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Precision medicine is a new health care concept intended to hasten progress toward individualized treatment and, in so doing, to improve everyone's opportunity to enjoy good health. Yet, this concept pays scant attention to opportunities for change in the social determinants that are the major drivers of health. Precision medicine research is likely to generate improvements in medical care but may have the unintended consequence of worsening existing disparities in health care access. For prevention, precision medicine emphasizes comprehensive risk prediction and individual efforts to accomplish risk reduction. The application of the precision medicine vision to type 2 diabetes, a growing threat to population health, fails to acknowledge collective responsibility for a health-promoting society. *Ethn Dis.* 2019; 29(Suppl 3): 669-674; doi:10.18865/ed.29.S3.669

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INTRODUCTION

Precision medicine is defined as a move from “one-size-fits-all” medicine to more individualized care, based on consideration of a person's genetics, environment, and lifestyle.¹ The goal is not merely to improve medical care but more broadly to “give everyone the best chance at good health.”² As a test of these claims, we consider how precision medicine might address one of our society's most confounding health problems: the increasing burden of type 2 diabetes (T2DM).

Nearly 10% of Americans have been diagnosed with diabetes, most with T2DM, and an estimated 2.9% have undiagnosed disease.³ Fully a third of Americans have “prediabetes,” ie, evidence of impaired blood sugar control that places them at increased risk to develop T2DM.³ T2DM also represents an important health disparity, with substantially higher rates for African Americans, Latinos, and American Indian and Alaska Native (AIAN) people compared with Whites.³ We argue that precision medicine offers potential benefits to patients with diabetes, but at the risk of exacerbating health care disparities. However, precision medicine fails to address the more fundamental problem of rising rates of T2DM.

Applying Precision Medicine Research Priorities to Care of Patients with T2DM

The Precision Medicine Initiative of the National Institutes of Health identified several scientific opportunities for precision medicine research, leveraging electronic health data and

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advances in genomics and molecular analysis (Table 1).¹ These approaches are well-established in diabetes research and indicate a role for precision

medicine in improving diabetes care.^{4,5}

Improvements in disease classification, for example, offer the opportunity to move beyond identification of the small subset of patients with monogenic forms of diabetes⁶ to the characterization of other clinically relevant subtypes of diabetes (eg, subtypes of T2DM that differ in likelihood of complications⁵). Improved disease classification could create opportunities to tailor the intensity of glucose control and medical surveillance to more precise measures of a patient's risk of adverse events.

New therapies may also emerge from precision medicine research. The Accelerating Medicine partnership, a public-private venture launched in 2014, provides access to data from large-scale T2DM genetic association studies to support understanding of disease mechanisms and development of new drug treatments.⁷ Other examples of precision medicine research include studies of the role of the gut microbiome in diabetes pathophysiology, which could lead to interventions involving probiotics or other manipulations of the gut microbiome,⁸ and pharmacogenomic research. The latter has iden-

tified gene variants associated with response to diabetes drugs, offering the possibility of developing genetic tests to tailor T2DM treatment.⁹

Thus, there is substantial hope that precision medicine research will expand opportunities to improve diabetes care. However, results from research in other disease areas suggest that benefits from precision medicine may be limited and costly. New approaches to cancer treatment, for example, often yield small increments in life expectancy at costs of \$50,000-\$100,000 or more.¹⁰ Among available pharmacogenomic tests, only a minority have convincing evidence of clinical utility, ie, evidence that test use improves health outcomes.¹¹ Even when benefits are substantial, cost may be problematic. For example, a new drug for cystic fibrosis offers significant health benefit – at a cost of \$272,000 per year.¹² Insurance co-pays are prohibitive for some (eg, \$3000 per month), and some Medicaid funders are reluctant to cover the drug.¹² Low-income and minority patients with T2DM already experience barriers to effective health care,¹³ with associated deficits in control of blood glucose.¹⁴ If precision

medicine interventions for T2DM are similarly costly, they may be beyond the reach of many patients, exacerbating existing disparities.

PRECISION MEDICINE AND T2DM PREVENTION

A transformative improvement in population health could be achieved, however, if precision medicine could address the increasing number of people affected by T2DM. Diabetes rates have been steadily rising since 1980, with T2DM accounting for 90%-95% of cases.^{3,15} Projections suggest that up to a third of the US population could have diabetes by 2050.¹⁵ This growing burden has significant health consequences. T2DM's cardiovascular, renal, and ophthalmological complications shorten lifespans and increase disability. Diabetes is also costly. Total diabetes-related expenses in 2015 (at a diabetes prevalence of under 10%) were estimated to be \$245 billion and medical expenditures for people with diabetes averaged 2.3 times higher than for people without the diagnosis.³ Prevention of T2DM is, thus, a

Table 1. Scientific opportunities for the Precision Medicine Initiative^a

Discovery of methods to measure disease risk based on environmental exposure, genetics and interactions between the two
Identification of genetic contributors to differences in drug response
Discovery of disease biomarkers associated with increased or decreased risk for developing common diseases
Use of mobile health (mHealth) devices to evaluate connections between health outcomes and activity, physiology and environmental exposures
Development of new classification of diseases
Empowerment of study participants with “data and information to improve their own health.”
Creation of a platform to enable clinical trials of targeted therapies

a. Adapted from the Precision Medicine Initiative web site¹

crucial issue for population health.

As with disease management, the precision medicine approach to prevention targets interventions to individual risk.^{16,17} This approach can offer powerful benefits when specific measures to reduce risk are required but are not appropriate for most people. For example, the special diet provided to infants with phenylketonuria is essential for their health but would be inadvisable for most people. Similarly, individuals with hemochromatosis require the institution of regular blood draws to reduce iron overload. The expansion of this prevention model to common complex diseases like diabetes is, however, problematic. The means to reduce risk in this case is through pursuit of a healthier lifestyle, that is, through increased physical activity and a diet that emphasizes plant-based foods and reduces fat and sugar intake. The role of risk information is to motivate a behavioral change that is advisable for everyone. For example, the Precision Medicine Initiative Working Group Report envisions “empowering participants with data to improve their own health...this information may promote healthier behavior...”¹⁸

Discussions of risk information in precision medicine often emphasize genetics,^{16,19} in line with a discourse that has characterized the human genome as an individual’s “instruction book,” allowing people to “focus on the things we need to pay most attention to and less on the things for which we are not so much at risk.”²⁰ Risk information may also derive from mobile devices or other measures that assess environmental and lifestyle factors (Table 1), or include psycho-

logical and socioeconomic factors.¹⁷

If risk information led to healthier lifestyles, it could significantly reduce the number of people with T2DM. However, the use of genetic risk assessment to reduce T2DM risk has been tested in three randomized controlled trials,²¹⁻²³ with negative results in all studies. Providing genetic risk information was no more effective than conventional risk counseling in changing patient behavior^{22,23} and did not increase self-reported motivation or adherence to a prevention program.²¹ One study also assessed the effect of a non-genetic measure of risk for T2DM (based on body mass index [BMI], age, and sex); provision of this risk information similarly had no effect on behavioral outcomes.²² These results are consistent with a meta-analysis that evaluated studies on the use of genetic risk information to motivate a range of behavioral changes; the study concluded that communicating DNA-based risk had little or no effect on risk-reducing behavior and would be an ineffective population health strategy.²⁴

There are additional problems with using genetic testing to assess risk for T2DM. It is arguably not needed, because risk for diabetes is readily assessed by family history, BMI, and measurement of a person’s serum HbA1c. More significantly, use of “precise” genetic measures could be counterproductive. For example, a study of a diabetes risk score found, as expected, that those with a low-risk score had about half the risk for developing T2DM as those with a high-risk score.²⁵ Yet, when the data were stratified by BMI, obese individuals with a low genetic risk had a 4-

5-fold higher likelihood of developing T2DM than normal-weight individuals with a high genetic risk. The genetic risk profile, in other words, was substantially less predictive than an individual’s BMI. Genetic testing could provide misleading risk information: an obese individual with a low-risk genetic score might assume that diabetes was not a concern and, conversely, a normal-weight person with a high-risk score might overestimate his risk. This result is consistent with the strong influence of lifestyle factors on diabetes risk.^{26,27} Related factors, such as physical activity level and intake of sugar-sweetened beverages, might moderate the effect of the genetic risk score in a similar way.

IS GENETICS A CAUSE OF DISPARITIES IN T2DM?

Because genetics is a contributor to T2DM risk, genetic differences have also been postulated as the cause of the higher prevalence of T2DM in minority populations,²⁸ with the implication that precision medicine approaches might differ in different groups. A notable example is the high prevalence of T2DM among Pima people in the United States, historically assumed to be due to genetics.²⁸ A recent study offers powerful evidence that social factors are the cause. In this study, US Pima were compared with a related indigenous population living in Mexico.²⁹ Although genetic studies confirmed the high genetic relatedness of the two populations, T2DM rates differed markedly. Pima living in Mexico had a T2DM prevalence of about 6%, in contrast

to nearly 40% in the US Pima.²⁹ The difference could be accounted for by differences in rates of obesity (much higher in the US Pima) and physical activity (much lower in the US Pima). Social contributors to the high prevalence of T2DM in the US Pima likely include: the loss of indigenous agriculture as a result of diversion of water resources to European settlers; the provision of surplus commodities high in simple carbohydrates and processed foods to a population rendered unable to produce its own food; poverty; and the stigma and discrimination that accompanied cultural loss.³⁰

This is not to deny that genetic risk may vary among different populations. Both molecular and family studies tell us that some individuals are genetically more likely than others to develop diabetes. The proportion of individuals with a diabetes predisposition might also vary across populations. For example, the Mexican Pima appear to have slightly higher rates of T2DM than their non-Pima neighbors (6% prevalence among Pima women compared with 4% in neighboring women), possibly signaling a higher prevalence of T2DM susceptibility.²⁹ And, genetic studies in the Gila River population, which includes members of the Pima and Maricopa tribes, have identified a potential contributor to diabetes risk: a novel loss of function variant in the *ABCC8* gene that is associated with a two-fold higher risk of T2DM.³¹ This gene is present in 3.3% of the population and has only a small impact on diabetes prevalence. While genetics may account for small differences in T2DM prevalence among different groups, genetic studies of T2DM are

consistent with epidemiological data pointing to the dominant effect of social determinants in T2DM risk.^{26,27,30}

SOCIAL DETERMINANTS OF T2DM RISK

In fact, the dramatic rise in T2DM is of recent vintage¹⁵ and, therefore, not a function of genetics. Rather, it is tied to trends that include the wide availability of inexpensive, high-calorie, high-carbohydrate snack foods and sedentary but busy lifestyles that encourage consumption of such foods.³² The association of T2DM risk with low income and education levels³ speaks to the disproportionate impact of these trends on economically disadvantaged people. Individuals who are working two jobs and balancing trade-offs between rent money and food choices may find fast foods the most convenient and cheapest available option. Expanding workdays and long commutes make regular exercise difficult, and many people lack convenient, safe places to walk or access to exercise facilities. As a result, they face higher risks not only for diabetes but for many other health risks associated with a sedentary lifestyle and poor nutrition.

The association of social factors with T2DM risk helps to explain why African Americans, Latinos, and AIAN people experience higher rates of T2DM than European Americans, and is also consistent with research pointing to root causes of health disparities.³³⁻³⁶ These root causes include factors such as access to adequate housing, food security, education, jobs, safe neighborhoods, affecting not only T2DM risk but health and longevity more generally.

LIMITATIONS OF THE FOCUS ON INDIVIDUAL RISK

The T2DM example points to the irony of focusing on individual risk in efforts directed toward promoting healthier lifestyles. There are strong reasons to favor policy-related and community-level efforts that increase individual capability to implement lifestyle change,³⁷ and create incentives to improve the availability of healthy food options and safe, accessible public spaces.^{38,39} Part of the irony is that the dietary and physical activity changes recommended to reduce T2DM risk are precisely those recommended to reduce the risk of hypertension, hyperlipidemia, coronary heart disease, and a host of other chronic conditions tied to western lifestyles.

These insights fuel national discussions and grassroots initiatives about ways to build a healthier society.^{36,38-42} Ideas for change, some being pursued in local or regional programs, include taxes on sugar-sweetened beverages, better food labeling, elimination of marketing of junk food to children, school-based health education and activity programs, community-based exercise facilities and walking zones, and a variety of initiatives to increase nutritional knowledge and access to healthy foods, including reservation-based traditional food programs and subsidies to low-income people. Evidence of benefit from such approaches is emerging. For example, consumption of sugar-sweetened beverages declined by half after institution of a tax on sugar-sweetened beverages in Berkeley, California, compared with comparison cities where consumption was unchanged.⁴³ Similarly, in-

stitution of a food labeling and food placement program in a workplace cafeteria was associated with a decline in calories from “least healthy” purchases, an increase in calories from “healthy” purchases, and an overall decrease in calories purchased.⁴⁴ These examples point to the significant potential for policy-based approaches to motivate healthier lifestyles.

If our society is to make a genuine commitment to improving population health, we must abandon the assumption that individual risk information is the key to prevention and pursue rigorous efforts to define the collective actions most likely to create a health-promoting society.

No single intervention will provide the solution, and each can be executed in various ways, with different levels of public and private investment. Interventions that are integrated within broader initiatives to address root causes of health disparities (eg, early childhood education, housing, employment, and community development³³⁻³⁶) may be the

most successful. Careful assessment is needed, so that the optimal interventions can be defined. The Precision Medicine Initiative has not yet been promoted as a platform for investigation of these types of efforts,¹ representing a potential lost opportunity.

INDIVIDUAL VS COLLECTIVE RESPONSIBILITY

If precision medicine places individual risk at center stage, it may in fact be transformative, although not in the way its proponents have so far suggested. US medical care is already characterized by a growing focus on risk identification and management.⁴³

Precision medicine is poised to accelerate this trend through the application of genomic risk analysis and wearable surveillance devices. In this new order, pursuit of good health becomes an individual effort to proactively identify and mitigate one’s health risks, rather than a shared effort to address upstream causes of poor health.

The precision medicine concept reinforces personal responsibility for health by assigning self-management tasks to individuals in response to a broad array of risk information, with the help of a clinician for those who have adequate health care access.¹⁷

Of particular concern, the precision medicine framing suggests that this responsibility represents “patient empowerment,” (Table 1)¹⁸ and is a positive good for those on the receiving end of risk information. It disregards the fact that many risks originate in adverse socioeconomic environments, or that deep disparities exist in the availability of the

resources and support needed for actions to protect one’s health. Perhaps the most harmful effect of this focus is that it creates a barrier to societal solutions. If our society is to make a genuine commitment to improving population health, we must abandon the assumption that individual risk information is the key to prevention and pursue rigorous efforts to define the collective actions most likely to create a health-promoting society.

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CONFLICT OF INTEREST

No conflicts of interest to report.

AUTHOR CONTRIBUTIONS

Research concept and design: Burke, Trinidad, Schenck; Acquisition of data: Burke, Data analysis and interpretation: Burke, Schenck; Manuscript draft: Burke, Trinidad, Schenck; Acquisition of funding: Burke; Administrative: Trinidad; Supervision: Schenck

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