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Educational and Ethical Considerations for Genetic Test Implementation Within Health Care Systems

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Abstract

Introduction: The precision medicine (PM) era presents unprecedented proliferation of genetic/genomic initiatives, information, and bioinformatic tools to enhance targeted molecular diagnosis and therapeutic treatments. As of February 29, 2020, the National Institutes of Health (NIH) National Center for Biotechnology Information (NCBI) Genetic Testing Registry contained 64,860 genetic tests for 12,268 conditions and 18,686 genes from 560 laboratories, and the Food and Drug Administration had 404 entries for pharmacogeneomic biomarkers used in drug labeling. Population-based research initiatives including NIH's *All of Us* and Veterans Affairs' *Million Veteran Program*, and the UK Biobank, combine use of genomic biorepositories with electronic medical records (i.e., National Human Genome Research Institute's [NHGRI's] electronic Medical Records and Genomics [eMERGE] Network). Learning health care systems are implementing clinical genomics screening programs and precision oncology programs. However, there are insufficient medical geneticists, nurse geneticists, and genetics counselors to implement expanding number of clinical genetic tests that are required for PM implementation.
Methods: A scoping review of current (2014–2019) trends in U.S. genomic medicine translation, PM health care provider workforce education and training resources, and genomic clinical decision support (CDS) implementation tools was conducted.
Results: Health care delivery institutions and systems are beginning to implement genetic tests that are driving PM, particularly in the areas of oncology, pharmacogenetics, obstetrics, and prenatal diagnostics. To ensure safe adoption and clinical translation of PM, health care systems have an ethical responsibility to ensure their providers and front-line staff are adequately prepared to order, use, and interpret genetic test information.
Conclusion: There are a number of high-quality evidenced-based educational resources and CDS tools available. Strong partnerships between health care system leaders, front-line providers and staff coupled with reasonable goal setting can help drive PM translation interests.

Keywords: ethical legal social implications; genetic tests; health care provider training and education; health care system implementation

Introduction

Precision medicine (PM) is an approach to treatment and prevention of disease that takes into account a patient's genes, lifestyle, and environmental characteristics.[1] The PM era presents unprecedented proliferation of genetic/genomic information and bioinformatic tools to enhance molecular diagnosis and therapeutic treat-

ments. There has been rapid growth in both number of genetic tests and Food and Drug Administration (FDA) approvals for drugs with pharmacogenetic labeling information. As of February 29, 2020, the National Institutes of Health (NIH) National Center for Biotechnology Information (NCBI) Genetic Testing Registry contained 64,860 genetic tests for 12,268 conditions

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and 18,686 genes from 560 laboratories, and the FDA had 404 entries for pharmacogenomic biomarkers used in drug labeling.[2,3]

Population-based biobank research initiatives including NIH's *All of Us*, Veterans Affairs' *Million Veteran Program*, and the UK Biobank combine use of genomic biorepositories with electronic medical records (i.e., National Human Genome Research Institute's [NHGRI] electronic Medical Records and Genomics [eMERGE] Network) to gain novel insights into candidate genes targets and complex gene–lifestyle interactions fueling development of chronic multifactorial diseases.[4–6] Learning health systems are beginning to implement clinical genomics screening programs to identify and reduce patient risk for development of adverse outcomes and diseases such as familial hypercholesterolemia and hereditary cancer syndromes, and PM-based treatments for oncology community health care settings.[7,8]

Although these large-scale research initiatives began the PM movement, the field is rapidly evolving and broadening beyond genetics/genomics to include information generated from wearable sensors and digital health devices, network biology and systems medicine, polygenic risk score prediction algorithms, bioinformatics data science and machine learning methodologies, and multiomics profiling for a variety of health and disease states (Table 1).[9–15]

Artificial intelligence—the use of computing frameworks, algorithms, and theories to facilitate tasks that normally require human reasoning and decision making, understanding, or perception to include techniques such as machine learning and natural language processing—is emerging as a key analytic tool to manipulate and derive meaningful and actionable insights within the vast amounts of big data from whole genome sequence, multiomics data, electronic health records (EHRs), and others.[23]

Novel genetic/genomic/-omics insights gleaned from technological, engineering, and computer science approaches to identify disease biology mechanisms, predict onset, and implement targeted treatments are envisioned to shift health care from a reactive practice model to a proactive model.[9,10] All health care paradigms utilizing genomic and molecular -omic data listed in Table 1 require the use of genetic tests, which are defined as "analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites in order to detect heritable disease-related genotypes, mutations, phenotypes, or karyotypes for clinical purposes."[24]

Table 1. Current and Emerging Terminology, Paradigms in Genomic Health Care

Term	Definition
Genomic medicine	"Emerging medical discipline that involves using genomic information about an individual as part of their clinical care (e.g., for diagnostic or therapeutic decision-making) and the health outcomes and policy implications of that clinical use."[16]
Network medicine	"Emerging field that combines systems biology and network science. It runs counter to the prevailing scientific reductionist trend that dominates current medical research on disease etiology and treatment. Reductionism relies on single molecules or single genes to provide comprehensive and robust insights into the pathophysiology of complex diseases. Similarly, current drug development methodologies target single molecules that very frequently fail because of the unforeseen and unintended effects that result from the application of this piecemeal approach to pharmacology. Emphasizes a more holistic approach through the identification and investigation of networks of interacting molecular and cellular components. When network medicine is integrated into biomedical research, it has the potential to transform investigations of disease etiology, diagnosis, and treatment."[11,17]
Personalized medicine	"Emerging practice of medicine that uses an individual's genetic profile to guide decisions made in regard to the prevention, diagnosis, and treatment of disease. Knowledge of a patient's genetic profile can help doctors select the proper medication or therapy and administer it using the proper dose or regimen."[18]
Precision medicine	"An emerging approach for disease treatment and prevention that takes into account individual variability in genes, environment, and lifestyle for each person."[1] In cancer, precision medicine "uses specific information about a person's tumor to help diagnose, plan treatment, find out how well treatment is working, or make a prognosis."[19]
Systems medicine	"New and emerging field that leverages complex computational tools to develop personalized assessments of disease risk and potential management options. Systems medicine seeks to enhance individualized diagnosis, prognosis, and treatment options. The introduction of Big Data has begun to require new types of physicians and biomedical scientists, which exploit modern computational sciences to process and analyze enormous quantities of information."[9,10,20]
Precision health	"Precision health is broader—it includes precision medicine but also approaches that occur outside the setting of a doctor's office or hospital, such as disease prevention and health promotion activities." This includes using targeted health information from patients' wearable sensors, implantable monitoring devices, and mobile devices for health prevention interventions."[21]
Precision public health	"Improving the ability to prevent disease, promote health, and reduce health disparities in populations by applying emerging methods and technologies for measuring disease, pathogens, exposures, behaviors, and susceptibility in populations; and developing policies and targeted implementation programs to improve health."[22]

Network medicine definition quote is verbatim from *Harvard Catalyst*, precluded by Chan and Loscalzo.[11] Systems medicine definition quote is verbatim from *1st International Conference in Systems Network Medicine Conference*, precluded by Auffray et al.[9] and Auffray.[10]

It is broadly recognized that genetics/genomics health care professionals are most readily able to use and to guide implementation of genetic tests into health care workflows; however, their numbers and scope are limited. Thus ensuring adequate workforce capacity and clinician education/training in these areas (for both genetics and nongenetics providers) is an ethical imperative to ensure clinical translation of PM across populations and within communities.

When the U.S. Congress appropriated funding for the Human Genome Project in 1990, a portion of its funding was devoted to the ethical, legal, and social implications (ELSI) of genetics/genomics research. In the light of any rapidly evolving biomedical scientific field, but particularly PM, there is an ethical duty to consider the implementation impacts of those technologies upon patients, their families, and society as a whole.[25] The NHGRI ELSI portfolio has expanded since its initial funding and now spans multiple domains, including the implementation of genetic/genomic tests into health care settings and health systems so as to ensure fair access, use, and reimbursement.[26]

In accordance with these stated priorities, a scoping review was conducted with the following research question: "what are the current trends in U.S. genetic test use, genetics/genomics healthcare workforce education and training, and available clinical translation tools for healthcare systems?" Highlights from this article were presented as part of the "Ethics and Educational Considerations in the Era of Precision Medicine" panel on September 12, 2019, at the *1st International Conference in Systems and Network Medicine, Applications of Systems Science and Thinking to Biomedicine.*[20]

Methods

A scoping review was performed to examine current trends (2014–2019) in U.S. health system genetic test use, health care provider workforce education and training in genetics/genomics, and available clinical decision support (CDS) tools for PM implementation. Biomedical and nursing databases searched included PubMed, CINAHL, and Google Scholar for international English articles of quantitative (clinical trials, implementation pilots, meta-analyses, and reviews), qualitative, and mixed-method research studies. MeSH search terminology criteria included Clinical Laboratory Improvement Amendments (CLIA)-certified laboratory genetic tests, health system implementation, genetic test implementation, ELSI, precision medicine/precision health genomic medicine implementation, workforce development, and CDS.

Specific health care disciplines reviewed included physicians, genetics counselors, and nurses, including gray literature on relevant credentialing and licensing statistics. Of the total 6242 records that were identified, 592 abstracts were reviewed, 186 full length reports and articles were read, and 51 full length articles were selected for the final scoping review. An additional 29 online resources for U.S. health system implementation of genetic tests were identified and practicable implementation frameworks with open-source tools highlighted.

Results

Genetic test use trends in the U.S. health care system

Use of genetic tests can be broadly categorized into diagnostic, predictive, and reproductive applications; however, to meet standards of clinical safety and quality, a genetic test must show sufficient analytical validity, clinical validity, and clinical utility before clinical translation and implementation can occur within regulatory and payer coverage frameworks.[24]

Genetic tests that incorporate multiomic information and the CDSs required for their implementation will still be expected to meet these performance standards, while also demonstrating sufficient economic value relative to costs.[27] The Centers for Disease Control and Prevention's (CDC) Public Health Genomics and Precision Health Knowledgebase curates various genetic test evaluation frameworks and evidentiary reports for genetic test performance outcomes for a wide range of health conditions, patient populations, and clinical settings.[28,29]

Although the number of genetic tests from CLIA-certified laboratories has increased in the NCBI Genetic Test Registry, these data do not provide an indication of current test utilization and spending within the U.S. health care landscape. An examination of the health care market diffusion patterns for various types of genetic tests and their associated clinical domain applications and challenges would help provide a roadmap for which to begin to prepare for the more technologically and computationally intensive multiomics translational tests.

A recent study of a U.S. commercial payer database spanning 28 health plans, all 50 states, and ~40 million covered lives reported a total of 75,000 genetic tests, with 14,000 new CLIA-certified laboratory genetic tests (single and multiple genes, exomes, whole genome, microarrays, sequencing, karyotype, and

circulating cell-free DNA) coming onto market during 2014–2017, and ∼10 new genetic tests coming onto the market daily.[30] Claims were curated into clinical domains by current procedural terminology (CPT) code and laboratory identification number to analyze genetic test utilization and spending patterns by quarter for the 3-year study period. Prenatal tests (33–43%), hereditary cancer tests (∼30%), oncology diagnostics and treatment (∼10%), and pharmacogenetic tests (<5%) accounted for the highest percentage of U.S. genetic test spending.

When reimbursed, genetic tests for diagnostics have strong rates and new CPT codes incorporating next-generation sequencing are coming online annually and becoming integrated into electronic medical records and payment systems. In 2018, ∼30 new CPT codes specific to PM (primarily oncology) were added, with CPT code 8146 for exome sequencing analysis with a maximum allowable limit of U.S. $12,000.[31] However, there are a wide range of incompatibilities between the evidence review process utilized within the insurance industry and the advanced technologies utilized in PM genetic tests. A review of three insurance coverage framework approaches with Medicare's national coverage determination process identified a number of possible evidence review pathways that could be revised to better allow for expanded access to next-generation tumor sequencing genetic tests.[32] It should be noted that although genetic test use and reimbursement cost trends do not constitute PM directly on their own, they are an indication of the foundational health system tools and architectural components required for PM implementation.

Workforce development

Mechanisms for ensuring adequate health care provider training in genetics/genomics are widely recognized as including academic and residency programs subject to accreditation requirements, licensure and specialty certification examination proficiency, continuing education licensure requirements, and point-of-care education mechanisms embedded within health care system information technology infrastructure. Table 2 highlights salient health care provider education and training resources by professional domain. Genetics/genomics education competencies and frameworks are available for generalist and specialty medical practice areas, for nongenetic health professionals, and for providers who received education and training before the PM movement.[33–35]

An adequate supply of health care providers with sufficient education and training to use genetic/genomic information in an ethical and responsible way that respects the dignity, privacy/confidentiality, and welfare of patients and their families, particularly marginalized subpopulations, is an important priority in biomedical technology dissemination. However, the segment of the health care workforce classically trained in genetics/genomics is routinely identified as insufficient for wide scale PM implementation.[36–38] To ensure adequate diffusion of this valuable specialty into under-resourced areas as the PM movement expands, this could be an area that may benefit from a more focused and structured workforce development analysis initiative, such as the process used by the U.S. Health Resources and Services Administration's (HRSA) National Center for Health Workforce Analysis.[39]

Physicians. Despite its recognized importance, number of medical geneticists and medical trainees entering clinical genetics is low, and approximately two-thirds of medical geneticists are approaching retirement age.[40–42] As of January 2018, the American Board of Medical Genetics and Genomics reported a total of $n = 2937$ diplomates ($n = 1583$ MD clinical genetics and genomics; $n = 155$ PhD medical genetics; $n = 323$ clinical biochemical genetics; $n = 775$ clinical cytogenetics and genomics; $n = 743$ clinical molecular genetics and genomics, and $n = 49$ clinical biochemical/molecular genetics; $n = 63$ medical biochemical genetics; $n = 9$ molecular genetic pathology).[43] To increase physician trainees entering this specialty, a number of career development strategies and educational framework mechanisms are proposed, with a particular emphasis on development of premedical undergraduate genomics curriculums.[37,40]

Genetic counselors. According to the American Board of Genetic Counseling, there are presently ∼5172 certified genetics counselors in the United States who practice in cancer, prenatal, and pediatric settings located in university medical settings, public/private hospital facilities, and diagnostic laboratories.[44,45] Presently in the United States, there are discrepant reports as to the presence and severity of a certified genetic counselor (CGC) shortage. A 2016 industry-sponsored workforce study of U.S.-based CGCs for 2017–2026 found that the U.S. CGC workforce had grown by 88% from 2006 to 2016, and is projected to expand another 72% in the next 10 years.[46] Conflicting with these trends are peer-reviewed scientific reports that identify insufficient

Table 2. Selected Genetics/Genomics Education and Training Resources by Health Care Professional Domain

Resource name	Website
Multidisciplinary	
American Society of Human Genetics (health care providers)	https://www.ashg.org/press/healthprofessional.shtml
	https://www.ashg.org/education/
American Society of Health-System Pharmacists	https://www.ashp.org/Pharmacy-Practice/Resource-Centers/Pharmacogenomics
Centers for Disease Control and Prevention	https://www.cdc.gov/genomics/resources/educational.htm
National Library of Medicine, Precision Medicine	https://ghr.nlm.nih.gov/resources#precision-medicine
NHGRI Genomics Competency and Curricular Resources	https://www.genome.gov/For-Health-Professionals/Provider-Genomics-Education-Resources
Method for Introducing a New Competency (MINC)	https://genomicsintegration.net/
Physicians	
American Academy of Family Physicians	https://www.aafp.org/afp/topicModules/viewTopicModule.htm?topicModuleId=56
American Academy of Pediatrics, Council on Genetics	https://pediatrics.aappublications.org/committee_on_genetics
American Board of Medical Genetics and Genomics	http://abmgg.org/
American College of Medical Genetics and Genomics	https://www.acmg.net/
American College of Obstetricians and Gynecologists	https://www.acog.org/About-ACOG/ACOG-Departments/Genetics?IsMobileSet=false
American Medical Association, Precision Medicine	https://www.ama-assn.org/delivering-care/precision-medicine
American Society of Clinical Oncology	https://www.asco.org/practice-policy/cancer-care-initiatives/genetics-toolkit/assessing-managing-your-patients-hereditary
Association of American Medical Colleges	https://www.aamc.org/
Association of Professors of Human and Medical Genetics	https://www.aphmg.org/
Jackson Laboratories Clinical and Continuing Education	https://www.jax.org/education-and-learning/clinical-and-continuing-education#
Inter-Society Coordinating Committee for Practitioner Education in Genomics (ISCC)	https://www.genome.gov/For-Health-Professionals/Inter-Society-Coordinating-Committee-for-Practitioner-Education-in-Genomics
Genetic Counselors	
American Board of Genetic Counseling	https://www.abgc.net/
National Society of Genetic Counselors	https://www.nsgc.org/
Registered Nurses	
American Academy of Nursing, Expert Panel on Genomic Nursing & Health Care	https://www.aannet.org/expert-panels/ep-genomic-nursing–health-care
American Nurses Association	https://www.nursingworld.org/practice-policy/nursing-excellence/ethics/genetics/
Global Genomics Nursing Alliance	https://g2na.org/
International Society of Nurses in Genetics (ISONG)	https://www.isong.org/
National Institute of Nursing Research	https://www.ninr.nih.gov/
Omics Nursing Science and Education Network (ONSEN)	https://omicsnursingnetwork.net/
Oncology Nursing Society, Precision Oncology	https://www.ons.org/learning-libraries/precision-oncology

CGCs across various specialties and inadequate distribution across geographic locales, particularly rural settings and the southern United States.[47] To address gaps in coverage, alternative health care delivery models to increase genetic counseling access in CGC-desert areas include telegenetic medicine and interactive web consults, greater health care workforce provider education and training (i.e., registered nurses [RNs], licensed clinical social workers) in CGC-limited settings, group counseling sessions, and cultivation of innovative institutional collaborations between rural facilities and larger academic partners.[48–50]

Nurses. RNs are the largest body of health care provider and play a key role in the provision of health care services to patients, families, and communities. The U.S. nursing workforce consists of 4,015,250 RNs (2,857,180 directly employed within the United States).[51] However, there are approximately $n = 350$ nurse clini-

cian, educator, and scientist members in the professional advocacy organization for genetics/genomics and approximately $n = 425$ graduates of the NIH National Institute of Nursing Research's (NINR) Summer Genetics Institute.[51–53] To facilitate content translation to the broader nursing community, essential genetic and genomic competencies, curricula guidelines, and outcome indicators were developed for U.S. entry level and advanced practice nurse programs and were endorsed and implemented by numerous professional nursing accreditation and certification organizations.[54,55] Knowledge standards for omic science doctoral nursing research programs were recently developed, in addition to genetic and genomic competencies for nursing informatics.[56,57] Lastly, a new Global Genomics Nursing Alliance (G2NA) aims to increase the integration of genomics into routine patient care in the general nursing community by providing a global catalogue of nursing education competencies and genomic nursing practice resources.[58]

Health system implementation frameworks and CDS

A number of learning health systems are pioneering PM advances through the implementation of genomic medicine screening programs to prevent, detect, and treat adverse health outcomes and chronic diseases. Examples of pharmacogenomic and genomic medicine implementation pilots integrated into health care delivery systems include: North Shore University Health System "DNA10K" population health primary care initiative, Intermountain Healthcare precision oncology program, and Geisinger MyCode Community Health Initiative.[8,59–66]

Although the American College of Medical Genetics and Genomics has issued a policy statement advocating for the return of information on 59 medically actionable genes after clinical exome and whole genome sequencing, complexities of incorporating genomic information into routine clinical practice are formidable in the absence of specialized training.[67]

Clinical implementation barriers for genetic tests and technologies are widely cited and contribute considerably to variable health care system uptake, even in the presence of documented clinical effectiveness.[68] The NHGRI Implementing GeNomics In pracTicE (IGNITE) Network framework identifies best practices and lessons learned to achieve sustainable adoption of genomic technologies in health care systems.[69–71]

Key components of best-practice implementation within health systems are the structured use of genomic information in clinical care that is linked to (and ideally) supported within the EHR to be guided by CDS. CDS "provides clinicians, staff, patients or other individuals with knowledge and person-specific information, intelligently filtered or presented at appropriate times, to enhance health and healthcare."[72]

CDS comprises a variety of rules, resources, and interventions that support clinical workflows at the point of health care delivery by a variety of health care providers, including computerized alerts and reminders to practitioners and patients, evidenced-based clinical guidelines, condition or test result-specific order sets, patient data reports and summaries, documentation templates, diagnostic support information, and contextual references to provide accurate health decision making.[73]

There are three levels of CDS, including passive (nonmandatory EHR resources available to a practitioner at the time of health care), asynchronous (provides information to a practitioner outside of clinical workflow such as an inbox message at the start of a workday), and active (presents information needed for decision making during the practitioner's clinical workflow, "just in time").[65] There are a wide range of guides and open source tools for genetic test implementation, including but not limited to: NHGRI IGNITE program's Genomic Medicine Knowledge Base, the Pharmacogenomics Clinical Annotation Tool (PharmCAT), the Displaying and Integrating Genetic Information through the EHR (DIGITizE) program, and the CDS knowledge base (CDS-KB).[74,75] For example, the IGNITE SPARK Toolbox feature provides a range of institutional assessment and CDS tools for genetic test implementation within health care systems, such as the CYP2C19 pharmacogenetic test and associated clopidogrel dosing procedure. Given 404 currently FDA approved pharmacogenomic biomarkers used in drug labeling, CDS tools are and will become essential to connecting patient genetic test results to the appropriate pharmacogenomic drug label indication.[3]

A key consideration to the implementation of any genetic test, PM CDS initiative for nongenetics health care providers, is ensuring that CDS alerts are structured into clinical workflows in ways that are not excessively burdensome.[75] Consequences of poorly implemented CDS are that providers minimize and ignore safety alerts thus jeopardizing patient safety in the event of a true alert that is inappropriately ignored or silenced.[76,78] Clinician burnout is identified as a key health policy issue requiring immediate action by a number of federal, regional, public, and private stakeholders to preserve well-being of practitioners in addition to providing high-quality and safe clinical care.[79]

There are broader patient safety frameworks available to guide judicious implementation of CDS so that its use achieves the aim of delivering safe and effective clinical interventions optimized for clinician and health care system workflows. Examples include the Health Information Technology (IT) Safety resource from The U.S. Department of Health and Human Services' Office of the National Coordinator for Health Information Technology (ONC), and the Agency for Healthcare Research and Quality Alert Fatigue resource.[73,80]

Discussion

Health care delivery institutions and systems are beginning to implement genetic tests that are driving PM. Genetic test use is trending up in terms of rapid U.S. market expansion as evidenced by increased annual

CPT claim registry and utilization outcomes in the commercial sector, particularly for prenatal and oncology applications, resulting in improved diagnostic and therapeutic tools for a wide range of hereditary and complex conditions. However, ELSI of genetic/genomic test implementation continues to be a priority to ensure adequate access and use of these cutting-edge biomedical advances, particularly for marginalized and vulnerable populations and ethnic minorities.

To ensure safe adoption and clinical translation of PM, health care systems have an ethical responsibility to ensure that their providers and front-line staff are prepared to order, use, and interpret genetic test information. In addition to accommodating genomic information use in CDS and EHR infrastructures, health care systems need to pay particular attention to nongeneticist health care provider workforce adequacy and preparedness to ensure safe application of these advances and drive effective workflow implementation.

There are a number of high-quality evidenced-based educational resources and CDS tools available. CDS and point-of-care "just-in-time" alerts and rapid education intervention tools are a primary pathway for health care providers to use and implement PM, but they must be wisely implemented to avoid health care provider alert fatigue and clinician burnout. This field can be particularly hampered by health care system EHR infrastructure limitations that are unable to support CDS innovations and workflow redesigns involving input and feedback from front-line providers. However, health care systems with cultures fostering strong partnerships between administrative leaders and front-line providers and staff, coupled with reasonable goal setting, will help facilitate PM translation interests.

Conclusion

The (PM) era presents an exciting yet daunting challenge to implement targeted molecular diagnostic and therapeutic treatments using genetic/genomic and omic information into routine health care settings. The fruits of large scale genomic and biobank research initiatives, population health programs, and the proliferation of bioinformatic tools provide learning health systems and front-line health providers powerful resources to prevent and treat a wide range of hereditary and chronic conditions across a wide range of patient care settings. Strategic planning to support health system infrastructure development that is able to incorporate genetic/genomic information, efficient EHR documentation, CDS capacity, and an adequate number of health care providers

trained to use genetic/genomic information will ensure ethical and safe adoption of PM clinical translation interests.

Authorship Confirmation Statement

The author listed designed and performed the literature review, compiled the article draft, reviewed it critically for content, approved the final article before publication submission, and agrees to be held responsible for all aspects of the study in ensuring that questions related to the accuracy or integrity of any part of the study are appropriately investigated and resolved.

Disclaimer

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Author Disclosure Statement

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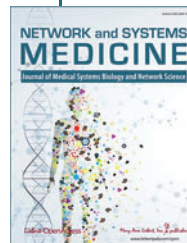
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Abbreviations Used

CDS = clinical decision support
CGC = certified genetic counselor
CLIA = Clinical Laboratory Improvement Amendments
CPT = current procedural terminology
EHR = electronic health record
ELSI = ethical, legal, and social implications
eMERGE = electronic Medical Records and Genomics
FDA = Food and Drug Administration
IGNITE = Implementing GeNomics In pracTicE
NCBI = National Center for Biotechnology Information
NHGRI = National Human Genome Research Institute
NIH = National Institutes of Health
NINR = National Institute of Nursing Research
PM = precision medicine
RN = registered nurse