





NURSING INFORMATICS UPDATE

Together into the future...

Pharmacogenomics and documentation

New partnerships target optimal care quality and outcomes

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Pharmacogenomics, the study of how genes affect a person's response to drugs, is a relatively new field that combines pharmacology (the science of drugs) and genomics (the study of genes and their functions) to develop effective, safe medications, with doses tailored to a person's genetic makeup.¹ Pharmacogenomics testing, another relatively new field, determines if a medication is right for the patient.²

Why's this so vital to nursing knowledge? We've entered an era in which medication administration is guided not only by the patient's ethnicity, but also the clinical guidelines for up to 36 medications currently used in practice.³ Take a moment to consider that there are now more than 200 U.S. Food and Drug Administration (FDA)-approved medications with pharmacogenomic recommendations.⁴ If these guidelines and tests are implemented, there can be significant improvements in patient safety, care quality, and outcomes, as well as lowered cost and decreased morbidity, mostly from monitoring and avoiding adverse drug reactions.⁵

Nursing's professional practice license mandates that medication administration, ordered by a physician or NP, must be performed by an RN, of which there are currently 3.4 million in the United States.^{6,7} The American Nurses Association (ANA) nursing documentation standards also uphold that the nurse must assess if the medication is appropriate for the patient's diagnosis, if the dose is appropriate, what the reaction to the medication is, and whether there are adverse reactions to the medication.⁶ This nursing process entails assessment; diagnoses/problems/clinical judgments; expected

outcome identification and planning; implementation; and evaluation toward attaining identified outcomes.⁸ Whereas medication documentation has been drilled into nurses as the five rights—right patient, right dose, right drug, right route, and right time—as the foundation of safe practice when administering medications, pharmacogenomics targets the right drug, for the right person, at the right dose. (See Table 1.)

Nurses with advanced prescriptive authorities also need to be well versed in pharmacogenomics guidelines and tests. These nurses have extra responsibilities in

many states for prescribing medications, in addition to reporting on adverse drug reactions. Also, informatics nurses implementing and updating electronic health records (EHRs) need to stay informed. The ANA recently added the concept of genetics/genomics to its third edition of *Nursing Informatics: Scope and Standards of Practice*. These standards state that informatics nurses must be able to “incorporate genetic and genomic technologies and informatics into practice” and “demonstrate in practice the importance of tailoring genetic and genomic information and services to clients based on their culture, religion, knowledge level, literacy, and preferred language.”⁹

There's an urgent need for information systems and communication teams within nursing, pharmacy, genetics, and medical practice to administrate and document medications delivered, and adverse drug reactions observed. Also necessary is further collaborative research into the implementation of pharmacogenomics guidelines, development of standards, and translation into clinical decision support systems within EHRs. How do we improve the clinical implementation of medication administration, observation, and evaluation of impact in this era of pharmacogenomics without enhancing the partnerships between nurses, pharmacists, geneticists, and physicians? Simply put, we can't.

Impact of safe drug practices

The goal of precision medicine is to identify when the evidence base supports the integration of genomics into medication

Table 1: A case study

Nurse N notes an order for codeine to be administered to a 9-year-old male child of African descent. She knows from the CPIC guidelines that codeine has the potential to be metabolized into its active form by the hepatic enzyme CYP2D6. Poor metabolizers are unlikely to benefit from codeine, and ultrarapid metabolizers may experience respiratory depression or sleep apnea even at normal doses. Signs of respiratory depression can occur up to 1 to 2 days after administering codeine. While accessing the CPIC guidelines, Nurse N also learns that about 29% of African/Ethiopian individuals are expected to be ultrarapid metabolizers of codeine.³⁷ She asks the physician if she should test the child for CYP2D enzyme, and is told that it isn't routine practice at their hospital. She then asks the pharmacist what alternative medications can be given. The pharmacist urges caution in using alternative analgesics, including oxycodone, hydrocodone, and tramadol, because they're also metabolized to some degree by CYP2D6. The pharmacist recommends that Nurse N watch for respiratory depression or sleep apnea, so she changes vital sign monitoring to every 2 hours.

The child states a 10+ on the pain scale, so Nurse N administers the codeine and later observes that his respiratory rate decreases to fewer than 5 breaths/minute. She notifies the physician and pharmacist. Appropriate intervention is ordered and administered. She continues to monitor the child's respiratory rate, which returns to normal within 15 minutes. Nurse N adds the information that the child can't metabolize codeine into her assessment and the fact that his mother couldn't tolerate codeine postpartum to the family history profile.

In their incident report, the entire team recommends that ethnic variability be considered when administering codeine and the CYP2D6 enzyme tested in select patients whose mothers taking codeine for pain have a history of sleepy infants after nursing them. In this case, the child had a positive outcome. However, the outcome could've resulted in death and lawsuits for the hospital, as was the case with a pediatric patient receiving codeine whose mother observed the breathless child on day 1 after an outpatient tonsillectomy.³⁸

decision making. In addition, the decision logic needs to relate the drug response to environmental and lifestyle differences that coexist. This approach enables more exact ways to identify the right drug with the optimal dosing to minimize adverse drug reactions for the individual patient.

In our current environment of precision medicine and pharmacogenomics, nurses have a right to access reliable drug information, guidelines, and expert pharmacists' opinions. Pharmacists are the "drug experts" on the team who nurses should have access to 24/7. When rounding to coordinate patient care, the physician, nurse, and pharmacist need to consider whether the drug prescribed is too new to be in a usual reference manual, on the computer, or informed by the patient's genetic disposition.

Assessing patients' pharmacogenomics activity, the team has to decide: 1) if the drug is toxic to the patient, but beneficial; 2) if the drug isn't toxic, but not beneficial; 3) if the drug is toxic, but not beneficial; or 4) if the drug isn't toxic, but beneficial. According to the FDA, approximately 7% of approved medications, accounting for approximately 18% of outpatient prescriptions, are associated with actionable genetic variations.¹⁰ Even the CDC recently estimated that 700,000 ED visits have resulted from adverse drug reactions; of these, up to 120,000 required hospitalization.¹¹ This translates into healthcare costs: an average ED visit costs more than genetic tests for adverse drug reactions, which can be performed for less than \$500.

Decision-support guidelines

The Pharmacogenomics Knowledge Base (PharmGKB) is a funded project by the National Institutes of Health (NIH).¹² In this project, scientists, clinicians, and pharmacists collect, curate, and disseminate evidence on the association between human genomic variation and differences in individual drug response. PharmGKB provides clinical associations that may require lowering doses or changing to alternative medications.

Currently, patient response to drugs is based on a synthesis of the literature and grading of evidence similar to the clinical practice guideline methodology. The level of evidence determines the strength of the guideline for clinical implementation. The Clinical Pharmacogenetics Implementation Consortium (CPIC) guidelines are made available from an open member organization managed at Stanford University and St. Jude Children's Research Hospital.^{13,14} There are currently 36 guidelines with sufficient evidence to implement in clinical practice. (See *Table 2*.) In addition, there are specific recommendations for warfarin, tamoxifen, selective serotonin reuptake inhibitors, and clopidogrel.¹⁵ As previously mentioned, the FDA has specific pharmacogenomics biomarkers on labels for drugs used in oncology, cardiology, neurology, infectious diseases, and psychology.⁴

Medication administration, effects, and outcomes are documented by nursing professionals in the EHR. This documentation facilitates real-time communication among pharmacists, physicians, and other healthcare providers.

Table 2: CPIC guideline drugs³

- Abacavir
- Allopurinol
- Amitriptyline
- Atazanavir
- Azathioprine
- Capecitabine
- Carbamazepine
- Citalopram
- Clomipramine
- Clopidogrel
- Codeine
- Desipramine
- Doxepin
- Escitalopram
- Fluorouracil
- Fluvoxamine
- Imipramine
- Ivacaftor
- Mercaptopurine
- Nortriptyline
- Ondansetron
- Paroxetine
- Peginterferon alfa-2a
- Peginterferon alfa-2b
- Phenytoin
- Rasburicase
- Ribavirin
- Sertraline
- Simvastatin
- Tacrolimus
- Tegafur
- Thioguanine
- Trimipramine
- Tropisetron
- Voriconazole
- Warfarin

Patient safety is optimized through EHR documentation, and collaboration is more effective and efficient. Cross-patient comparisons can be made when standards are utilized, terms are defined, and common models and frameworks based on evidence are used. Previously, documentation has focused on medication safety, concentrating attention on preventing administration and dosing errors, and monitoring adverse drug reactions and events. The areas of medication errors include prescribing, transcribing, dispensing, and

administering. Pharmacogenomics information can guide optimal medical selection, dosing, drug interaction, and risks for adverse drug reactions based on variation in drug metabolism, including the patient's ability to metabolize, overmetabolize, undermetabolize, or not metabolize the drug.

A whole genome sequencing for a single patient can produce about 1 terabyte of data for a one-time analysis.¹⁶ The average genomic report is 30 pages of very dense information.¹⁷ If a single pharmacogenomics test is done, such as testing single-nucleotide polymorphism or performing a drug metabolism enzymes and transporters platform, a much smaller amount of genetic data is produced. However, the patient may be required to have his or her genomics analyzed at the time of diagnosis and integrated with lab data, clinical observations, tissue biopsy information, histopathology, radiology, and other imaging data. The data volume is so large at diagnosis, treatment, and subsequent evaluations that it can be considered big data. Nurses, pharmacists, and physicians need to have roadmaps and algorithms for integrating these data into current clinical practice and EHRs.

One such roadmap developed by the NIH is a project called ClinGen. This resource has an authoritative source of information on the clinical relevance of genomic variance and genes. Its purpose is to build a central knowledge base for use by other software developers and for adoption in precision medicine. The database provides the answers to three questions: 1) What's the pathogenicity of

the genetic variant?, 2) Is the genetic change associated with a healthcare condition?, and 3) Is the genetic information clinically actionable? Working groups include knowledge curation; education; and information technology (IT), such as implementation into EHRs, policy, and advisors.¹⁸ One project developed to model workflow and algorithms for computerized decision support integrated into the EHR is taking place at St. Jude's Hospital.¹⁹ Other projects supported by the NIH are Implementing Genomics in Practice (IGNITE) and the Electronic Medical Records and Genomics (eMERGE) Network.^{20,21}

Displaying and Integrating Genetic Information Through the EHR, or DIGITize, is a collaborative project of the Health Level 7 Genomics Policy Conference and the National Academy of Medicine Roundtable on Translating Genomic-Based Research for Health.²² Companies have agreed to draft a vision for implementation of genetics/genomics and pharmacogenomics data into the EHR. They concurred in 2015 that Substitutable Medical Applications, reusable technologies (SMART) and Fast Healthcare Interoperability Resources (FHIR) should be tested to determine if open applications can connect genomics information into vendor EHRs. It's expected that these will be recommended standards for integrating all genetic information into the EHR at some point this calendar year.

The National Academy of Medicine (NAM) launched pilot studies to concentrate on pharmacogenomics implementation with vendors, starting with

HLA-B and abacavir because of the known 6% of patients with life-threatening hypersensitivities. The second pilot project is with thiopurine S-methyltransferase (TPMT) and azathioprine because patients have a risk of myelosuppression.²³ To facilitate communication and understanding of the new guidelines implemented into clinical practice, several initiatives have been supported by the NIH and the NAM.

One project implementing computerized decision support into the EHR alerts clinicians that a genetic test may be indicated and changes in drug dosing may be required. For example, a patient taking a thiopurine may have TPMT enzyme activity and would be at risk for myelosuppression if the commonly prescribed dose of 6-mercaptopurine were given. The CPIC guidelines recommend giving a patient with TPMT enzyme activity a 30% to 70% lower than recommended dose. On November 2, 2016, the NIH announced a \$6.3 million grant to integrate patient outcomes into the EHR via a multisite consortium, including several universities throughout the United States.²⁴

Integrating SMART and FHIR, several apps are in development for cancer diagnosis and treatment with pharmacogenomics. One new app connects to Gene Wiki, My Cancer Genome, and HemOnc.org, synthesizing information and standardizing formats to bring to healthcare providers.²⁵ This app explains how common epidermal growth factor receptor, or EGFR, mutations are in patients and how often the exon 19 deletion is found.

Another app is called 2bPrecise, with a cloud-based genomics and

precision medicine solution that uses clinical genomic ontology and data harmonization to return merged and semantically harmonized information in a machine readable and structured format.²⁶ The NIH is piloting the use of 2bPrecise at the point of care.

One precision medicine software company is focusing on data integration, decision support, clinical workflow, and a learning health framework for genomic data in the EHR.²⁷

The final app involves the use of genomic treatments in community

ics. What are some possible models for integrating the information into the EHR through the nursing process?

In genomics literature, patient assessment can be expanded to a concept called the RAPID risk assessment: 1) assess family history and other pertinent data (Does anyone in the family have a history of adverse reactions to particular drugs?); 2) identify the pedigree (patient ethnicity); 3) establish the probability of a genetic condition or predisposition to an adverse drug reaction;

drug reactions are all components of the nurse's role in medication administration and evaluation. (See *Figure 1*.)

As previously mentioned, standards of practice for integrating genetics and genomics into nursing informatics have been developed.⁹ In addition, formal competencies in genetics and genomics have been defined for RNs and advanced practice RNs (APRNs).^{30,31} General genetics/genomics competencies for physicians have also been developed.³² Following the consensus



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oncology patients in medical home care.²⁸ This application is using decision support with clinical treatment protocols. The treatment team includes oncologists, diagnostic radiologists, NPs, pharmacists, medical technicians, and care coordinators working together as community responders. The data are integrated with lab, radiologic, and molecular testing at each state of diagnosis for 12 cancers with treatment protocols.

Nursing practice implications

The previous examples of integrating guidelines into EHRs are more closely related to medical integration of pharmacogenom-

ics. 4) assess the risk and communicate with a genetic counselor or geneticist (if available), pharmacist, and physician; and 5) assess a management strategy (recommending that pharmacogenomics tests be done and/or that the NP or physician changes the patient's medication orders based on observed adverse drug reactions).²⁹

Putting the new pharmacogenomics influences into the nursing process; performing the RAPID risk assessment; communicating with geneticists, genetic counselors, pharmacists, and physicians; administering medications based on pharmacogenomics guidelines; and monitoring possible adverse

model, a panel on pharmacist pharmacogenomics competencies was published in 2012.³³ Despite these competencies, there's an urgent need to educate a critical mass of nurses about genetics/genomics and pharmacogenomics.

In addition, the need remains for more international coalitions to build on the current competency resources and optimize strategies for implementing genetics/genomics and pharmacogenomics into the EHR for point-of-care decision making. To that end, last year, a group of international informatics nurses met in Switzerland to identify the competencies needed to

move forward with integrating genetics/genomics and pharmacogenomics competencies into the EHR and nursing practice through nursing informatics.³⁴

Also, the Global Genomic Nursing Alliance, another international nurse group representing 19 countries, aims to: 1) accelerate integration of genomics into everyday nursing practice; 2) establish a global nursing alliance for knowledge mobilization and action around development in nursing and genomic health-care; 3) create a roadmap for integrating genomics into nursing education, practice, and research; and 4) prioritize the collaborative efforts to realize a roadmap.³⁵ An America leader of this group believes that embracing genomic healthcare requires “a prepared workforce that can inform, educate, and empower people. This represents a significant challenge as deficits in nurses’ knowledge

and skills in genomics are widely acknowledged.”³⁶

Opportunities for national and international collaboration abound, but issues include funding these large networks of information, developing resources for nurses, drafting policies, and ensuring educational competencies. Repositories exist for identifying proteins for pharmacogenomics, but there’s no database for identifying the common adverse reactions or symptoms observed by nurses. (See Table 3.) Clinical decision support needs to be developed that integrates genetics/genomics and pharmacogenomics into the nursing process. Tools must be created to transform the CPIC guidelines, in addition to drug-drug interaction and drug overdose guidelines, into user-friendly formats for nursing documentation. Standards and policies need to be adopted to integrate these

Table 3: Selected adverse drug reactions

- Anemia
- Bone marrow (hypocellular)
- Decreased breath rate/sounds; apnea
- Disseminated intravascular coagulation
- Febrile neutropenia
- Hemolysis
- Hemolytic-uremic syndrome
- Leukocytosis
- Lymph node pain
- Myelosuppression
- Spleen disorder
- Thrombotic thrombocytopenic purpura

guidelines into the EHR and clinical decision support systems. Standard nursing terminologies should become inclusive of genetics/genomics and pharmacogenomics terms.

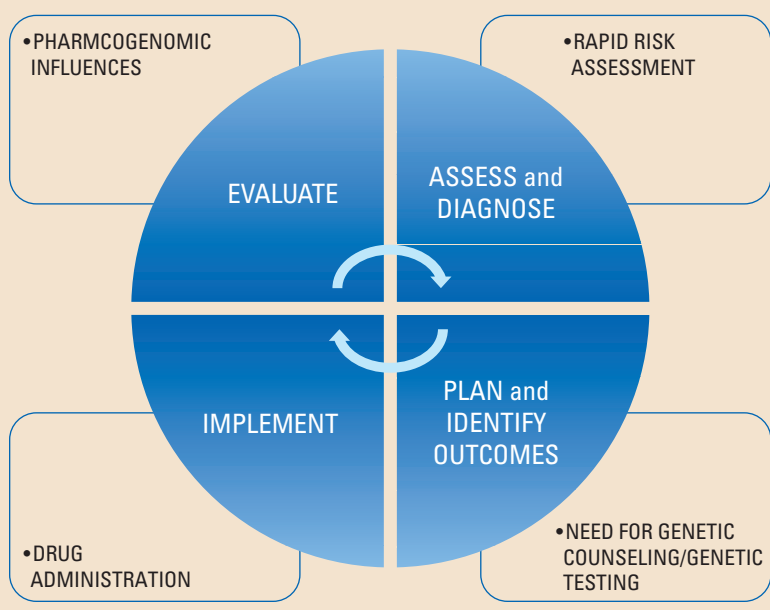
Challenges to address

There are six recommended content areas for nurse administrators to focus on when supporting nurses to integrate pharmacogenomics into patient care.

1. Nurses need continuous education—pharmacogenomics information changes rapidly. Lack of knowledge is a principal obstacle to translation of precision medicine findings into clinical practice. The nursing profession should be knowledgeable about the relevance of pharmacogenomics to patient care. We need a cadre of genetically literate nurses in administration, practice, informatics, genetic counseling, policy making, research, and academic centers.

2. The nursing profession needs data and standard terminology, including transmission, integration, and vocabulary standards.

Figure 1: Integration of the nursing process with pharmacogenomics and RAPID risk assessment



3. Nurses must be active participants in regulations and policies on genetics/genomics and pharmacogenomics. These include workforce regulations and policies, especially for APRNs who prescribe medications, and professional standards organizations. Data-sharing standards and policies also require nursing input. Ethical/legal and social policies remain a huge influence on adopting genetics/genomics and pharmacogenomics discoveries.

4. Nurses must be involved in healthcare IT and shaping the next generation EHR that includes genetics/genomics and pharmacogenomics. Nurses need to influence key stakeholders and vendors to include family health history and ethnicity in nursing assessments going forward. As previously mentioned, more clinical decision support should be developed for nurses to integrate CPIC guidelines, RAPID risk assessments, observations, and documentation of potential and real adverse drug reactions into the EHR.

5. Nurses need to be engaged in continually updating research that includes pharmacogenomics content and evaluating the outcomes for quality, safety, and cost impacts of nursing care. Measuring comparisons of management strategies and outcomes will occur when sufficient funding is available for nurses to conduct such studies.

6. Nurses must remain engaged in the innovative software that's attempting to translate pharmacogenomics into clinical practice. Translation into clinical practice should be broad to include not only the EHR, but also mobile devices and social media.

Advancing through collaboration

If pharmacogenomics is integrated into the nursing process, patient safety, care quality, and outcomes can improve. Nurses, pharmacists, and other clinicians require training in pharmacogenomics competencies to effectively use them in clinical practice. Genetics and genomics competencies are available for nurses regardless of their degree, clinical role, or specialty. We must continue to work together through the identified challenges to implement pharmacogenomics into nursing practice. **NM**

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