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A Blueprint for Genomic Nursing Science

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Abstract

Purpose—This article reports on recommendations arising from an invitational workshop series held at the National Institutes of Health for the purposes of identifying critical genomics problems important to the health of the public that can be addressed through nursing science. The overall purpose of the Genomic Nursing State of the Science Initiative is to establish a nursing research blueprint based on gaps in the evidence and expert evaluation of the current state of the science and through public comment.

Organizing Constructs—A Genomic Nursing State of the Science Advisory Panel was convened in 2012 to develop the nursing research blueprint. The Advisory Panel, which met via two webinars and two in-person meetings, considered existing evidence from evidence reviews, testimony from key stakeholder groups, presentations from experts in research synthesis, and public comment.

Findings—The genomic nursing science blueprint arising from the Genomic Nursing State of Science Advisory Panel focuses on biologic plausibility studies as well as interventions likely to improve a variety of outcomes (e.g., clinical, economic, environmental). It also includes all care settings and diverse populations. The focus is on (a) the client, defined as person, family, community, or population; (b) the context, targeting informatics support systems, capacity building, education, and environmental influences; and (c) cross-cutting themes. It was agreed that building capacity to measure the impact of nursing actions on costs, quality, and outcomes of patient care is a strategic and scientific priority if findings are to be synthesized and aggregated to inform practice and policy.

Conclusions—The genomic nursing science blueprint provides the framework for furthering genomic nursing science to improve health outcomes. This blueprint is an independent recommendation of the Advisory Panel with input from the public and is not a policy statement of the National Institutes of Health or the federal government.

Clinical Relevance—This genomic nursing science blueprint targets research to build the evidence base to inform integration of genomics into nursing practice and regulation (such as nursing licensure requirements, institutional accreditation, and academic nursing school accreditation).

Genomic developments are changing health care. And because nursing is a fundamental provider of health care, genomics is also changing the profession of nursing (Calzone et al., 2010). Discoveries such as mapping the human genome and the illumination of genomic variation associated with health, disease, and management options are being translated into practice. All aspects of the healthcare continuum are influenced by genomic developments. As such, the use of genomic information and technology is no longer dependent on referral to a genetic specialist, but has transitioned into nonspecialty healthcare delivery. Clinical applications include using genomics to identify at-risk individuals, screen and diagnose disease, clarify prognosis, and optimize drug therapy to maximize therapeutic benefit and minimize adverse outcomes. Therefore, nurses must be competent in genomics to provide safe, cost-effective, quality health care (Calzone et al., 2010).

Basic and applied research lay the foundation and provideS the evidence for integrating genomics into practice. This body of science includes the identification and understanding of biologic mechanisms and pathways important for later intervention developments, characterization of genomic markers to identify individuals at risk for adverse health

conditions and outcomes, as well as the development and testing of interventions and treatments that are tailored to an individual and family's genetic make-up.

Background

The National Institutes of Health (NIH) and Health Resources and Services Administration (HRSA) have led several U.S. initiatives to prepare the nursing workforce to apply genomics in patient care and to provide educational support for advanced practice nurses who often provide genomic information to patients and their families (Grady & Collins, 2003; Jenkins, Grady, & Collins, 2005). In 2004, the National Human Genome Research Institute and the National Cancer Institute collaborated to establish the U.S. Genetic/Genomic Nursing Competency Initiative (GGNCI). The first GGNCI outcome was to obtain consensus on essential genomic nursing competencies that have been endorsed by 50 nursing organizations and that apply to all registered nurses regardless of specialty, role, or academic preparation (Consensus Panel on Genetic/Genomic Nursing Competencies, 2009; Jenkins & Calzone, 2007). In 2012, through a second consensus process, graduate genetic and genomic competencies were published (Greco, Tinley, & Seibert, 2012). Parallel efforts by the NIH include the Summer Genetics Institute (SGI). Sponsored by the National Institute of Nursing Research (NINR), the SGI provides participants with a foundation in molecular genetics appropriate for use in research and clinical practice. The NINR additionally provides training in genomics through institutional training grants as well as through fellowship and career development awards.

The recent Institute of Medicine (IOM) report on the future of nursing indicates that preparing nurses for expanded roles entails timely changes in scope of practice and nursing education (IOM, 2011). These essential genetic and genomic competencies provide the basis to guide such changes (Consensus Panel on Genetic/Genomic Nursing Competencies, 2009; Jenkins & Calzone, 2007). It is noteworthy that these authoritative documents do not address the strategic imperative of measuring the impact of competencies on cost, quality, and outcomes of care. This evidence gap served as the motivation for this State of the Science Initiative.

Nursing, the largest and most trusted healthcare profession, can facilitate the responsible translation of genomics into health care (Calzone et al., 2010). However, evidence exists that nurses and nursing faculty have limited genomic competency (Calzone, Jenkins, Yates, Cusack, McBride, 2008; Edwards, Maradiegue, Seibert, Macri, & Sitzer, 2006; Jenkins & Calzone, 2012; Maradiegue, Edwards, Seibert, Macri, & Sitzer, 2005). As a result, nursing's capacity to deliver safe and effective genomic-based health care needs enhancement. International nursing leaders are also faced with the challenge of implementing strategies to effect changes in the nurse workforce to harness genomics to improve healthcare processes and outcomes (Kirk, Calzone, Arimori, Tonkin, 2011).

In an attempt to address this competency gap, the GGNCI convened a meeting of key stakeholders to establish a genetic and genomic nursing competency strategic implementation plan (Genetic/Genomic Nursing Competency Initiative, 2006). Recommendations from this meeting included coordinating strategic plan activities around three priority areas: practicing nurses, academics, and regulation or quality control. The recommendations also identified the need for an infrastructure to coordinate strategic plan activities. From the strategic plan, the GGNCI prioritized efforts aimed at the regulatory environment, defined as nursing licensure requirements, institutional accreditations such as the Joint Commission, and academic nursing school accreditation. Emphasis on regulation is valuable because it has the potential to have an immediate impact as well as long-term, measurable outcomes. Influencing the regulatory environment is driven in part on evidence,

in this case whether nurses who are competent in genomics positively impact the public's safety or health outcomes. Another goal of the GGNCI was to determine gaps in the evidence of genomic nursing science and chart the path toward filling the gaps through a nursing science blueprint. To achieve this, a Genomic State of the Science Advisory Panel was established.

Aims of This Initiative

The Genomic Nursing State of the Science Advisory Panel proposes a blueprint that can be used to focus efforts to fill the gaps identified through analysis of the evidence, expert evaluation of the current state of the science, and public comment.

Methods

Three approaches were used. First, evidence reviews were conducted to determine what evidence existed regarding genomically targeted research and healthcare outcomes. Second, members of the Advisory Panel met four times, twice by webinar and two face-to-face meetings, to establish the science blueprint. Third, public comment was solicited through a web-based feedback mechanism at genome.gov, and all comments were reviewed for inclusion.

Evidence Reviews

A review of NINR supported research studies highlights the fact that the NINR has long recognized the need for basic and applied research that lays the foundation for integrating genomics into practice. Through its research grants, training efforts, and intramural research, the NINR is actively working to improve the understanding of health and disease through greater understanding of the role of genomics and its clinical applications. Several genomic studies funded by the NINR were reviewed. For example, in one study, investigators found that gene expression patterns in chronic wounds can guide treatments to expedite wound healing (Tomic-Canic, Ayello, Stojadinovic, Golinko, & Brem, 2008). Another study identified an association between single nucleotide polymorphisms (SNPs) in the tryptophan hydroxylate (*TPH*) gene and symptoms (e.g., bloating, diarrhea) in patients diagnosed with irritable bowel syndrome (Jun, Kohen, Cain, Jarrett, & Heitkemper, 2011). Other research examined the role of genomic variants in patients recovering from severe traumatic brain injury. This study provided evidence for an association between genetic polymorphisms in the neuroglobin gene and patient outcomes measured by Glasgow Outcome Scale scores (Chuang et al., 2010). Additional information on NINR-supported research is available on the NIH Research Portfolio Online Reporting Tools (RePORT) website (http://report.nih.gov/).

In addition to assessing the NINR-funded research studies, a systematic literature review was conducted to answer the following question: What health outcomes are associated with nursing care that incorporates genetic and genomic principles, technology, and information? Details about this systematic review are provided in supplemental materials (these materials are published only with the online version of the article). The review identified seven heterogeneous studies that provided insufficient evidence to answer the question. Even though significant investments are being made in genomic nursing science, nursing is like other professions in that there are still gaps in research focused on competency in genomics and the impact on patient safety and health outcomes. The next step in this initiative was to assemble an advisory panel to delineate priorities to be targeted through a science blueprint.

Establishing the Nursing Science Blueprint

The interprofessional Genomic Nursing State of the Science Advisory Panel consisted of 2 coordinators and 14 individuals. Members were selected by the coordinators (who are also the co-chairs of the GGNCI) based on their expertise in genomics, nursing research, nursing workforce issues, system change, health services measurement, and evidence-based synthesis.

The majority of the discussions focused on gaps surrounding current science highlighted by the evidence reviews and identified critical genomics problems important to the health of the public. The Advisory Panel identified critical outcome indicators, specific populations for study, and research direction, and made the decision to align recommendations with areas of the NINR Strategic Plan. Finally, the Advisory Panel addressed methods for obtaining broader stakeholder input on the draft science blueprint, building capacity for genomic science and practice integration, establishing opportunities for interdisciplinary research collaboration, and assuring inclusion of minority populations in research studies.

Public comment was solicited for a 30-day comment period through a web-based feedback mechanism at genome.gov. Notification of the request for public comment was provided on the genome.gov homepage, the American Academy of Nursing Genetic Healthcare Expert Panel listserv, the International Soiety of Nurses in Genetics listserv, the American Nurses Association Smartbrief, the Genetic/Genomic Nursing Competency listserv, the NINR Summer Genetics Institute graduate list, and a Nurse Practitioner listserv. Nineteen public comments were received and the specific comments can be viewed at http://www.genome.gov/27549386.

Genomic Nursing Science Blueprint

Genomic Nursing Research Priority Considerations

Establishing the science blueprint began with an advisory panel discussion about the scope of genomic nursing practice. Clinical applications of genetic and genomic knowledge for nurses have implications for care of persons, families, communities, and populations across the lifespan. The scope of genomic nursing care is broad, encompassing risk assessment, risk management, treatment options (i.e., pharmacogenomics), and treatment decisions. Care provided along the life continuum is often designed and provided by an interdisciplinary team. Research measuring the impact of genomics care needs to be considered in an interprofessional context, and therefore, interdisciplinary research partnerships are highly valued. Research questions should be focused on the critical genomics problems identified as a priority for the health of the public (i.e., high risk, high impact, high volume, high cost) and interventions likely to improve outcomes of a diverse nature (i.e., clinical, economic, environmental). Gaps in current knowledge highlighted in the evidence reviews were also useful in considering the priority research topic areas. The Advisory Panel recommended that nursing scientists focus on conducting research that produces clinically relevant evidence along the translational science continuum (Khoury et al., 2007) utilizing multifaceted methodologies and measurements (i.e., biologic plausibility studies, case studies, patient surveys, and qualitative and quantitative research). Crucial to the successful attainment of recommended evidence-based practice is availability of nurse investigators who are prepared to study such critical problems. In addition, nurse investigators should build on work that already exists (i.e., research, collaborations, and standardized outcome measures) because it advances scientific knowledge and understanding more rapidly and efficiently.

Recommended Future Nursing Science Blueprint

A set of broad research themes described in the NINR Strategic Plan was used as a framework for this effort (National Institute of Nursing Research, 2012). The blueprint was aligned as recommended by the Advisory Panel with four of the NINR Strategic Plan areas (health promotion and disease prevention, advancing the quality of life, innovation, and training; Table 1). Additional cross-cutting themes were identified. The Advisory Panel determined that the key areas for nursing research reside within two major areas: research focused on clients and research exploring the context in which health care is delivered.

Research Focused on the Client

Research provides the evidence needed to guide practice along the continuum of genomic-based health care for the client (broadly defined as the person, family, communities, and populations). Genomic care is provided in all healthcare settings with input from both generalist and specialist nurses. The nursing science blueprint targets research likely to improve a broad set of client outcomes. Recommendations for genomic research within the theme of health promotion and disease prevention include the categories of risk assessment, communication of risk information, and effects on decision-making utilizing decision support resources and information.

Quality of life may also be positively influenced by nurses who are competent in genomics. One research category within this theme includes the measurement of the psychosocial and ethical implications of genomic information for individuals and their families. For example, the value of communication and education about genomic interventions such as pharmacogenomics is poorly understood. Other suggested research topics include symptom management and assessing client self-management and expectations of the healthcare providers when encountering genomic-based health care for common complex diseases (i.e., cancer, cardiovascular, and mental health).

A third theme centers around the innovations associated with new genomic technology and methodologies. Outcomes of genomic technology innovations, such as whole genome sequencing, are an area requiring further exploration. Informatic support systems developed to facilitate the research process and measurement of outcomes should be examined. The context of intervention and innovation affects the outcomes of care provided and the ability to measure those effects. The Model of the Work System (Carayon & Smith, 2000; Smith & Carayon-Sainfort, 1989) provides an ergonomic lens through which to view organizational, technological, environmental, and task-related factors that impact the work of the nurse engaged in direct patient care activities. Physical and social environmental influences to consider include background issues such as the current healthcare reform effort and economic influences including the economic value of nursing. Environmental factors may also encompass local healthcare system variables such as informatics support systems enabling or preventing documentation, communication, and capturing of genomic information.

Research Focused on the Context

Capacity building of the profession is a contextual concept that includes training more nurse scientists to include genomics in their studies, or to specifically design and implement genomics-based research with an emphasis on the ability to quantify the contribution of genomics nursing to patient outcomes. Preparing the existing nursing workforce as well as clinical and administrative leaders is essential to advance appropriate genomics integration into practice. Environmental influences impacting the strategic readiness of our discipline also includes the education of nurse leaders such as nursing faculty that integrate genomics in teaching the next generation of nurses.

Cross-cutting Themes

Broader influences that apply to any of the research topic areas were included as part of the blueprint. Each of these themes, categorized into health disparities, cost, policy, and public education, need to be considered as a component of any genomic nursing research initiative.

Operationalizing the Nursing Science Blueprint

Infrastructure—Several infrastructure elements must be put in place before this blueprint can be fully operationalized. Administrative nursing leaders in healthcare systems were identified as important for moving this science blueprint forward. Designing, implementing, and evaluating the clinical and educational infrastructures to support genomic capacity and competency of all nurses is key to successful healthcare outcomes. Identification of policies and procedures that need to be created or refined often begins with the clinical leader's recognition of changes required to facilitate new technology and information diffusion. Research about the influence of policies and procedures on healthcare outcomes in clinical settings is a current gap, and clinical administrators can be critical to creating the nursing infrastructure that identifies genomics practice as a strategic imperative and uses research to guide practice innovation and improvement.

Another important aspect of implementing the science blueprint is developing the infrastructure for nurses to conduct genomic research. Over the past decade, federal agencies such as the NINR and HRSA have built capacity for research and training in genomics and genomic applications. The Summer Genetics Institute is just one example of these types of initiatives. Through these initiatives nurses are becoming more competent in conducting genomics-based nursing science; however, further capacity building is needed.

Measurement—Implementation of these science blueprint priority areas would be improved if existing measures were adapted for genomic use, and standard measures, processes, and outcomes for genomics were created and included in all nursing research (McAllister et al., 2008). Building capacity to measure the impact of genomically focused nursing practices on patient care quality, costs, and outcomes is essential to advance public policy, to guide clinical strategic planning, and to optimize the synthesis of evidence to inform practice. Database infrastructure to capture recommended measures and genomic information is also needed. Suggested resources to consider for identification and selection of measures include PhenX (http://www.phenxtoolkit.org), PCORI (http://www.pcori.org), PROMIS http://www.nihpromis.org/), and nursing sensitive measures such as NQF (http://www.qualityforum.org/Home.aspx), Collaborative Alliance for Nursing Outcomes (CALNOC; http://www.CALNOC.org), and NDNQI (https://www.nursingquality.org/). Measures that extend beyond the physical dimensions of outcomes (i.e., biobehavioral, social, and values) that may have sensitivity or emotional effects should also be included in nursing research. There are many nursing research opportunities at the junction of genomics and ethics, many of which can be found in Badzek, Henagan, Turner, & Monsen (2013), in this issue.

Funding—Funding for the nursing science blueprint should be explored by agencies and investigators to further interdisciplinary genomics team science. Funding may be available from federal or private resources. The NINR provides funding opportunities for advancing nursing science through its research, training, and career development programs (http://www.ninr.nih.gov/ResearchAndFunding/). Applications focused on genomics are accepted in response to directed funding announcements (such as requests for applications and program announcements), as well as in response to investigator-initiated (“parent”) funding announcements. The HRSA focuses on the workforce, providing funding for nursing education and interprofessional collaborations. More information about HRSA funding

opportunities are available (http://bhpr.hrsa.gov/nursing/index.html). Other federal agencies (e.g., the Agency for Healthcare Research and Quality, Centers for Disease Control and Prevention, other NIH institutes) may also offer funding for collaborative genomics research. Small business innovation research and small business technology transfer programs (http://www.sbir.gov/), administered by several federal agencies, may serve as valuable options for developing genomics innovations that can be commercialized and transitioned into practice. The Advisory Panel also recommended that researchers engage the American Academy of Nursing, the American Organization of Nurse Executives, and foundations such as Macy, Hartford, and Robert Wood Johnson regarding partnerships for research and communicating the significance of the integration of genomics.

Limitations

This Genomic Nursing State of the Science Initiative provided an opportunity for a diverse group of nursing and other professionals to dialogue about the goals and possible strategic targets of genomics nursing research. It remains a work in progress, however, and many opportunities for future expansion remain. The systematic literature review was limited by its focus on the discipline of nursing and research of practice outcomes of genomic nursing, and additional reviews incorporating literature from the interprofessional community are recommended.

This initiative assembled leaders in nursing, medicine, and other professions with broad expertise in research, policy, nursing process, genetics-genomics, leadership, and measuring evidence-based outcomes. The members provided their perspectives on the subject, but some areas may not have been identified as a high priority for nursing research. To address this limitation, the Advisory Panel posted the draft science blueprint for public comment and considered each comment in the final recommendations depicted in Table 1. This blueprint provides a starting point for further dialogue and a context for recommended action to stakeholders.

Conclusions

As we move into the 21st century, genomics will underlie all of health care and therefore is fundamental to all nursing practice. Research focused on the value of nursing in the delivery of effective genomics-based care for individuals, families, communities, and populations will accelerate the translation of evidence into practice. The Advisory Panel identified areas of nursing research that will generate evidence about how genomic nursing can contribute to improved client health outcomes. Both client and context need to be considered when operationalizing the blueprint for nursing science. Expansion of research activities in the identified areas hinges on the degree to which stakeholders feel such research is of value, the availability of well-trained investigators, and adequate funding. Continued genomics-based nursing research that can ultimately be translated into patient care is critical for moving health care forward, and as nurses are frequently on the forefront of patient care, it is essential that nurse scientists have the knowledge and skills they need to participate in and conduct this research. Expanding the capacity of nurse scientists to conduct genomic research will promote application of research discoveries to benefit clients. This blueprint provides the platform for moving nursing science forward to address identified gaps and responsibly translate genomics into cost-effective healthcare outcomes.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1

Nursing Genomic Science Blueprint Mapped to National Institute of Nursing Research (NINR) Strategic Plan Areas

NINR strategic plan areas	Specific nursing research categories	Advisory panel genomic nursing research topic areas[a]
Health promotion and disease prevention	Risk assessment	a. Biologic plausibility (e.g., pathways, mechanisms, biomarkers, epigenetics, genotoxicity)
		b. Comprehensive screening opportunities (e.g., family history, identify risk level [population-based average and elevated])
		c. Components of risk assessment (e.g., biomarkers, family history)
		d. Risk-specific healthcare decision making
	Communication	a. Risk communication (e.g., interpretation, timing, risk reports to the healthcare provider and client[b])
		b. Informed consent
		c. Direct-to-consumer marketing and testing (e.g., uptake, utilization, dissemination)
	Decision support	a. Informed consent
		b. Match of values/preferences with decision made
		c. Risk perception/risk accuracy
		d. Effect of decision support on decision quality (e.g., knowledge, personal utility)
Advancing the quality of life	Family	a. Family context (e.g., family functioning, and structure, family relationships, and communication)
		b. Ethical issues
		c. Healthcare provider communication with families
	Symptom management	a. Biologic plausibility (e.g., pathways, mechanisms, biomarkers, epigenetics)
		b. Clinical utility
		c. Personal utility
		d. Pharmacogenomics (e.g., therapy selection, medication titration)
		e. Decision making
		f. Evidence-based effectiveness of approaches
	Disease states (encompassing acute, common complex and chronic)	a. Genomic-based interventions that reduce morbidity and mortality
		b. Gene/environment interactions (e.g., epigenetics, genotoxicity)
		c. Pharmacogenomics
		d. Evidence-based effectiveness of treatments/support
	Client self-management	a. Collecting and conveying information that informs self management (e.g., family history)
		b. Lifestyle behaviors
		c. Environmental exposure and protection (e.g., occupational)
		d. Synergy of client and provider expectations (e.g., client/family centered care)
		e. Personal utility

NINR strategic plan areas	**Specific nursing research categories**	**Advisory panel genomic nursing research topic areas**[a]
Innovation	Technology development	a. Incorporation of new technologies (e.g., whole genome sequencing) b. Ethics c. Policy and guidelines to support applications d. Applications (e.g., clinical and analytic validity, and clinical utility) e. Genomic bio informatics f. Translation, dissemination, implementation **i.** Use of technology in information delivery **ii.** Performance improvement by provider (e.g., point-of-care support) **iii.** Resources that support genomic research (e.g., registries of tools, best practices, nursing outcomes)
	Informatics support systems	a. Data storage and use to facilitate research process and outcomes b. Facilitate cross-generational sharing of genomic data (e.g., family history, laboratory analyses) c. Managing, analyzing, and interpreting genomic information (e.g., sequencing data) d. Point-of-care decision support for client and healthcare provider e. Common terminology and taxonomy f. Common formats for data storage/exchange and queries
	Environmental influences (encompassing physical, social environments and policy context)	a. Evidence-based guidelines b. Healthcare reform c. Economics (e.g., cost effectiveness) d. Regulatory gaps and/or variability
Training	Capacity building	a. Training future nursing scientists in genomics b. Preparing nursing faculty in genomics c. Education of current and future workforce in genomics (e.g., research nurse coordinators, advanced practice nurses, other healthcare professionals) d. Preparation of nurse scientists to lead interprofessional teams e. Preparation of clinical and administrative leaders to advance appropriate genomics/genetics integration into practice f. Innovative uses of biorepositories (e.g., informed consent, result interpretation) g. Bioethics
	Education	a. Optimal methods to train the existing nursing workforce in genomics b. Optimal methods to train the nursing leadership in genomics to support genomic translation, research, and practice c. Optimal methods to integrate nursing genomic competencies in basic-prelicensure and postlicensure in academic programs
Cross-cutting themes		

NINR strategic plan areas	Specific nursing research categories	Advisory panel genomic nursing research topic areas[a]
	Health disparities	a. Racial, ethnic, socioeconomic, and cultural influences on disease occurrence and response to disease and treatment
		b. Genomic health equity (e.g., access)
		c. Diseases that disproportionately affect specific groups (e.g., minorities)
		d. Targeted therapeutics
		e. Overcoming misinformation and genomic “myths”
	Cost	a. Cost effectiveness
		b. Comparative effectiveness
		c. Value
	Policy	a. Policy as context of science
		b. Research to inform policy
	Public education	a. Health literacy
		b. Genomic literacy

[a]The nursing science blueprint serves as a platform for potential interprofessional collaborations that can include but are not limited to the any healthcare discipline, basic and behavioral scientists, ethicists, business, and/or informatic professionals.

[b]*Clients* refers to persons, families, communities, and/or population.