Genetics in Medicine (2022) 24, 512–520

ELSEVIER

Genetics in Medicine

www.journals.elsevier.com/genetics-in-medicine

ACMG STATEMENT

Points to consider to avoid unfair discrimination and the misuse of genetic information: A statement of the American College of Medical Genetics and Genomics (ACMG)

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Disclaimer: This statement is designed primarily as an educational resource for medical geneticists and other clinicians to help them provide quality medical services. Adherence to this statement is completely voluntary and does not necessarily assure a successful medical outcome. This statement should not be considered inclusive of all proper procedures and tests or exclusive of other procedures and tests that are reasonably directed to obtaining the same results. In determining the propriety of any specific procedure or test, clinicians should apply their own professional judgment to the specific clinical circumstances presented by the individual patient or specimen.

Clinicians are encouraged to document the reasons for the use of a particular procedure or test, whether or not it is in conformance with this statement. Clinicians also are advised to take notice of the date this statement was adopted, and to consider other medical and scientific information that becomes available after that date. It also would be prudent to consider whether intellectual property interests may restrict the performance of certain tests and other procedures.

ARTICLE INFO

Article history:
Received 29 October 2021
Accepted 1 November 2021
Available online 16 December 2021

Keywords:
Data protection
Direct-to-consumer testing
Genetics discrimination
Genetic privacy
Informed consent

Introduction

In this era of precision medicine, the incorporation of genetic and genomic information, herein referred to as genetic information, into health care has gained unprecedented attention. As a result of the rapid decline in the cost of DNA sequencing, these data are now routinely used for diagnostic purposes and preventive health screening. In addition to the application of genetic information to support diagnosis and management, consumers may directly access various genetic testing–based products for medical and nonmedical uses, and some employers now offer wellness genetic testing to their employees as a benefit.[1] In a study published nearly 30 years ago, Billings et al[2] documented discrimination based on genetic diagnosis, test results, or family history in a variety of social institutions. The first American College of Medical Genetics and Genomics (ACMG) points to consider document to address the prevention of unfair genetic

The Board of Directors of the American College of Medical Genetics and Genomics approved this statement on October 19, 2021.
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doi: https://doi.org/10.1016/j.gim.2021.11.002

Table 1 Summary of legislation and enforcement pertinent to genetic privacy and discrimination

Legislation and Enforcement	Protection Offered	Limitations/Details
Equal Employment Opportunity Commission (EEOC), 1965	An administrative agency that enforces federal laws making it illegal to discriminate against a job applicant or an employee because of the person's race, color, religion, sex (including pregnancy, transgender status, and sexual orientation), national origin, age (40 or older), disability or genetic information[a]; the regulations apply to all types of work situations, including hiring, firing, promotions, harassment, training, wages, and benefits	Most employers with at least 15 employees are covered by EEOC laws (20 employees in age discrimination cases) Most labor unions and employment agencies are also covered
American with Disabilities Act (ADA), 1990, amended 2008	Among other provisions, individuals with physical or mental impairment (manifested genetic conditions included) that substantially limits major life activities are protected against discrimination in employment; also included is being regarded as having a disability and being associated with someone who has a disability	
Health Insurance Portability and Accountability Act (HIPAA), 1996	The HIPAA Privacy Rule provides national standards for the protection of certain health information (PHI)[b] by covered entities[c] and their business associates The Privacy Rule provides additional guidance and protection of information related to individuals enrolled in federally funded and some privately funded research The Security rule establishes a national set of standards related to administrative, technical, and physical safeguards to protect electronic PHI, including antidiscrimination protections that are currently enforced under ERISA Genetic information is included as health information covered by HIPAA, including data generated through research	Providers that do not submit electronic claims or other electronic transactions may not be considered covered entities under the HIPAA Privacy Rule (eg, some DTC testing companies) The Privacy Rule generally allows disclosure of PHI for the purpose of treatment, payment, or other health care operation The Privacy Rule allows disclosure of de-identified and anonymized health information, including genetic information The Privacy Rule does not extend to information related to all forms of research
The Employee Retirement Income Security Act (ERISA), 1974	Prohibits discrimination in group health plan coverage based on genetic information Sets minimum standards for most voluntarily established retirement and health plans in private industry to provide protection for individuals in these plans ERISA enforcement includes genetic information through HIPAA	ERISA does not cover group health plans established or maintained by governmental entities, churches for their employees, or plans that are maintained solely to comply with applicable workers compensation, unemployment, or disability laws ERISA does not cover plans maintained outside the United States primarily for the benefit of nonresident aliens or unfunded excess benefit plans

(continued)

Table 1 Continued

Legislation and Enforcement	Protection Offered	Limitations/Details
Genetic Information and Nondiscrimination Act (GINA), 2008	Title I prohibits group and individual health insurers from using a person's genetic information to determine eligibility or premiums; it also prohibits health insurers from requesting or requiring genetic information, including any requirement that a person undergo a genetic test to collect genetic information for underwriting decisions Title II prohibits employers from using a person's genetic information in making employment decisions such as hiring, firing, job assignments, or any other terms of employment Title II prohibits employers from requesting, requiring, or purchasing genetic information about a person or their family members, with some exceptions; one exception is the collection of genetic information in voluntary workplace wellness programs	Does not apply to individuals manifesting symptoms of a genetic disorder Does not apply to other forms of insurance (life, disability, or long-term care insurance) Does not extend to certain sectors of the population (employers with <15 employees) Does not apply to those who receive their health insurance through the Federal Employee Health Benefits plan, Indian Health Service, Veterans Health Administration, or members of US military covered by Tricare; these groups may have internal guidelines for protection
Patient Protection and Affordable Care Act (ACA), 2010	Prohibits a health plan from establishing lifetime or annual limits on the dollar value of benefits Prohibits a health plan from rescinding coverage for an individual or family member except in the case of fraud or intentional misrepresentation of material fact Prohibits a health plan from establishing individual eligibility rules or to set premiums based on pre-existing condition, medical history, claims history, receipt of health care or genetic information	Essential health benefits are defined by each state and may not cover necessary care for an individual with a genetic condition (eg, medical food for inborn errors of metabolism) Requires insurers to cover certain preventive services free of charge; however, the guidelines for preventive services may not align with surveillance guidelines for individuals with a genetic predisposition (eg, colonoscopies without cost sharing begin at age 50, but those with a Lynch Syndrome variant are recommended to receive colonoscopies at ages below that of the general population)

[a]Genetic information as defined by Genetic Information and Nondiscrimination Act includes family medical history, manifestation of a genetic condition in family members, genetic test results, or genetic services provided to an individual or family members. Genetic test includes analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detect a genotype, variant, or chromosomal change.

[b]Protected Health Information includes demographic information; past, present, and future physical or mental health condition; health care provided to an individual; and past, present, and future payment for health care provided to an individual.

[c]Covered entity includes health care providers, health care institutions, health plans, and health care clearinghouses.

discrimination based on genetic disease risk was published 10 years later and focused on discrimination in health insurance and employment.[3]

In this updated document, we review the progress made by summarizing current federal legislative protections noting real and potential gaps and expand the dialogue concerning genetic discrimination by considering representative areas of social justice, equity, and life and disability insurance. Issues surrounding genetic discrimination are based on real and perceived ability of others to access individuals' genetic information and use it to harm or unfairly disadvantage them. In this way, informed consent, privacy, and security of genetic information are related issues requiring ongoing attention as more data are generated, shared, and stored. We address just a few representative areas to illustrate present and future considerations to prevent unfair genetic discrimination.

We recognize that clinical and research laboratories routinely share de-identified, aggregate, or anonymous genetic data. The National Institutes of Health Genomic Data

Sharing policy[4] sets forth guidelines for specific National Institutes of Health–funded human genomic research and data repositories (eg, ClinVar[5]). There are many examples of genomic or even disease-specific databases that are supported by other research groups or institutions that are publicly accessible. This type of data sharing is critical for interpretation and classification of variants and their association with human phenotypes. In addition, de-identified or anonymous residual biospecimens are used in a variety of important ways. This points to consider document is not intended to limit these activities but does bring attention to the importance of disclosure of potential uses of an individual's data or specimen.

Framework for Discussion of Unfair Genetic Discrimination

Unfair genetic discrimination arises when unjust or prejudicial genetic criteria are used to discriminate among individuals or groups or when genetic information is put to wrongful use. In the context of uses of genetic information, the word discrimination has 2 connotations. The first is general and neutral, in which concerning ways information may be used to distinguish between different cases. In this sense, discrimination is not inherently unfair. The capacity to properly discriminate between relevant and nonrelevant types of information is necessary for all clinical judgment. Recognizing appropriate distinctions between groups is essential for making decisions about health care and health-related services. For example, it may be necessary to distinguish genetic causes of a health condition from social, environmental, cultural, or behavioral causes to allow for appropriate management and interventions. Making that distinction requires scientifically valid discrimination. However, some uses of genetic information are problematic, particularly when they adversely affect access to health care and related services or compromise autonomy, privacy, or confidentiality.

In its second, narrower connotation, discrimination concerns the way genetic information may be illicitly used in a prejudicial way. The ever-increasing use and sharing of genetic information highlights persisting legislative and policy gaps in protection, creates new potential wrongs and risks of undue harm, and may increase public concerns and fears about the uses and misuses of their genetic information. In this document, context will usually make it clear as to when we are using discrimination in a general, neutral way and when we consider it in its narrower negative sense. To make explicit the narrower use, we use the phrase "unfair discrimination."

All have an obligation to treat others fairly. This obligation applies to laboratories that provide genetic tests and to clinical geneticists and genetic counselors. It also applies to insurers and those they insure and to employers' interactions with employees. Beyond this general obligation, health services providers have additional fiduciary obligations to care for their patients and protect potentially sensitive information gathered in the provision of clinical care, including the use of genetic data that might be used to unfairly discriminate. These obligations include meeting an appropriate standard of care for all patients, eg, support for patient autonomy, shared decision-making related to genetic testing, and a testing consent process that fully informs the patient about the reasons for testing and any other use of their data or specimen beyond the requested testing. For clinical professionals and laboratories that offer genetic services, justice calls for advocacy to assure necessary genetic services and testing are available and accessible to all.

Summary of Pertinent Legislation and Recommendation for Expanded Protections

Major federal legislation and enforcement regulations related to privacy, security, and use of health information and genetic discrimination are summarized and presented chronologically for historical context (Table 1). Early legislation designed to protect against employment discrimination has been updated over time to include protection against unfair uses of genetic information. Many states have enacted further protections related to genetic information and potential discrimination.[6,7] However, there are still important limitations in the protection offered by federal legislation, eg, individuals manifesting symptoms of a genetic disorder are not afforded protection under the Genetic Information and Nondiscrimination Act (GINA).[8] For this reason, the Patient Protection and Affordable Care Act of 2010 is a landmark piece of legislation that offers certain additional protections to individuals with preexisting conditions, including genetic disorders.[9] Although GINA was enacted to provide assurance to individuals that their genetic information could not be used to discriminate in employment or health insurance, the vast majority of adults are not familiar with the protections offered by GINA or its limitations.[10] Additionally, many health care providers are not aware of or sufficiently familiar with GINA to be able to effectively counsel their patients about the protections offered by it.[11] This lack of understanding of legislative protections, both by patients and by health care providers, may prevent individuals from realizing the benefits of genetic services and testing, not only for themselves but also for their family members.

Genomic medicine is practiced across many domains, including primary and specialty clinical care, research, public health, and even direct-to-consumer business models. Any individual's genomic data may be found and used in more than 1 domain at any time throughout a lifetime. Each of these domains is governed, in whole or part, by specific laws and regulations, with ample potential for uncertainty or conflict.[12] Regardless of how or where the request for genetic testing is initiated, current technology allows the entire

exome or genome sequence to be generated even when more specific or limited testing is requested and reported. Even somatic testing has the capacity to infer or suggest potential for a germline variant. The raw data set may be requested by the patient and/or provider and may be shared or reanalyzed by a third party at the time of testing or at any point in the future.[13]

While Clinical Laboratory Improvement Amendments–certified clinical testing laboratories are considered covered entities under the Health Insurance Portability and Accountability Act (HIPAA),[14] the potential for sharing genetic data and identifiable health information by laboratories or third parties that are not considered covered entities is not adequately covered by existing legislation. In one recent review of genetic privacy legislation, the authors concluded that "few, if any, applicable legal doctrines or enactments provide adequate protection or meaningful control to individuals over disclosures that may affect them,"[15] suggesting that this is an important area that deserves significant resources and attention. Stewardship of genomic data is now addressed in a separate ACMG policy document and supports the need for establishing standards for the sale, transfer, and exchange of human clinical and genomic data.[16] In addition, issues specifically related to privacy and data protection are considered separately below.

This points to consider statement addresses unfair discrimination arising from genomic data uses in real-world settings; it does not examine data protection in human research.

However, it is undeniable that clinical data are often used in research and research data sometimes have clinical implications. The Common Rule,[17] which is the basic Department of Health and Human Services policy for protection of human subjects, limits its applicability to research with identifiable private information and identifiable biospecimens. However, the Common Rule acknowledges that identifiability is a moving target.[18]

A person's genetic material is the result of basic biologic processes beyond individual control and thus should be free from discrimination or favoritism.[19] The combination of genetic sequence variants, epigenetic control of gene expression, and environment that leads to symptom or disease expression is still largely unknown in most cases, and existing understandings may change over time with new information. Our evolving interpretation of the genetic and genomic contribution to human health and disease must be considered when developing or revising legislation and policy addressing the collection and use of genetic information.

Points to consider include the following:

- Updated and future legislation related to genetic discrimination must consider the various domains in which genetic and genomic information are generated and shared.
- GINA should be expanded to include protections for individuals manifesting symptoms of a genetic condition, whether or not they have undergone confirmatory genetic testing.
- Individuals with a genetic diagnosis or at higher risk for a genetic condition must continue to be protected against health insurance discrimination related to eligibility and cost.
- Increasing usage of clinical, consumer-initiated, and workplace genomic testing requires robust educational initiatives related to federal and state-specific protections against genetic discrimination. Such education should be directed toward health professionals, employers, and the general public.

Social Justice and Equity

We cannot ignore the historical connection of genetics with eugenic beliefs and practices. The practice of genetics has perpetuated racism and unfair discrimination.[20] There are no standard definitions of race, ethnicity, or ancestry because these terms apply to the clinical practice of human genetics, but race and ethnicity are acknowledged to be social and cultural constructs, not based on genetic variation. Genetic testing does, however, make use of information about global ancestral populations and sequence variation, especially in variant interpretation.[21]

Racial and ethnic minorities are among the underserved populations for genetic services in the United States. These populations have reduced access to genetic testing,[22] and medical mistrust results in underutilization of genetic counseling and testing.[23-26] As a result of this history, genetic databases are largely composed of individuals of European ancestry. Thus, there is a reduced ability to interpret disease-causing variants in individuals of non-European ancestry.[27] Furthermore, there are significant limitations to testing based on self-reported ethnicity, which, when used for carrier screening, has been shown to result in false negative results.[28] These examples illustrate how past and present concerns about genetic discrimination can lead to further disparities in genetic diagnosis and treatment. As one way to address these disparities, the ACMG now recommends that carrier screening for autosomal recessive and X-linked conditions should be population neutral and more inclusive of diverse populations.[29]

Unfair genetic discrimination arises in many different spheres, including institutional (eg, genetic databases, insurance), societal, and interpersonal spheres. Catz et al[24] studied attitudes related to genetic testing in underserved and minority populations. They documented concerns about the privacy of test results and the perception that genetic testing may be misused by society, eg, sex selection or trait selection.[24] Discrimination in the interpersonal sphere is under-researched and merits more attention.[30] Interpersonal genetic discrimination in the literature is poorly defined but includes discrimination that occurs through personal interactions. For example, participants in Huntington disease study groups, including those at risk of and those with

Huntington disease gene expansion, reported various forms of adverse interpersonal experiences involving family, friends, colleagues, and others, including bullying, abandonment, ostracism, or cruelty.[31]

Genomic research is uniquely positioned to distinguish between genetic and nongenetic causes of health disparities. As one way to address the disparities in clinical genetics and basic and clinical research, the National Human Genome Research Institute has published an action agenda with the purpose of increasing diversity in the genomics workforces stating, "the promise of genomics cannot be fully realized without successfully attracting, developing, and retaining a diverse research and clinical workforce that more closely resembles the population of the U.S."[32] In the field of genetics, there must be continued focus on equitable access to testing, appropriate treatments, and care, while acknowledging that other societal disparities exist that can lead to adverse health outcomes, which must also be addressed.[33]

Points to consider include the following:

- Every human life has equal value and rights; therefore, genetic information should not be used to perpetuate racism, superiority, or discrimination.
- The terms race, ethnicity, and ancestry must be defined, and guidelines for data collection and use must be determined and standardized for all research and practice, including genomic medicine and research.
- Concerted effort and research are needed to increase the diversity of genetic databases, to improve variant interpretation in diverse populations, and to facilitate the study of genetic, environmental, social, and structural determinants of health.
- Training and employment opportunities in the field of genetics must make significant efforts to reflect the diversity of the population to be served.
- Research is needed to better define unfair genetic discrimination in the interpersonal sphere so that it can be addressed effectively.
- Genetic health care disparities must be acknowledged and addressed through targeted education, research, and expansion of access to genetic services.

Life and Disability Insurance

Use of genetic information in the underwriting of life and disability insurance remains controversial. However, advancements in addressing potentially discriminatory practices can be made even when controversies remain unresolved. Current federal laws prohibiting the use of genetic information in health insurance underwriting do not generally apply to life and disability insurance, although some states have enacted legislation prohibiting the use of genetic information for coverage and premiums by providers of life and long-term care insurance.[34,35] Insurers routinely use potentially sensitive, nongenetic health information for the determination of eligibility and rate setting; for example, some family history or a personal diagnosis of diabetes or hypertension may adversely impact one's ability to purchase disability and life insurance. The adverse effect of using genetic information on eligibility or rates would thus not be exceptional. In contrast, when underwriting health insurance, objections to using genetic information are best understood in relation to broader objections to using any risk or pre-existing medical conditions as a basis for penalizing or excluding individuals from obtaining health insurance. While these protections are based on the belief that people should have a general right to basic health care, there is not a similar consensus that people have a general right to purchase life or disability insurance. Furthermore, while it may be "inherently unfair to penalize someone for their genetic makeup,"[19] it may also be unfair when individuals learn about their own genetic makeup and then use that information to decide whether they purchase life or disability insurance while withholding this information from the insurer. Prohibiting insurers from using genetic information in life and disability insurance may thus introduce a problematic imbalance in how such information might be used. This may adversely alter insurance underwriting in a way that has unanticipated consequences for both the industry and the individuals who are, or wish to be, insured.

Here we have made a concerted effort to acknowledge and fairly represent the legitimate concerns of insurers who are worried about the asymmetric uses of genetic information. However, recognition of legitimate areas of ongoing controversy should not be a basis for suspending efforts to address the practices of some insurers in this area that are clearly unwarranted and thus ought to be targets of social action directed toward the elimination of discrimination. For example, some who offer life or disability insurance may require a blood or other biologic sample. These insurers may demand, as a condition of application, a blanket consent for all tests, specified and unspecified, that might be done with that sample. This consent may include storage and sharing information or test results for other purposes beyond those related to the specific application for life or disability insurance. One thing should be clear: if genetic information is to be used, all planned and potential tests and any other uses of the information should be communicated to the applicant explicitly as part of informed consent. This statement, which supports transparency and informed consent for any genetic testing performed as part of a life or disability insurance application, should not be interpreted as sanctioning such a use. It only states that if there is to be such testing, this must be explicitly acknowledged, and any uses of the information must be restricted to the specific purpose for which an individual authorizes the test.

Points to consider include the following:

- There are relevant differences between health insurance and disability or life insurance. Ongoing work is needed to better understand how and when genetic

information may fairly be used in life and disability insurance.
- General consent forms that allow insurers to conduct genetic tests without informing individuals should be prohibited. The consent process and documentation should specify all tests to be performed with a biologic sample.
- Results of genetic tests collected or performed by insurers should only be used for the specific application permitting the specimen collection and should not be shared with other companies or used for other purposes without explicit authorization by the applicant.

Importance of Privacy and Data Protection to Avoid Discrimination

Advances in genomic medicine are based on de-identified or anonymized genomic data that have been shared from a variety of sources, but there are increasing concerns about the potential for unfair discrimination using genetic information as more data are generated and shared. Medical mistrust by racial and ethnic minority populations often includes concerns about racial discrimination based on potential breaches of privacy and confidentiality of test results.[24,36,37] Historical uses of genetic testing in the workplace sometimes included screening programs to exclude individuals from employment or other benefits.[38] The emerging model of workplace genetic testing, in contrast, claims a preventive health approach as an employee benefit. Aggregate data may be provided to or accessed by the employer or the employer's health plan. However, it is both possible and concerning that individual data may be exposed.[39]

All individually identifiable health information, including individually identifiable genetic information, is considered protected health information or protection of certain health information, under the HIPAA Privacy Rule, which regulates its use and disclosure. Although de-identified genetic data currently lie outside of HIPAA protections, the potential for reidentification is evolving over time, thus creating a greater potential for genetic discrimination. Moreover, some genetic data may be so unique (eg, from a single family) that they may be readily identifiable notwithstanding standard deidentification precautions.

States have also enacted a range of legislation and regulations related to genetic privacy, including some that specifically address anonymized data and sample retention.[6,7] The existing patchwork of federal and state legislation leaves laboratories with the duty to set their own security procedures and guidelines, informed by HIPAA and other regulatory policies. Given that genetic information is potentially generated and shared across entities in various locations and over time, privacy and data protection of genetic information, including cybersecurity, should be addressed at a national level to provide at least minimal standards to prevent breach of data security, especially by entities not bound by HIPAA or other regulations. Informing individuals about how their genetic information and any residual specimen may be used and strengthening data protection, represents one means of addressing concerns and preventing unfair discrimination. Comprehensive evaluation of and recommendations for strengthening privacy and security protection for genomic data are beyond the scope of this statement but the recent ACMG statement related to stewardship of genomic data considers related policies.[16] Issues related specifically to workplace genomic testing are also currently being addressed in a separate Social, Ethical and Legal Issues Committee work group with recommendations forthcoming.

Points to consider include the following:

- The definition of de-identified data should be reanalyzed on a frequent basis with the risks of reidentification and discrimination balanced against the benefits that sharing genetic data provide in contributing to biomedical research.
- To address concerns about potential misuse of genetic information, a transparent informed consent process for genetic testing must include clear and concise language disclosing potential uses of the genetic information and biologic specimen, including the individual's
  - rights and ability to access their own genomic data
  - ability to control the use and sharing of their data and information, including any limitations on that authority
  - ability to withdraw consent to any further use and sharing of data and the process for doing so
- To prevent unfair genetic discrimination resulting from workplace genomic testing, federal and state privacy laws, including treatment and use of aggregate data, need comprehensive re-examination.
- All individuals with access to employer-sponsored or -supported genomic testing, including those not currently covered by Title II of GINA, should be protected against any form of discrimination from the employer, employment agency, labor organizations, and training programs at all steps in the employment process.
- No genetic information linked to individual identifiers should be accessed or used by public or private entities without individual consent, except where permitted by law.
- Federal legislation should continue to evolve to address rigorous analog and electronic data protection standards for all public and private entities in possession of or with access to individually identifiable health information, including genetic information. Legislation should include provisions for enforcement and penalties for breach of standards and any unauthorized access of genetic information.

Conclusion

Advances in our understanding of human health and disease are now often based on shared genomic data. Thus, our attention must focus on proper and just use of these data for both the individual and society, recognition of how the data might be used to unfairly discriminate now or in the future, and developing strategies to prevent or mitigate such misuse. We must be sensitive to both real and perceived concerns about genetic discrimination. This can be addressed, at least in part, by a detailed informed consent conversation for any genetic testing that addresses the use of genetic data and any privacy concerns. Robust federal legislation protecting privacy and security of genetic information as an integral part of health information is critical. Finally, we must actively work to increase the representativeness of reference databases and the diversity of the genetics workforce.

While this document has more broadly addressed issues of genetic discrimination than past documents, we must recognize that genetic information has the potential to contribute to unfair discrimination in other areas of society such as education, housing, finance, and law enforcement, especially as the availability of medical and nonmedical genetic data continues to rapidly expand. The ACMG recognizes its critical role in identifying and preventing unfair genetic discrimination and will continue to advocate in support of legislation, research, and education to this end.

Conflict of Interest

M.V. reports receiving a salary/stock from Invitae Corporation. K.W.'s contributions were supported by a grant from the Health Resources and Services Administration (HRSA.gov) (award number: UH7MC30776). All other authors declare no conflicts of interest.

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