Public Health Genomics

Perspectives

Public Health Genomics 2023;26:183–187
DOI: 10.1159/000534365

Received: August 1, 2023
Accepted: September 26, 2023
Published online: September 29, 2023

Consideration of the Beneficiary Inducement Statute on Access to Health Care Systems' Population Genetic Screening Programs

Aurora M. Washington[a] Kimberly Foss[b] Joan H. Krause[c] Arlene M. Davis[a]
Kristine J. Kuczynski[a] Laura V. Milko[b] Jonathan S. Berg[b] Megan C. Roberts[d]

[a]Department of Social Medicine, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA; [b]Department of Genetics, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA; [c]School of Law, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA; [d]School of Pharmacy – Division of Pharmaceutical Outcomes and Policy, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA

Keywords
Health equity · Precision medicine · Population genetics · Genetic screening

Introduction

Population genetic screening (PGS) enables the detection of unselected individuals in the general population who unknowingly carry a pathogenic variant in a gene that is causally associated with a particular monogenic disease. Presymptomatic screening facilitates early detection and proactive health care for people with these rare conditions, including additional testing and surveillance for individuals who receive a positive result. Tier 1 genomic applications are defined by the CDC Office of Public Health Genomics as those which have a significant potential for positive impact on public health based on available evidence-based guidelines and recommendations. Currently, it focuses on three applications: hereditary breast and ovarian cancer syndrome, Lynch syndrome, and familial hypercholesterolemia. These were recommended by the Genomics and Population Health Action Collaborative of the National Academies of Sciences, Engineering, and Medicine, as ideal candidates for pilot DNA-based screening programs in healthy adults [1] because they are well-understood and highly penetrant conditions with established medical management guidelines. Currently, these conditions are considered a public health burden because individuals and families affected by them could significantly improve morbidity and mortality through early detection and intervention [2]. Despite this logic, the use of PGS has not been widely adopted [3, 4]. There are various barriers that have prevented a wide adoption of genetic screenings in the USA including a general lack of knowledge about genetics, perceptions of probability/risk, perceived lack of utility, and the potential harmful implications to patients [5–7]. The potential downsides of PGS could include low positive predictive value of certain types of results, overdiagnosis and overtreatment due to incomplete penetrance and variable expressivity of the condition, unexpected discovery of misattributed parentage, and unanticipated violations of autonomy, privacy, confidentiality, and career/health care equity [8–12].

Costs as a Barrier for PGS

A more tangible, central issue is the actual costs of PGS and the differing price tags which are based on the party responsible for payment. There are various ways to

karger@karger.com
www.karger.com/phg

Correspondence to:
Aurora M. Washington, auroraw@email.unc.edu

address the cost of genetic screening, including but not limited to private health insurance coverage (through an employer or individual plans), government-funded health programs (Medicare, Medicaid), sponsored (free) testing by a health system or philanthropic organization, or payment directly by the consumer. Many of the initial efforts in creating access to PGS have occurred through research programs and/or biobanks [3] which enable screening to be provided without charge to participants but are subject to human subjects research oversight and other limitations imposed by federal or state law, institutional policy, Institutional Review Board oversight, and/or by private sponsors. Research is also a fundamentally different enterprise than clinical care, where financial cost to the participant is a less common concern.

However, for screening programs in clinical practice the various modes of payment each have accompanying challenges and considerations for the payors, the patient-recipients, and the screening program itself. The "list price" of a genetic panel that is seen by a given entity may not reflect the actual cost of performing the test or the payment made by that party. For example, a clinical laboratory may charge "full price" to an insurance company, even though the actual amount reimbursed is likely to be only a fraction of that price, and may or may not cover the actual cost of conducting the test. However, because PGS is still relatively new in the health care space, insurance companies are not currently covering this type of screening, citing lack of evidence of medical necessity. Historically, genetic testing has only been ordered for individuals with a personal or family history suggestive of a genetic condition and criteria have been developed to determine if a patient has a high enough pretest probability for the testing to be medically necessary and therefore a covered service. While genetic tests have been ordered on an as needed basis by health care providers, preemptive genetic screening is not currently a clinical offering. Given the uncertainties of insurance coverage for preemptive genetic screening, companies are also offering this type of test to the general population at prices in the range of USD 100–2,000. This aligns with the increased popularity of direct-to-consumer (DTC) testing companies, although it is essential to note that the genetic analysis completed in the DTC realm is typically very different than a clinical genetic test. DTC genetic tests are often used for a variety of reasons, such as learning about genetic ancestry, recreational information about traits like eye color or earwax type, and variable information about genetic risk of disease (the clinical validity of which depends on the testing platform used and type of analysis applied). On the other hand, clinical genetic testing is typically focused on comprehensive analysis of a set of genes to identify variants responsible for monogenic conditions [13]. While DTC genetic testing gives increased access to genomic screening and testing, it also has the potential of making it a boutique health care offering for the well-to-do who can afford it. Lastly, DTC genetic testing has potential to create issues of consumers misunderstanding or misinterpreting their results and needing a physician to provide the proper context.

Anti-Kickback Statute and the Beneficiary Inducement Statute

Pilot clinical implementation of PGS programs face a unique set of challenges related to the lack of insurance coverage, or other means of support, for patients who may benefit from the programs. In order to reduce barriers to access and provide broad availability of genomic screening to its members, a health entity may wish to offer the testing at low or no cost. However, the provisions of federal law, particularly the Anti-Kickback Statute (AKS) and the Beneficiary Inducement Statute (BIS), could interfere with the ability for beneficiaries of federal health care programs (Medicare and Medicaid) to receive low- or no-cost testing. The AKS prohibits the offer, payment, solicitation, or receipt of remuneration to induce someone to refer patients or to purchase, order, or recommend items/services paid for by federal health care programs. The AKS was enacted in 1972 as an amendment to the Social Security Act, and its reach and penalty provisions were significantly expanded in 1977. The statute is intended to limit the influence of financial incentives on health care referral and purchasing decisions. Concerns include overutilization, increased program costs, corruption of medical decision-making, patient steering, and unfair competition. Many states have their own AKSs, although they differ in scope. Some apply only to state public health care programs (including Medicaid), while others reach all payors including private insurers, making them even broader than federal law; moreover, some impose criminal penalties similar to federal law, while others merely subject violators to disciplinary action. Depending on the state, these laws may also pose additional problems for PGS [14–16].

While the AKS could apply to benefits given directly to patients, the statute is most often invoked against financial relationships between and among health care

providers. A separate federal statute enacted in 2002, called the Beneficiary Inducements Statute, targets financial benefits given directly to patients. The BIS imposes civil money penalties against health care providers who offer or transfer remuneration to a Medicare or state health care program beneficiary. This is to prevent indirectly influencing the beneficiary's selection of providers, practitioners, or suppliers for the order or receipt of any item or service for which payment may be made, in whole or in part, by Medicare or a state health care program. In layman's terms, the provision states that a recipient of Medicare or Medicaid cannot be offered free services or anything with a monetary value by any health care providers, as it may be an incentive for the patient to seek treatment with that provider rather than others.

BIS Exemptions

While the BIS was created to deter the persuasion of patients to seek services and items with certain providers after free or discounted incentives, there are exceptions which make the actions of concern permissible without risk of penalty, and ensure that these individuals have equitable access to care. Health care providers can tailor their offering programs to meet the requirements of the exceptions in order to avoid penalty. In addition, for reassurance they can request an advisory opinion from the Office of the Inspector General (OIG) on whether they are protected from penalty under a civil money penalties, AKS, and BIS exemption. This legal determination often depends on the value of what is being offered, the obligation to bill for subsequent care, medical action appropriateness, the clinical and personal benefits, and the criteria being followed. There are 10 overarching BIS exemptions; three of those could be used as protection from penalty for PGS. As per the Code of Federal Regulations – Title 42, Chapter V, Subchapter B, Part 1003, Subpart A – the three most relevant exemptions for PGSs are:

A) "Incentives given to individuals to promote the delivery of preventive care services where the delivery of such services is not tied (directly or indirectly) to the provision of other services are reimbursed in whole or in part by Medicare or an applicable state health care program. Such incentives may include the provision of preventive care but may not include – (i) cash or instruments convertible to cash; or (ii) an incentive whose value is disproportionally large in relationship to the value of the preventive care service (i.e., either the value of the service itself or the future health care costs reasonably expected to be avoided as a result of the preventive care).

B) The offer or transfer of items or services for free or less than fair market value by a person, if – (1) the items or services are not offered as part of any advertisement or solicitation; (2) the offer or transfer of the items or services is not tied to the provision of other items or services reimbursed in whole or in part by the program under Title XVIII or a state health care program (as defined in section 1128(h) of the Act); (3) there is a reasonable connection between the items or services and the medical care of the individual; and (4) the person provides the items or services after determining in good faith that the individual is in financial need.

C) The offer or transfer of items or services for free or less than fair market value by a person if – (1) the items or services consist of coupons, rebates, or other rewards from a retailer; (2) the items or services are offered or transferred on equal terms available to the general public, regardless of health insurance status; and (3) the offer or transfer of the items or services is not tied to the provision of other items or services reimbursed in whole or in part by the program under Title XVIII or a state health care program (as defined in section 1128(h) of the Act)."

Health care providers may offer programs for more costly services as incentives to promote the delivery of preventive care services. While genetic screening is not specifically viewed as a preventive service at this time, the goal of screening is to help identify individuals with an increased risk of health complications so preventive services (such as mammography and colonoscopy, which, of note, are covered by federal insurance plans) can be implemented. Health care providers have also requested guidance from the OIG and been permitted to offer free services in the past. For example, OIG Advisory Opinion No. 21-12 involved a case where providers requested to offer free items and services to treat complications that occur within 90 days of a joint replacement procedure. In this case, the OIG opined that this offering of free items and services was permissible even though the proposed arrangement by the requestor would generate prohibited remuneration under the AKS and BIS. If certain circumstances were true, the OIG would not impose administrative sanctions on the requestor in this instance. The rationale for the OIG decision is informative because it reasons that the program was designed to promote quality of care and better outcomes, had a low risk of interfering with or skewing clinical decision making, was unlikely to lead to overutilization or inappropriate utilization of items, and that patient steering was unlikely. While the offer in OIG AO No. 21-12 was not as proactive as in screening, it is relevant because both services promote better health care outcomes and benefit patients. Also, neither interferes with clinical decision-making;

neither leads to patient steering and overutilization or inappropriate utilization of items/services; and neither causes an increase in medically necessary care. Like the No. 21-12 case, PGS could result in decreased costs to federal health care programs by detecting manageable conditions before they are burdensome financially to Medicaid/Medicare and/or physically to patients.

As PGS programs increase across the country (Foss et al. [3]; Williams and colleagues [9]), groups have found a variety of mechanisms to avoid conflicts with the BIS. Many providers are now offering PGS through a research project with informed consent that is separate from clinical care. Since research has other funding mechanisms, payment for this screening is not relevant to the BIS. It is important to note that research testing often includes other aspects of genetic analysis, such as bio-banking and/or the participant agreeing to their DNA being used for other research purposes, which may raise concerns for some individuals who are only interested in screening for actionable genetic conditions. Genetic screening offered in a research setting will also likely require a clinical confirmation step, in which after a genetic result is found through research analysis, another DNA sample will need to be analyzed in a clinical laboratory and a clinical report to be issued. This clinical report is then utilized for follow-up care and familial cascade testing. Other PGS groups offer gene analysis at a self-pay price, which is often less costly than clinical testing but still associated with a "sustainable value" and therefore not in conflict with the BIS. Other PGS programs are state-funded or have waivers from accountable care organizations. While there are a variety of mechanisms to work around the BIS, each can present additional barriers. Potentially, an all-inclusive and straightforward mechanism could be for a health care system to cover the cost of screening for all patients.

Another possible way to ensure equitable PGS and off-set burdensome costs to patients could be through health care reform, which is a strict political process that occurs when concerned parties address the government about grievances [17]. For example, there was an expansion in federal insurance health care coverage after successful lobbying for the Affordable Care Act [18]. For an increase in coverage to be implemented, stakeholders must demonstrate a clear benefit clinically, personally, and fiscally for the financial risk parties. This process is labor-intensive and often results in extended timelines for resolution, but it is also a more permanent solution.

Implications for PGS and Public Health Genomics

As with many clinical innovations, there is often a period in early clinical adoption in which emerging evidence for the potential benefits of a new clinical service precedes inclusion in clinical guidelines and insurance coverage decisions. This early clinical adoption phase is critical for establishing the implementation and impact of PGS. Inclusion of representative populations is particularly important to mitigate potential inequities in access from the start as well as to continue to collect clinical data that is representative of the general population to demonstrate clinical effectiveness. Patients with Medicaid and/or Medicare may be especially vulnerable to inequities related to access to preventive services, in part due to such federal statutes that aim to protect them but instead may block their access to a beneficial service. Research has demonstrated that those with low family income [19, 20] and older adults [21, 22] are less likely to engage in preventive services. Thus, as PGS expands into clinical settings, consideration of the BIS will be important to ensure inclusion of patients with Medicaid and Medicare. As noted above, each path forward offers potential benefits and drawbacks to equity in clinical PGS, and perhaps multiple strategies will be required to attain equitable dissemination of health innovations such a PGS during early adoption. While we do not have the answer to what the optimal path forward is, surely this issue will resurface as public health genomics expands.

Statement of Ethics

This article was composed by researchers who are cognizant of the ways in which structural inequities inform all social relationships, including those that impact research. Authors drafted this article with respect for cultures, communities, and the public's personal knowledge. All ethical principles inform our approach to this perspective.

Conflict of Interest Statement

The authors have no relevant conflicts to disclose.

Funding Sources

This perspective publication was supported in part by the National Human Genome Research Institute of the National Institutes of Health under award number R21HG012672, and the Program for Precision Medicine in Health Care (PPMH) at the University of North Carolina at Chapel Hill School of Medicine provided funding and institutional support.

Author Contributions

Aurora M. Washington, Joan H. Krause, and Megan C. Roberts: substantial contribution to the concepts presented in this piece, as well as the analysis and interpretation of information required to make a comprehensive document; and contributed to drafting the work and reviewing it critically for important intellectual content. Kimberly Foss, Arlene M. Davis, Jonathan S. Berg, Kristine J. Kuczynski, and Laura V. Milko contributed to drafting the work and reviewing it critically for important intellectual content.

References

1 Murray MF, Evans JP, Angrist M, Uhlmann WR, Lochner Doyle D, Fullerton SM, et al. A proposed approach for implementing genomics-based screening programs for healthy adults. NAM Perspect; 2018 Dec 3 [cited 2023 Jul 12]. Available from: http://nam.edu/a-proposed-approach-for-implementing-genomics-based-screening-programs-for-healthy-adults.

2 Abul-Husn NS, Soper ER, Braganza GT, Rodriguez JE, Zeid N, Cullina S, et al. Implementing genomic screening in diverse populations. Genome Med. 2021 Dec;13(1):17.

3 Foss KS, O'Daniel JM, Berg JS, Powell SN, Cadigan RJ, Kuczynski KJ, et al. The rise of population genomic screening: characteristics of current programs and the need for evidence regarding optimal implementation. J Pers Med. 2022 Apr 26;12(5):692.

4 Haverfield EV, Esplin ED, Aguilar SJ, Hatchell KE, Ormond KE, Hanson-Kahn A, et al. Physician-directed genetic screening to evaluate personal risk for medically actionable disorders: a large multi-center cohort study. BMC Med. 2021 Dec;19(1):199.

5 Alcalay RN, Kehoe C, Shorr E, Battista R, Hall A, Simuni T, et al. Genetic testing for Parkinson disease: current practice, knowledge, and attitudes among US and Canadian movement disorders specialists. Genet Med. 2020 Mar;22(3):574–80.

6 Andrade C. Understanding relative risk, odds ratio, and related terms: as simple as it can get: (clinical and practical psychopharmacology). J Clin Psychiatry. 2015 Jul 22;76(07):e857–61.

7 Pinzón-Espinosa J, Van Der Horst M, Zinkstok J, Austin J, Aalfs C, Batalla A, et al. Barriers to genetic testing in clinical psychiatry and ways to overcome them: from clinicians' attitudes to sociocultural differences between patients across the globe. Transl Psychiatry. 2022 Oct 11;12(1):442.

8 Andrews LB. Assessing genetic risks: implications for health and social policy. Washington, DC: National Academy Press; 1994.

9 Katz AE, Nussbaum RL, Solomon BD, Rehm HL, Williams MS, Biesecker LG. Management of secondary genomic findings. Am J Hum Genet. 2020 Jul;107(1):3–14.

10 Eno C, Bayrak-Toydemir P, Bean L, Braxton A, Chao EC, El-Khechen D, et al. Misattributed parentage as an unanticipated finding during exome/genome sequencing: current clinical laboratory practices and an opportunity for standardization. Genet Med. 2019 Apr;21(4):861–6.

11 Roche MI, Griesemer I, Khan CM, Moore E, Lin FC, O-Daniel JM, et al. Factors influencing NCGENES research participants- requests for non-medically actionable secondary findings. Genet Med. 2019 May;21(5):1092–9.

12 Meagher KM, Berg JS. Too much of a good thing? Overdiagnosis, or overestimating risk in preventive genomic screening. Per Med. 2018 Sep;15(5):343–6.

13 Ariel Precision Medicine. What's the difference between clinical genetic testing for diseases and direct to consumer Genome testing? 2020. [cited 2023 Aug 19]. Available from: https://arielmedicine.com/clinical-genetic-testing-vs-direct-to-consumer-genome-testing/.

14 Ohio Rev. Code Ann. § 2913.40. Available from: https://codes.ohio.gov/ohio-revised-code/section-2913.40.

15 NC. Gen Stat. § 90-401. Available from: https://www.ncleg.gov/enactedlegislation/statutes/html/bysection/chapter_90/gs_90-401.html.

16 Cal. Bus. & Prof. Code § 650. Available from: https://california.public.law/codes/ca_bus_and_prof_code_section_650.

17 Willson PD. The importance of lobbying to advance health and science policy. Acad Med. 2020 Jan;95(1):13–5.

18 Karch A, Rosenthal A. Framing, engagement, and policy change: lessons for the ACA. J Health Polit Pol L. 2017 Apr;42(2):341–62.

19 Dusic E, Bowen DJ, Bennett R, Cain KC, Theoryn T, Velasquez M, et al. Socioeconomic status and interest in genetic testing in a US-based sample. Healthcare. 2022 May 10;10(5):880.

20 Norris HC, Richardson HM, Benoit MAC, Shrosbree B, Smith JE, Fendrick AM. Utilization impact of cost-sharing elimination for preventive care services: a rapid review. Med Care Res Rev. 2022 Apr;79(2):175–97.

21 Ogden LL, Richards CL, Shenson D. Clinical preventive services for older adults: the interface between personal health care and public health services. Am J Public Health. 2012 Mar;102(3):419–25.

22 Forde C, Brunstrom K, Woodward E, Bowers N, Pereira M, Wallace AJ, et al. Uptake of presymptomatic testing for *BRCA1* and *BRCA2* is age, gender, offspring and time-dependent. J Med Genet. 2021 Feb 1;58(2):74–8.