can influence the process at every step. The study of environmental influences on gene expression is called *epigenetics*. By extension, the study of environmental influences on the expression of genes that affect response to drugs is known as *pharmacoepigenetics*. Together, pharmacoepigenetics and pharmaco-omics can help clinicians tailor treatments to patients' unique needs, which is the practice known as precision medicine (see Figure 1).

PRECISION MEDICINE AND NURSING CARE

In precision medicine, a patient's course of treatment, medications, and dosages are influenced by pathophysiologic, behavioral, genetic, and environmental (including socioeconomic) factors. Precision medicine affects nearly every aspect of nursing care, from admission assessment and collection of family history to postdischarge monitoring, regardless of the nurse's work setting, academic preparation, or clinical specialty.[21] During the initial patient encounter, nurses document a comprehensive list of health issues experienced by all family members, including those who have died, especially if death was sudden or occurred at an early age. For example, a family history of sudden death in a patient presenting with syncope and a prolonged QTc interval should alert the nurse to refer the patient for further testing, including genetic testing. Studies have shown that long QT syndrome (LQTS) has genetic causes in at least 75% of those affected.[22] However, congenital LQTS and drug-induced LQTS share many common features. Referral will expedite appropriate diagnostic testing, including genetic testing as indicated, and determine the appropriate diagnosis and treatment. Working as a team, the nurse and the patient or family members identify health trends in the family history, paying special attention to diagnoses, symptomology, causes of death, and sensitivity or adverse reactions to any drugs, such as those metabolized by the CYP2D6 enzyme.

Ultrarapid metabolizers. In 2012, Kelly and colleagues reported on two cases of death and one case of life-threatening respiratory depression following codeine administration to children who had undergone adenotonsillectomy for obstructive sleep apnea.[23] Postmortem genotyping revealed that one of the children who died was an ultrarapid metabolizer of codeine owing to CYP2D6 gene duplication. In the second case of death, postmortem blood samples strongly suggested that the child was also an ultrarapid metabolizer of codeine because the concentration of morphine was exceptionally high compared with that of codeine. In the third case, the child was successfully resuscitated after having been found unresponsive with a fever of 100°F (37.8°C) and an oxygen saturation level of 65%. Subsequent genotyping suggested she was an extensive codeine metabolizer, but morphine levels suggested ultrarapid metabolism, which was inconsistent with her genotype.

Nurses may soon find pharmacogenomic data with clinical decision support incorporated into EHRs.

Restrictions on codeine and tramadol. CYP2D6 genetic variability among patients has led the FDA, American Academy of Pediatrics, Clinical Pharmacogenetics Implementation Consortium (CPIC), World Health Organization, and European Medicines Agency to issue restrictions, strong warnings, and recommendations on codeine.[10, 24-26] In addition, the FDA has restricted the use of tramadol (Conzip, Ultram), which is also metabolized, at least in part, by the CYP2D6 enzyme. Both drugs are now contraindicated by the FDA in the treatment of children under age 12 and in those under age 18 in the presence of obesity, obstructive sleep apnea, or severe lung disease. Tramadol is further contraindicated in the treatment of pain in children under age 18 following tonsillectomy or adenoidectomy. Likewise, breastfeeding mothers are warned not to use medications containing either of these drugs.[24, 26] The CPIC guidelines recommend that codeine should be avoided in all CYP2D6 ultrarapid or poor metabolizers to lower the respective risks of toxicity and poor analgesia, and they point out that CYP2D6 is also involved in the metabolism of other opioids, including hydrocodone (Hysingla, Zohydro) and oxycodone (OxyContin and others).[10]

While nurses may not know a patient's genotype at the point of care, they can report any family history of codeine sensitivity to the prescribing clinician and take precautions any time codeine is administered, monitoring patients—particularly

pediatric patients—frequently for signs of respiratory depression. Nurses can also bear in mind that patients who report no response to codeine may not be drug seeking but rather poor metabolizers of the drug. Alternative analgesics may be considered.

Preemptive genotyping. With pharmacogenomic data increasingly incorporated into drug labels, researchers have begun to suggest that there may be a role for preemptive genotyping in such areas as anesthesia[27] and statin therapy.[28] Nurses may soon find pharmacogenomic data with clinical decision support incorporated into electronic health record systems.[28]

Targeted cancer therapies. Oncology nurses have long helped patients understand how precision medicine affects cancer treatment, explaining how cancers are evaluated for specific treatments; how treatments are administered; and the treatment's mechanism of action, as well as associated risks, benefits, and adverse effects. Numerous cancers can now be targeted by small molecule inhibitors, such as monoclonal antibodies, which are created in a laboratory to find and destroy particular cancer cells. For example, bevacizumab (Avastin) is a monoclonal antibody that destroys cancer cells by stopping angiogenesis. Others, such as trastuzumab (Herceptin) and cetuximab (Erbitux), target epidermal growth factor receptors that are important for cell growth in some breast and colorectal cancers.[29]

Selected Genetics, Genomics, and Precision Health and Medicine Resources

FOR NURSES

American Nurses Association
Genetics and Personalized Medicine
www.nursingworld.org/practice-policy/nursing-excellence/ethics/genetics

American Society of Human Genetics
Health Provider Genetics Resources
www.ashg.org/press/healthprofessional.shtml

International Society of Nurses in Genetics
www.isong.org

National Human Genome Research Institute
www.genome.gov

National Institute of Nursing Research (NINR)
Precision Medicine and NINR-Supported Nursing Science
www.ninr.nih.gov/researchandfunding/precisionmedicine#.V8QxtZgrLcs

National Institutes of Health (NIH)
All of Us Research Program, NIH Precision Medicine Initiative
https://allofus.nih.gov

PharmGKB
www.pharmgkb.org

University of Utah Genetic Science Learning Center
https://learn.genetics.utah.edu

FOR PATIENTS

NIH U.S. National Library of Medicine
Genetics Home Reference: Your Guide to Understanding Genetic Conditions
https://ghr.nlm.nih.gov

What is direct-to-consumer genetic testing?
https://ghr.nlm.nih.gov/primer/testing/directtoconsumer

PRECISION MEDICINE IN NURSING RESEARCH

In 2012, the Genomic Nursing State of the Science Advisory Panel developed a blueprint that identified priority areas for nursing research in genomic science.[30] Williams and colleagues expanded the work of the panel in a bibliometric review that examined data-based genomic nursing articles published between 2010 and 2014.[31] Their findings indicated that the majority of nursing research conducted within that period had focused on biologic plausibility and that there were substantial gaps in the areas of ethics and clinical usefulness. The National Institute of Nursing Research (NINR) incorporated elements of the blueprint into its 2016 strategic plan, and Eggert outlined how the blueprint and the NINR strategic plan link to nursing research categories, suggesting opportunities for nurse researchers in this area.[32]

Nurse scientists at the NINR have developed a model to guide research in symptom science.[33] The model begins with a patient presenting with complex symptoms. The symptoms undergo phenotypic characterization based on biological and clinical data, which provide the researcher a means of identifying biomarkers. Ultimately, the biomarkers yield clinical applications that improve symptoms. Nurses at all levels of education, working in all health care settings, can use this model to inform potential research projects.

For example, when a team of researchers led by a nurse scientist investigated the clinical usefulness of plasma tau concentrations after sport-related traumatic brain injury (TBI), they discovered that athletes who had elevated levels of this biomarker after sustaining a concussion demonstrated delayed recovery.[34] The work of these researchers could

lead to the development of a reliable, rapidly available test for identifying athletes requiring a longer recovery period before returning to play after TBI.

IMPLICATIONS FOR NURSE EDUCATORS

In 2009, the American Nurses Association (ANA) published *Essentials of Genetic and Genomic Nursing: Competencies, Curricula Guidelines, and Outcome Indicators*, which recommends that academic faculty collaborate with other disciplines to incorporate genetic and genomic information in courses and participate in both National Council Licensure Examination (NCLEX) and certification test development to ensure that test items assess knowledge of pertinent aspects of genetics and genomics.[35] Practicing nurses are encouraged to pursue this information through continuing education. Calzone and colleagues describe outcome indicators for genetics and genomics nursing competencies.[36] Several resources are available to nurses working to advance their knowledge in these areas (see *Selected Genetics, Genomics, and Precision Health and Medicine Resources*).

Key competencies for nursing practice include the following[35]:

- advocating for patients' access to genetic and genomic resources, services, and support groups, such as condition-specific groups, genetic support groups, and rare diseases groups
- incorporating technologies specific to genetics and genomics into nursing practice
- presenting information to patients in a way that is appropriate to their culture, religion, knowledge, and literacy level, and in their preferred language

Nurses may need to expand or acquire skills in the following areas[35]:

- identifying relevant genetic, environmental, and genomic information in patients' health histories
- generating and documenting a pedigree based on available family history
- identifying patients who may benefit from genetic and genomic information based on assessment data
- understanding the ethical, legal, fiscal, and societal issues related to genetic and genomic information

Since patients may need help interpreting and understanding genetic and genomic information, nurses need to have a good understanding of these topics in order to provide appropriate support.

For nurses in advanced practice, the ANA and the International Society of Nurses in Genetics published the *Essential Genetic and Genomic Competencies for Nurses with Graduate Degrees*, which identifies 38 competency areas, ranging from genetic risk assessment and clinical management to leadership and research.[37]

AN INTEGRAL PART OF HEALTH CARE DELIVERY

The rapid development of genetic and genomic technologies and related discoveries has dramatically changed the delivery of health care. Nursing science will continue to contribute to this area of research. Incorporating knowledge gained from the various omics sciences helps nurses build on skills they already possess, such as collaboration, patient advocacy, patient and family education, patient assessment, and documentation. Developing a strong knowledge base in these sciences and technologies will ensure that nurses can collaborate effectively with patients and other health care providers to advance the goal of precision medicine for the benefit of all patients. ▼

For five additional continuing nursing education activities on the topic of genomics, go to www.nursingcenter.com/ce.

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