



Strengthen federal and local policies to advance precision health implementation and nurses' impact on healthcare quality and safety

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Executive summary

The American Academy of Nursing (The Academy) supports sustaining and building on institutional and regulatory policies to ensure that adequate infrastructure and workforce is in place for precision health implementation by nurses and other healthcare team members. In order to realize anticipated improvements in healthcare quality and safety, the Academy will continue to provide opportunities in the area of precision health policy development to Academy Fellows and nurses across the nation. In 2016, H.R. 34—the 21st Century Cures Act—was signed into law under the 114th Congress. This law supports the United States Department of Health and Human Services in the pursuit of precision health, with the goals of advancing disease prevention, diagnosis and treatment, as well as implementation of greater data sharing. Nurses are essential members of the health care team and continue to have a major role in precision health, however, more can be done if appropriate infrastructure is put into place to support precision health implementation and direct the goals toward improving healthcare quality and safety.

The American Academy of Nursing (The Academy) fully endorses the policy recommendations that aim to strengthen nurses' impact on advancing the implementation of precision health. The Academy supports nurses across the nation to: (a) participate in policy development and implementation of precision health across clinical and research settings; (b) ensure the routine collection of standardized nursing care data in electronic health records (EHRs), advocate for the collection and proper storage of additional data elements to more effectively apply genomic information, and demand that decision support mechanisms be developed and made available in EHRs to support the safe, secure, and effective use of genomic data; (c) understand and address gaps in what patients, research participants, and the public need to know about precision health implementation; and, (d) advocate for sufficient training, resources and continuing education on implementation of precision health including but not limited to, patient education and health literacy assessment, data security, decisions regarding return of genomic results, and clinical support for interpreting and acting upon genetic test results and clinically actionable findings. Furthermore, the Academy calls on the Department of Health

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and Human Services to strengthen requirements for electronic health records vendors and healthcare institutions to integrate precision health decision support technologies and data security measures that will improve nurses' ability to make a positive and sustained impact on healthcare quality and safety.

Background

On October 8, 2017, a Policy Dialogue was held at the American Academy of Nursing annual conference entitled *Policy on Precision Health: Addressing the Intersections Between Omics, Informatics and Bioethics*. The panel was composed of Dr. Janet Williams representing the Genomics & Health Care Expert Panel, Dr. Kathleen McCormick representing the Informatics Expert Panel and Dr. Dara Richardson-Heron, Chief Engagement Officer of the National Institutes of Health *All of Us* research program. Several key issues regarding the role of nurses in precision health and health policy implications emerged as a result of the dialogue and discussion.

The full implications of precision health

Following the passage of H.R. 34, the 21st Century Cures Act, into law in 2016, precision health has been widely expected to change the face of health care, allowing for personalized disease prevention and treatment based on each individual's genomic information. In order for this goal to become reality, the health care infrastructure must support the collection and interpretation of health information in conjunction with the individual's social and lifestyle data, biological specimens including DNA, behaviors and their environmental context. Precision health capitalizes on the informatics infrastructure in order to facilitate interventions aimed at helping individuals achieve well-being and optimal health (Khoury, Iademarco, & Riley, 2016). The goal of precision health is intended to provide a schema, or blueprint, for lifestyle and interventions over the life course. These advancements, however, are hindered by inadequate data collection mechanisms in the electronic health record (EHR), as well as privacy and discrimination concerns (Hickey, Katapodi, Coleman, Reuter-Rice, & Starkweather, 2017).

Privacy and discrimination concerns regarding genomic data use in health care raise several ethical and legal concerns that remain to be addressed in precision health implementation. The primary concern is the risk of loss of privacy once an individual's genome is identified and shared. In addition, genomic information could potentially be misused or used against individuals and families to discriminate or restrict access to care and optimal treatments. For example, genomic data could be used to limit options for care or treatment

and restrict health insurance coverage or payment. While there are laws that help to protect some aspects of information privacy and misuse, there are other areas that remain vulnerable. The Genetic Information Nondiscrimination Act of 2008, also referred to as GINA, is a federal law that prevents discrimination from health insurers and employers based on DNA and genomic information. However, this law does not cover military personnel and does not extend to discrimination in the acquisition of life insurance, disability insurance and long-term care insurance. Proposed legislation, such as H.B. 1313, that would allow employer-sponsored workplace wellness programs to collect genetic information and issue penalties for non-disclosure and/or lifestyle choices. This bill is an example of how policy could promote genetic discrimination instead of protecting the privacy of individuals and families (Hudson & Pollitz, 2017; Pollitz & Rae, 2017).

In addition, issues of health literacy, transparency in marketing of genetic testing and data security are key issues confronting healthcare providers, individuals and families who are engaged in precision health initiatives across the nation (Williams et al., 2015). Some of these critical issues are being addressed through existing policies that apply to participants engaged in research, such as the National Institutes of Health *All of Us* research program. However, failure to expand these protections for healthcare consumers outside of research could compromise a major goal of precision health in improving access to healthcare and strengthening the progress that has been made in quality and safety (McCormick & Calzone, 2016). In addition to addressing the ethical and legal concerns of precision health, the advances in health for the healthcare consumer can only be realized if the information is readily accessible and usable to clinicians through the electronic health record (EHR).

The information technology infrastructure required to support precision health

The Office of the National Coordinator for Health Information Technology (ONC) is authorized by the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009 to support adoption of health information technology (HIT) and promote health information exchange to improve healthcare. The HITECH Act established ONC in law and provides the U.S. Department of Health and Human Services with the authority to establish programs to improve health care quality, safety and efficiency through the promotion of HIT, including EHRs, and private and secure electronic health information exchange. ONC authors regulations that set the standards and certification criteria that EHRs must meet to assure health care professionals and hospitals that the EHR systems they adopt are capable of performing certain functions.

Although ONC has published data security principles for implementation of precision health, the guide is not a requirement of healthcare entities because it goes beyond what is currently required for compliance with the HIPAA Security Rule's requirements for risk assessment and management (U.S. Department of Health & Human Services, The Office of the National Coordinator for Health Information Technology, 2017). In order to gain a deeper understanding of the HIT infrastructure requirements that will be necessary to support precision health, the ONC launched several pilot programs in 2016, Sync for Science and Sync for Genes. Sync for Science (S4S) was launched in February 2016 to make it safe for patients to share EHR data with researchers. The more recent launch of Sync for Genes will enable sharing of clinical genomic data in standard formats that are useful in research and point of care implementation (U.S. Department of Health & Human Services, 2017; U.S. Department of Health & Human Services, 2017). In addition, the implementation of privacy and security safeguards is being piloted, and these studies are expected to share best practices for broader implementation.

Nurses and precision health information technology

The HIT infrastructure has the potential to improve quality, safety, reduce costs, and improve the delivery of care through the integration of individual genomic data into EHRs that contain other vital care information that collectively influence the accuracy of precision health (McCormick, 2017). High quality nursing data gathered in the EHR can provide crucial information for precision health. Such information should include the clinical decision-making, interventions and outcomes that nurses deliver while caring for individual patients. In addition, there are several other ways that nurses can contribute to the advancement of precision health. One way would be to incorporate the rapid risk assessment into the overall patient assessment reported in EHRs collectively by the health team members.

A rapid risk assessment is a structured process of identifying risks based on identification of key information from all readily available sources, use of systematic appraisal of the best scientific evidence and/or specialist expert knowledge available at the time, in order to provide a clear estimate of the scale of the health threat while documenting the level of uncertainty (Maradiegue et al., 2016; McCormick, 2017; McCormick & Calzone, 2016). Incorporating the genomic rapid risk assessment into nursing and other healthcare provider assessments within the EHR would facilitate decision-making and documentation on issues of healthcare quality and safety related to genomic test results (McCormick & Calzone, 2016).

A second way precision health can be advanced by nurses is through supporting the collection of other important data elements in the EHR, including patient reported race ethnicity, and ancestry, a minimum three-generation family history and social determinants of health. Additional functionality of the EHR would enhance nursing delivery of precision health, including the ability to determine risk for unintended drug responses such as inadequate therapeutic response or adverse reactions related to toxicity or hypersensitivity; documentation fields for communication with genetic counselors and genetically trained nurses, consultants, pharmacists, and/or physicians and team members caring for patients/clients; and documentation fields for patients/client entry of their response to personal and/or family health issues relative to their personalized management strategy.

A third way is to ensure that the EHR (database and architecture) connects the results of genomic tests to recommended interventions, both pharmacological and non-pharmacological, and patient outcomes. For example, in order to improve safe prescribing and delivery of medications, prescribers and frontline nurses need information on the patient's predicted response to medications. Improvements in tracking adverse drug events could occur if documentation of adverse drug reactions, effect of drug-drug interactions, drug doses prescribed and administered, and medication adherence in the EHR were connected. Documentation of adverse drug reactions could be linked with a real-time reporting system to the Food and Drug Administration (FDA). In addition, it would benefit nurses and other healthcare providers in their quest to improve healthcare quality and safety if the Clinical Pharmacogenomics Implementation Consortium (CPIC) guidelines were incorporated into the EHR (Caudle, Klein, & Hoffman, 2014; U.S. Department of Health & Human Services, 2017). These measures would enable decision support for assessing and monitoring the effects of drug-drug interaction, as well as provide dosing guidelines (CPIC) on how to adjust treatment of certain medications based on a person's genetic information. In sum, nurses can have a major impact on the advancement of precision health through: (a) ensuring the routine collection of standardized nursing care data in EHRs, (b) advocating for the collection and proper storage of additional data elements to more effectively apply genomic information, and (c) demanding that decision support mechanisms be developed and made available in EHRs to support the safe, secure, and effective use of genomic data.

There several federally funded initiatives designed to accelerate evidence generation and resource development necessary for precision health implementation. Currently, the clinical relevance of genetic and genomic findings is being compiled through a project known as ClinGen, an NIH-funded central resource. ClinGen aims to improve patient care through accurate interpretation of variant information that guide downstream therapeutic recommendations. Data sharing, knowledge

curation, and technology development through ClinGen efforts will accelerate the understanding of genomic variation and implications for healthcare (Rehm et al., 2015). Another project, known as the Pharmacogene Variation (PharmVar) Consortium is building a central, searchable repository that will use standard human genome build references to identify variations and enable the standard assignment of star alleles/haplotypes from various genomic platforms, including short and long read sequencing platforms (Gaedigk et al., 2017). This resource aims to facilitate the interpretation of pharmacogenetic test results to guide precision health. An additional NIH-funded resource, PharmGKB, provides information about how human genetic variation affects response to medications (U.S. Department of Health & Human Services, 2017). PharmGKB collects, curates and disseminates knowledge about clinically actionable gene-drug associations and genotype-phenotype relationships. It provides dosing guidelines for how to adjust treatment of certain medications based on a person's genetic information. The progress of these projects is being disseminated through the Pharmacogenomics Research Network, a national network of clinicians and researchers who are interested in pharmacogenomics (Pharmacogenomics Research Network, 2017). In addition, several national initiatives have been established to facilitate strategies to integrate genomics into EHRs and provide clinical decision support, including the Implementing Genomics in Practice, or IGNITE, a consortium established in 2013 that brings together six NIH-funded projects and a coordinating center (Sperber et al., 2017). Another NIH-organized and funded consortium, the Electronic Medical Records and Genomics, or eMERGE, Network initially focused on combining deidentified genomic data from biorepositories with deidentified EHR data for discovery purposes (Gottesman et al., 2013). Phase III of the eMERGE Network is focused on implementation of genomics into clinical practice and related ethical and social issues (Fossey et al., 2018). It is anticipated that use of the technologies, discoveries, and resources generated from these large initiatives will guide decision-making of nurses and other healthcare professionals at the point of care and make a significant impact on quality and safety.

Responses and policy options

In 2009, the nursing profession established genomic competencies and outcome indicators to prepare the workforce for the integration of genomics in healthcare (American Nurses Association, 2009). In addition, the National Institute of Nursing Research (NINR) included genomics as a strategic theme in 2000 and has supported genomic research for the past two decades. Beyond supporting the Summer Genetics Institute (SGI) since 2000, NINR has been providing immersion training on Big Data over the past several years to prepare

nurses to engage in the quest for integrating clinical and omic data. As part of NIH policy to accelerate interdisciplinary precision health implementation, institutions which receive federal funding, such as entities applying for consortiums or networks, could have a competitive advantage by including elements of importance to nurses and other healthcare providers as well as incorporating indicators of healthcare quality and safety, such as:

- Data fields for documenting genomic rapid risk assessments.
- Collection of patient reported ethnicity/race, ancestry, a minimum three generation family history and social determinants of health.
- Algorithms to predict risk for unintended drug response.
- Clinical decision support tools that incorporate guidelines for therapeutic recommendations based on a person's genetic information.
- Documentation fields to draw connection between pharmacogenomic test results and selection of specific medications or interventions based on the results, and the patient's response, including observed adverse drug reactions.
- Documentation fields for communication with genetic professionals and nurses, consultants, pharmacists, and/or physicians and team members with specialty training in genetics.
- Patient entry of personal and/or family health issues relative to their personalized management strategy.

The U.S. Department of Health and Human Services could implement the ONC principles for precision health as regulations for EHR vendors in preparation for full implementation of precision health. This would require legislation to tighten HIPAA Security Rule's requirements for risk assessment and management. In addition, the U.S. Department of Health and Human Services could lead the development and passage of legislation to expand protections of genomic information for healthcare consumers in order to address the key challenges facing precision health implementation.

The American Academy of Nursing's position

Leveraging the advances in precision health implementation to improve the practice of nurses and strengthen nursing's impact on healthcare quality and safety is a policy issue of great interest to the Academy. The Academy's strategic plan includes a goal to support policies and practice design that promote registered nurses as clinicians in care coordination, including but not limited to the integration of genomics in healthcare, goal 2.3 (American Academy of Nursing, 2017).

Recommendations

The following recommendations were derived from the Policy Dialogue and further refined by the Expert Panels. The Academy fully endorses these recommendations to strengthen federal and local policies that will advance precision health implementation and the impact of nurses on healthcare quality and safety:

Nursing profession

- Contribute knowledgeable leadership in research and clinical settings, to institutions and the public, as well as to institutional review boards on the potential benefits and challenges of precision health implementation and ethical issues that remain to be addressed.
- Ensure routine collection of standardized nursing care data in EHRs, advocate for the collection and proper storage of additional data elements to more effectively apply genomic information, and demand that decision support mechanisms be developed and made available in EHRs to support the safe, secure, and effective use of genomic data.
- Engage in designing and developing IT infrastructure to integrate data sources and provide clinical support to provide genomic testing results to providers in an interpretable format and a timely manner.
- Understand and address gaps in what patients, research participants, and the public need to know about precision health implementation.
- Advocate for sufficient training, resources and continuing education on implementation of precision health including but not limited to, patient education and health literacy assessment, data security, decisions regarding return of genomic results, and clinical support for interpreting and acting upon genetic test results and clinically actionable findings.

U.S. department of health and human services

- Promulgate rules to update HIPAA Security Rule's requirements for risk assessment and management that are appropriate for precision health implementation.
- Expand policies on protection of genomic information for research participants to all healthcare consumers.

Healthcare systems

- Invest in the IT infrastructure to integrate data sources and provide clinical support to provide genomic testing

results to providers in an interpretable format and a timely manner.

- Promote direct patient data entry into the EHR as a critical data source and to fully recognize patients as partners in their health care.
- Provide continuing education for nurses and other healthcare professionals on precision health implementation.
- Educate patients and families on the goals, benefits and limitations of omics in research, clinical practice implementation, and precision health.

Vendors of electronic health records (EHRs)

- Incorporate data fields for documentation of genomic rapid risk assessments: race, ethnicity, ancestry, four generation family history and social determinants of health; communication with a genetic nurse/counselor, pharmacist, and/or physician; decisions based on genomic test results, changes in care and the patient's response.
- Incorporate genomic implementation guidelines, such as the CPIC guidelines, into the electronic health record.
- Enable nurses and other healthcare professionals to enter standardized documentation of unintended drug responses in the EHR.
- Develop clinical decision supports that integrate genomic risk, effects of drug-drug interaction, adherence factors and prescribed / administered dosing with point of care therapeutic recommendations to improve drug response and safety.
- Develop a real-time reporting system that establishes links with standardized drug response data documented in the EHR to the FDA.

Public health researchers and clinicians

- Assess pharmacogenomic contributions to over-the-counter drugs.
- Develop methods to identify outliers who do not have the anticipated response to algorithms derived from precision health.
- Develop registries in partnership with the FDA and health care reimbursement agencies such as CMS to contact patients when new genomic testing and medications with fewer pharmacogenomics adverse reactions are developed.

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