

September 2021
Volume 27 Number 9-a

JMCP

JOURNAL OF
Managed Care +
Specialty Pharmacy

jmcp.org

SUPPLEMENT

2021 PhRMA Foundation Health Disparities Challenge Award

FUNDING STATEMENT

This supplement was funded by the Pharmaceutical Research and Manufacturers of America (PhRMA) Foundation, which also provided the prize money for the Health Disparities Challenge Award.

Valuing diversity in value assessment: introducing the PhRMA Foundation Health Disparities Challenge Award

Eberechukwu Onukwugha, MS, PhD

Throughout the entire history of the field, value assessment researchers have been working to ensure that health care decision makers are equipped with the best evidence and most rigorous models available.

More recently, partially as a result of the public health and social challenges that defined 2020, more members of the value assessment community have begun to ask difficult questions about the field's current approach to issues of health equity—and whether the community has done enough to ensure all voices are appropriately represented in decision making and evidence generation. It is becoming increasingly clear that we cannot fully understand value in health care without first examining the factors that underlie and reinforce health disparities in the United States.

A successful examination of value in health care will require that the value assessment community rethink present conceptions of value and identify the gaps where the empirical research on value assessment falls short in terms of its attention to health disparities, social determinants of health, and structural inequities.

As a first step to filling these gaps, last year the Pharmaceutical Research and Manufacturers of America (PhRMA) Foundation launched a new annual award program soliciting research proposals that evaluate how the field of value assessment can better serve diverse populations and

address the drivers of health disparities. Candidates were asked to submit proposals that advanced solutions to the following question: *How can value assessment methods and processes better account for populations that are typically underrepresented in research and drivers of health disparities?*

The following series will present the 4 winners of this innovative award mechanism. In their own way, each winning team has made a substantial contribution to what I expect will be a growing movement to make the value assessment field more inclusive and better attuned to the needs of diverse populations.

In first place, Eline M. van den Broek-Altenburg, Jamie S. Benson, and Adam J. Atherly of the Larner College of Medicine at the University of Vermont, Burlington, along with Stephane Hess of the Choice Modelling Centre & Institute for Transport Studies at the University of Leeds in the United Kingdom conducted an analysis of COVID-19 vaccine preferences among underrepresented populations. Using latent class analysis, the team built a model identifying key factors underlying the disparities in COVID-19 vaccination and found that health care interventions intended to reduce health disparities that do not reflect the underlying values of individuals in underrepresented populations are unlikely to be successful.

In second place, Surachat Ngorsuraches of Auburn University

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J Manag Care Spec Pharm.
2021;27(9-a)

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in Alabama describes 2 approaches to empirically address health equity in value assessment: using a discrete choice experiment to elicit preferences from individuals on preferences value attributes with a latent class model to derive the value of equity and using a flexible choice model to value health equity. Both approaches aim to capture patient preferences and ensure the systematic consideration of equity in health care decision making.

For third place, 2 teams tied for the foundation's award. Leticia R. Moczygemba, Carolyn M. Brown, and Michael Johnsrud of the Texas Center for Health Outcomes Research & Education (TxCORE) at the University of Texas—Austin propose a 2-pronged

strategy to increase the diversity of populations that participate in research and address drivers of health disparities to better inform value assessment. The first part of this strategy consists of a comprehensive national campaign to inform, create buy-in, and generate excitement for participation in research. Following this, the researchers propose an expediting of current methodological initiatives to require a minimum set of patient-reported social determinants of health elements to be collected and reported in research, including clinical trials and observational studies as a way to enhance the information used in value assessment frameworks.

At the University of Florida in Gainesville, Vakaramoko Diaby, Askal Ali, Aram Babcock, Joseph Fuhr, and Dejana Braithwaite examine emerging value assessment frameworks in the United States and present examples where evidence on outcomes and preferences for value do not take into

consideration diverse perspectives. They then identify possible solutions to improve existing value assessment methods and use a hypothetical case study to illustrate an alternative value assessment framework to evaluate prevention choices for women at high risk of developing breast cancer.

These proposals are an important first step towards meaningfully re-focusing value assessment through a health equity lens. I am confident that, in future years, the body of research exploring the intersection of value assessment and health equity will only continue to grow. If the following proposals are any indication, this growth will be inclusive, representative, and transformative. Please take some time to review the following papers, each of which considers health equity and value assessment in a different, though no less important, context.

I hope you are as excited as I was to learn about these proposals.

DISCLOSURES

No funding supported the writing of this article. The author has received grants from BeiGene, Ltd., and Pfizer, Inc., and advisory board fees from PhRMA Foundation.

1st Place: The effect of unobserved preferences and race on vaccination hesitancy for COVID-19 vaccines: implications for health disparities

Eline van den Broek-Altenburg, PhD, is Assistant Professor of Radiology, Vice-Chair for Population Health Science at the University of Vermont Medical Center. She holds a doctoral degree in health services research (2018), master of science degree in public health (2014) and master's degree in political science (2003). Her research focuses on modeling demand for health care services and insurance, patient-centered value assessment, physician decision making, access to care, and health disparities. She also leads evaluations of the clinical and economic effects of value-based payment reforms and interventions using electronic health records and claims data.

For the past decade and a half, Dr. van den Broek-Altenburg has collaborated with clinicians, researchers, and policymakers seeking to develop standardized quantitative measures to compare health systems and assess health system performance. Since the global outbreak of COVID-19, Dr. van den Broek-Altenburg has contributed to a number of population health studies, including 1 identifying factors that may increase or decrease the risk of infection, an international study analyzing COVID-19 vaccine preferences, and international studies gathering behavioral epidemiology data documenting the impact of the crisis on individuals in health, financial, and psychological terms.

In 2005, Dr. van den Broek-Altenburg founded a health policy think tank in The Hague and, serving as its director until 2012, was in charge of its research agenda, including the procurement of grants from public and private organizations. Between 2003 and 2012, she also worked as a health policy fellow with research institutes in the United States and Europe and was a health policy adviser in the Dutch and European Parliaments. She contributed to the public debate by publishing scholarly papers and op-eds, and she was frequently seen and heard in the media. In 2012, she returned to academia and has since won several awards and grants for her research.

Stephane Hess, PhD, is an internationally recognized expert in the data-driven study and mathematical modeling of human choice behavior. He has made contributions to the state of the art in the specification, estimation, and interpretation of such models, as well as in facilitating the transition of ideas and approaches across disciplines, notably by also working in mathematical psychology and behavioral economics. Although a majority of his applied work has been conducted in the field of transport, he is also very active in health and environmental economics.

He is Professor of Choice Modelling and Director of the Choice Modelling Centre at the University of Leeds, United Kingdom, where he is based in the Institute for Transport Studies. He is also Honorary Professor in Choice Modelling in the Institute for Transport and Logistics Studies at the University of Sydney, Australia, and Honorary Professor of Modelling Behavior in Africa at the University of Cape Town, South Africa. He is also the founding editor in chief of the *Journal of Choice Modelling* and the founder and steering committee chair of the International Choice Modelling Conference.

He has been involved as a principal or coinvestigator in academic projects with a combined income generation of more than £11.9M, including the European Research Council (ERC)-funded consolidator grant DECISIONS and the ERC-funded advanced grant SYNERGY. His contributions have been recognized by the 2017 and 2019 International Choice Modelling Conference awards for the most innovative application of choice modeling; the 2014 Outstanding Young Member of the Transportation Research Board (TRB) award for exceptional achievements in transportation research, policy, or practice; the 2010 Fred Burggraf award handed out by the TRB; the 2005 Eric Pas award for the best doctoral dissertation in the area of travel behavior modeling; and the 2004 Neil Mansfield award presented by the Association for European Transport.

Jamie Benson, BA, is an aspiring physician-scientist and a recent graduate from the University of Vermont (UVM), Burlington. He has made contributions to the fields of prehospital care research, population-level trauma system design, and choice modeling. He is early in his research career, and is actively pursuing additional training in geospatial modeling and artificial intelligence for clinical research.

He is a research specialist in the Department of Radiology at the University of Vermont Larner College of Medicine, as well as an advanced emergency medical technician and Pediatric Emergency Care Coordinator for Vermont EMS District 6. He serves on the Vermont HeartSafe Advisory Board and the Vermont EMS Protocol Committee and served on the medical logistics team of the Vermont State Emergency Operations Center during the COVID-19 pandemic.

He has engaged as coauthor and first author on academic papers and presentations spanning the fields of choice modeling, health economics, traumatic injury scoring, and COVID-19. His contributions have been recognized twice by the American College of Surgeons Own H. Wangenstein Excellence in Research Award. Upon graduating from UVM, he was awarded the Elmer Nicholson Achievement Prize for outstanding student leadership and academic contributions in his field.

He is currently beginning the journey of applying to medical school and hopes that his training and firsthand experience in research, rural health, and health equity will allow him to better care for his future patients and to create systems which help reduce barriers to accessing quality care for those in need.

Adam Atherly, PhD, is the Founder and Director of the Center for Health Services Research at the Larner College of Medicine at the University of Vermont, Burlington. Dr. Atherly's research targets health economics, with an emphasis on the economics of aging and consumer decisions regarding health plan choice. His research spans numerous methodological and topical areas, including health care spending and expenditure modeling; scale development and psychometric analysis; evaluation of efforts to improve quality of care and patient safety; and cost-effectiveness analysis. Dr. Atherly holds a doctoral degree in health services research, policy and administration from the University of Minnesota, Minneapolis.

2nd Place: Using latent class and quantum models to value equity in health care: a tale of 2 stories

Surachat Ngorsuraches, PhD, is an Associate Professor at Harrison School of Pharmacy, Auburn University, Alabama. He is a pharmacist by training. He earned his doctoral degree in social and administrative pharmacy from University of Wisconsin-Madison. He has more than 25 years of experience in teaching, conducting research, and leading administrative teams. He has been the principal investigator of several extramural funding research projects and the corresponding author for the publications on those projects. His research areas include pharmaceutical economics and policy, focusing on patient preference and patient-centered value assessment. He received multiple research grants and contracts from various agencies including the National Multiple Sclerosis Society (NMSS), Pharmaceutical Research and Manufacturers of America Foundation, and Patient-Centered Outcomes Research Institute (PCORI). Currently, he is a member of the International Society of Pharmacoeconomics and Outcomes Research. He has served the NMSS and the national multiple sclerosis patient-powered research network (MS-PPRN) initially supported by PCORI in various roles, eg, advisory committee member for projects.

3rd Place (tie): "It's Time to Represent": shifting the paradigm to improve the quality of inputs into value assessment frameworks

Leticia R. Moczygemba, PharmD, PhD, is an Associate Professor in the Health Outcomes Division and Associate Director of the Texas Center for Health Outcomes Research and Education at The University of Texas College of Pharmacy (UTCOP), Austin. Her research program focuses on working with communities and health systems to mitigate health disparities by developing patient-centered interventions to optimize medication use and health outcomes. Guided by the principles of community-based participatory research, she routinely uses qualitative and quantitative techniques; program evaluation; and the science of quality improvement to advance the health of homeless, low-income, rural, and older individuals. She teaches in the doctor of pharmacy and graduate programs and has a passion for mentoring doctor of pharmacy students who are interested in research and academic careers. Dr. Moczygemba was a Virginia Commonwealth University (VCU) Blick Scholar and a National Institutes of Health (NIH) KL2 Scholar in Richmond. She was also a 2017 NIH mHealth Scholar. She was selected as an American Pharmacists Association Fellow in 2020. Dr. Moczygemba received her doctor of pharmacy and doctoral degrees from the UTCOP in 2004 and 2008, respectively, and has been recognized with the UTCOP Distinguished Young Alumnus Award. She was a faculty member at VCU from 2008 to 2016.

Carolyn Brown, PhD, is Professor and Co-Director of the Center for Health Outcomes Research and Education (TxCORE) in the Health Outcomes Division, College of Pharmacy at University of Texas (UT) at Austin. She is a health outcomes researcher with a focus on patient health and treatment behaviors (medication adherence; complementary and integrative therapies) in chronic diseases. Her research studies are theoretically driven and employ both qualitative and quantitative methods to examine cultural and social needs that impact quality of care and outcomes in chronic illness, patient activation, and access to care. She teaches pharmacy graduate and undergraduate students and mentors many students and faculty. Dr. Brown has an extensive history of university and national service and was recently selected as a member of the inaugural cohort of the Provost's Distinguished Service Academy at the UT Austin in honor of her outstanding service at UT and beyond; excellence in scholarship; and commitment to fostering leadership around diversity, inclusion, and mentoring. Dr. Brown received her bachelor of science degree in pharmacy from Xavier University of Louisiana and doctorate in pharmacy health care administration from the University of Florida.

Michael Johnsrud, PhD, RPh, is Executive Director of the Texas Center for Health Outcomes Research and Education (TxCORE) and a senior research scientist in Health Outcomes at The University of Texas at Austin College of Pharmacy, where he designs and conducts research to analyze how prescription drugs, medical devices, and various clinical interventions and services impact resource utilization and patient health outcomes and quality of life. Dr. Johnsrud has particular expertise in prescription drug pricing, as well as coverage and reimbursement policy in Medicaid, Medicare, and private-sector health plans, in addition to the economics of the marketplace for community pharmacy and prescription drug benefit programs.

Before his role at TxCORE, Dr. Johnsrud was a Senior Vice President at Avalere Health in Washington, DC, where he led the Health Economics and Advanced Analytics Practice. While at Avalere Health, Dr. Johnsrud provided strategic and scientific guidance to the firm's clients to support the design and generation of clinical and economic evidence to inform stakeholders in the marketplace in determining the value of various medications and interventions.

Before joining Avalere Health, Dr. Johnsrud was Associate Director of The Center for Pharmacoeconomic Studies at The University of Texas at Austin College of Pharmacy. He has published numerous articles over the course of his career related to pharmaceutical economics, medication adherence, and the value and cost-effectiveness of prescription drugs and clinical interventions across a variety of different therapeutic areas.

Dr. Johnsrud received his bachelor of science degree in pharmacy from the University of Iowa and master of science and doctoral degrees in pharmacy administration from the University of Texas at Austin. He is a registered pharmacist in Iowa and Texas.

3rd Place (tie): Incorporating health equity into value assessment: frameworks, promising alternatives, and future directions

Vakaramoko Diaby, MSc, CRA, PhD, is currently an Assistant Professor in the Department of Pharmaceutical Outcomes and Policy (POP) in the University of Florida (UF) College of Pharmacy in Gainesville. He serves as the track director for the POP online master of science degree program, where he oversees the development and growth of the applied pharmacoeconomics track. He is affiliated with the UF Center for Drug Evaluation and Safety and is an active member of the Cancer Control Population Sciences program of the UF Health Cancer Center (UFHCC).

Dr. Diaby graduated with a doctoral degree in pharmaceutical sciences (population health) at University of Montreal (Quebec, Canada) and completed a coveted post-doctoral fellowship in health economics and decision sciences at the Programs for Assessment of Technology in Health—McMaster University (Hamilton, Ontario, Canada).

Over the past 8 years, Dr. Diaby has taught several courses to pharmaceutical degree, online master's degree, and doctoral degree students and has supervised numerous doctoral degree and master of science degree students. Dr. Diaby's interests are in comparative effectiveness and cost-effectiveness research in oncology, with a focus on determinants of health disparities and their integration into value assessments. He is also interested in bridging health technology assessment and decision making using multicriteria decision analysis, as well as assessing the value of next-generation sequencing.

Dr. Diaby has published more than 50 peer-reviewed publications, including 2 book chapters. He was the principal investigator (PI) on a pilot project grant from the National Institutes of Health (NIH)/National Institute on Minority Health and Health Disparities, received a Mitacs grant (Canada), and currently serves as a project-agnostic investigator on an NIH/National Human Genome Research Institute grant. Dr. Diaby completed a subaward from a U54 center grant to study the impact of heat-related illness on the gross domestic product, agricultural, and health sectors of the Southeastern and Coastal Center for Agricultural Health and Safety catchment area. He also recently completed a pharmacogenomics foundation grant to assess the cost-effectiveness of rapid whole-genome sequencing in critically ill pediatric patients. Dr. Diaby served as a health economist on an HIV telemedicine grant sponsored by the CDC. He is a PI and a co-PI on 2 industry contracts, Pfizer and Merck, respectively. He is a grant peer-reviewer for 3 international agencies (United Kingdom, New Zealand, and The Netherlands) and a peer-reviewer for several academic journals. Dr. Diaby was an academic editor for the journal PLOS One and currently serves on the editorial board of *Pharmacoeconomics Open*.

Askal Ayalew Ali, MA, PhD, is a health economist and outcomes researcher by training. She currently serves as an Assistant Professor in the Division of Economics, Social and Administrative Pharmacy (ESAP), College of Pharmacy and Pharmaceutical Sciences (CoPPS), Institute of Public Health (IPH), Florida A&M University in Tallahassee. Her responsibilities span teaching, research, and service to the college and the university. She has been teaching pharmaceutical degree and graduate students at Florida A&M University since 2016. In 2017, she received the teacher of the year award from the CoPPS-IPH for her excellence in teaching. She is also mentoring 5 doctoral degree students and served as graduate dissertation committee member in ESAP and IPH. Dr. Ali earned a master's degree in economics from the Department of Economics, Eastern Illinois University, Charleston, and graduated with a doctoral degree in health outcomes and pharmacoeconomics from Florida A&M University.

Dr. Ali's research interests focus on investigating disparities in access to care and health outcomes related to cancers. In addition to addressing disparities in health outcomes, her research focuses on comparative effectiveness research and economic evaluation. Dr. Ali has published more than 20 peer-reviewed papers. She was a principal investigator on a mini-medical marijuana research and educational grant from Florida A&M University and is also a co-investigator on a grant project titled "Test Up Now Education Program," funded by the National Institute on Minority Health and Health Disparities research subproject with U54 RCMI Grant, 2019-2024. Furthermore, Dr. Ali serves as reviewer for numerous journals.

Dr. Ali's long-term goals consist of identifying attributes and risks that can be minimized to help dampen the number of people with cancer and reduce racial and ethnic disparities, leading to better usage of health care interventions.

Aram Babcock, PharmD, MS, MBA, is a current graduate student and doctoral degree candidate in the Department of Pharmaceutical Outcomes and Policy (POP) in the University of Florida (UF) College of Pharmacy in Tallahassee. He has worked as both a graduate teaching and research assistant within the department, including the pharmacy skills lab where he helped train future pharmacists in various facets of the curriculum. Dr. Babcock's research interest includes pediatric mental health, health economic evaluation, and oncology. He has several publications as first author and several more as a contributing author. Under the tutelage of Dr. Karam Diaby, he has also been involved in numerous projects, including a grant to assess cost-effectiveness of rapid whole-genome sequencing in pediatric patients.

Dr. Babcock received his master's degree in pharmacoepidemiology and pharmacoeconomics from The University of Rhode Island, Kingston, as well as his master of business administration and doctor of pharmacy degree. Dr. Babcock has maintained his professional licensure as a pharmacist in Florida and Rhode Island.

3rd Place (tie): Incorporating health equity into value assessment: frameworks, promising alternatives, and future directions *(continued)*

Joseph Fuhr, MA, PhD, is a seasoned economist with more than 40 years of experience in academia and consulting. He is Professor Emeritus of economics at Widener University, Chester, Pennsylvania. He is currently an Adjunct Professor in the Pharmaceutical Outcomes and Policy online graduate program. Dr. Fuhr's responsibilities include teaching and providing instructional consultation to support the growth of the applied pharmacoeconomics (APE) track. He currently serves as a senior fellow with The American Consumer Institute and Ambassador for the Internet Innovation Alliance.

Dr. Fuhr received his master's degree and doctoral degree from Temple University and his bachelor's degree from LaSalle University, both in Philadelphia, Pennsylvania. His primary research areas are antitrust, health economics/pharmacoeconomics, telecommunications, and sports economics. In health care, he has written on accountable care organizations, hospital mergers, specialty hospitals, exclusive arrangements, health insurance, bundling, and doctor's fees. In pharmacoeconomics, he has written on cost:benefit analysis, biosimilars, and predictive modeling. He has published more than 60 journal articles. He has taught graduate classes in health economics, pharmacoeconomics, and pharmaceutical ethics. Finally, Dr. Fuhr has been an expert witness on numerous cases and has worked on various consulting projects.

Dejana Braithwaite, PhD, currently has a joint appointment as Professor in the Department of Epidemiology and the Department of Aging and Geriatric Research at the University of Florida (UF), Gainesville. She also serves as the Associate Director for Cancer Population Sciences of the UF Health Cancer Center.

Dr. Braithwaite graduated with a doctoral degree in epidemiology at University of Cambridge (UK) and completed a post-doctoral fellowship in Cancer Epidemiology at the University of California, San Francisco.

Dr. Braithwaite's research is focused on the intersection of cancer and aging, with the overarching goal of advancing and applying knowledge about aging to cancer population science. She has led numerous large-scale multidisciplinary National Institutes of Health-funded efforts of breast and lung cancer screening, risk factors, and outcomes, including the R01 Breast Cancer Surveillance Consortium (BCSC), R01 Personalized Lung Cancer Screening Network (PLuS), P50 UCSF Breast Cancer SPORE, and P30 UCSF Center for Aging in Diverse Communities. As principal investigator or investigator on several of these grants, Dr. Braithwaite has developed cohorts of individuals at risk for invasive cancer and developed comprehensive databases that include pathologic, clinical, biomarker, and risk factor data, as well as follow-up for subsequent disease and death. Her work has been cited by guideline panels, such as the American Cancer Society, the US Preventive Service Taskforce, and the American College of Obstetricians and Gynecologists. As such, Dr. Braithwaite's work is poised to inform precision screening policy and clinical decision making among older population subgroups for whom the net benefits of screening are currently highly uncertain. Dr. Braithwaite's work has published extensively in high impact journals including *Journal of the American Medical Association*, *The Lancet*, *Nature Medicine*, and *Journal of the National Cancer Institute*.

JMCP

September 2021 | Volume 27 | Number 9-a

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- S2** The effect of unobserved preferences and race on vaccination hesitancy for COVID-19 vaccines: implications for health disparities
Eline van den Broek-Altenburg, PhD; Adam Atherly, PhD; Stephane Hess, PhD; and Jamie Benson, BA
- S12** Using latent class and quantum models to value equity in health care: a tale of 2 stories
Surachat Ngorsuraches, PhD
- S17** "It's Time to Represent": shifting the paradigm to improve the quality of inputs into value assessment frameworks
Leticia R Moczygemba, PharmD, PhD; Carolyn Brown, PhD; and Michael Johnsrud, PhD, RPh
- S22** Incorporating health equity into value assessment: frameworks, promising alternatives, and future directions
Vakaramoko Diaby, PhD; Askal Ayalew Ali, PhD; Aram Babcock, PharmD, MS, MBA; Joseph Fuhr, PhD; and Dejana Braithwaite, PhD

The effect of unobserved preferences and race on vaccination hesitancy for COVID-19 vaccines: implications for health disparities

Eline M van den Broek-Altenburg, PhD; Adam J Atherly, PhD; Stephane Hess, PhD; and Jamie Benson, BA

ABSTRACT

BACKGROUND: Reducing the extra burden COVID-19 has on people already facing disparities is among the main national priorities for the COVID-19 vaccine rollout. Early reports from states releasing vaccination data by race show that White residents are being vaccinated at significantly higher rates than Black residents. Public health efforts are being targeted to address vaccine hesitancy among Black and other minority populations. However, health care interventions intended to reduce health disparities that do not reflect the underlying values of individuals in underrepresented populations are unlikely to be successful.

OBJECTIVE: To identify key factors underlying the disparities in COVID-19 vaccination.

METHODS: Primary data were collected from an online survey of a representative sample of the populations of the 4 largest US states (New York, California, Texas, and Florida) between August 10 and September 3, 2020.

Using latent class analysis, we built a model identifying key factors underlying the disparities in COVID-19 vaccination.

RESULTS: We found that individuals who identify as Black had lower rates of vaccine hesitancy than those who identify as White. This was true overall, by latent class and within latent class. This suggests that, contrary to what is currently being reported, Black individuals are not universally more vaccine hesitant. Combining the respondents who would not consider a vaccine (17%) with those who would consider one but ultimately choose not to vaccinate (11%), our findings indicate that more than 1 in 4 (28%) persons will not be willing to vaccinate. The no-vaccine rate is highest in White individuals and lowest in Black individuals.

CONCLUSIONS: Results suggest that other factors, potentially institutional, are driving the vaccination rates for these groups. Our model results help point the way to more effective differentiated policies.

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J Manag Care Spec Pharm.
2021;27(9-a):S4-S11

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Reducing health disparities has become a national priority,¹⁻³ especially during the COVID-19 vaccine rollout. On December 14, 2020, the first Americans received a COVID-19 vaccine outside the ongoing clinical trials. As the supply of vaccines was limited at first, the Centers for Disease Control and Prevention (CDC) Advisory Committee in Immunization Practices (ACIP) recommended that initial supplies of COVID-19 vaccine be allocated to

health care personnel and long-term care facility residents, followed by frontline essential workers and people aged 75 years and older.⁴ Among their 3 main goals for whom should be offered COVID-19 vaccines, the first was to reduce the extra burden COVID-19 has on people already facing disparities.

Research has consistently shown that the COVID-19 pandemic is disproportionately affecting those who

are in already disadvantaged situations or groups.^{5,6} Early data from the COVID-19 pandemic showed that Black and Latino populations in the United States were 3 times more likely to contract COVID-19 than White residents and nearly twice as likely to die from it.⁷ This is reflected in initial barriers to vaccine access.⁸ Early reports also show disparities in vaccination rates: Black Americans were receiving COVID-19 vaccinations

at dramatically lower rates than White Americans in the first weeks of the rollout.⁹ In the states that have released vaccination data by race, White residents were being vaccinated at significantly higher rates than Black residents, in some cases 2 to 3 times higher.¹⁰ Recent reporting data also showed that the share of vaccinations among Black and Hispanic residents is smaller than their share of deaths in their states; for the Hispanic population, it is also smaller than their share of COVID-19 cases.⁹

The reason for the differing rates of vaccinations is unclear. The inequality could be caused by structural or systematic racism¹¹ or by higher vaccine hesitancy among Black and Hispanic communities or by other factors.^{12,13} Beckman et al recommended that health care providers engage with these communities to overcome vaccine hesitancy and provide appropriate public health information.^{14,15} However, these collective efforts do not acknowledge that vaccine hesitancy can be caused by a myriad of underlying differences among subgroups—or that the difference could be due to factors other than hesitancy. Potential other factors range from easily observable attributes, such as lack of income or education, to attributes that are harder to observe such as effects of structural or institutional racism. The objective of this study was to identify key factors underlying the disparities in COVID-19 vaccination.

Methods

DATA AND STUDY DESIGN

Our data are based on a survey of a representative sample of the population of the 4 largest US states (New York, California, Texas, and Florida). Respondents were sampled from an online Qualtrics panel from August 10 through September 3, 2020, and were representative with respect to the state and US population in terms of age, gender, and race.

Participants were asked to imagine a situation where a number of vaccines for COVID-19 had been developed. These vaccines would have undergone all required testing and received regulatory approval for use in humans. They were then presented with 6 scenarios, or choice tasks, where in each task, 2 possible vaccines were described with the following 7 attributes: (1) *risk of infection*—the number out of every 100,000 vaccinated people who would still get infected when coming in contact with an infected person; (2) *risk of serious illness*—the number out of every 100,000 vaccinated people who, if infected, would develop serious symptoms; (3) *estimated protection duration*—the

expected length of time that the protection provided by the vaccine will last before a new course of vaccination is needed; (4) *risk of mild side effects* (such as numbness or a rash at the injection site, or a headache)—the number of people out of 100,000 that suffer mild side effects from the vaccine; (5) *risk of severe side effects* (such as an allergic reaction requiring further medical treatment)—the number of people out of 100,000 that suffer severe side effects from the vaccine; (6) *waiting time*—how long people need to wait to obtain the vaccine for free; and (7) *fee*—how much people need to pay to obtain the vaccine immediately.

The vaccines also varied by 2 key population attributes: (1) *population coverage*: the share of the population that have already been vaccinated, and (2) *exemption from international travel restrictions*: the exemption from travel restrictions related to COVID-19 for vaccinated people. This includes quarantine in some countries before and/or after travel.

In each scenario, respondents were asked to choose 1 of the 2 offered vaccines or choose to not be vaccinated. If they chose 1 of the vaccines, they would have the option to wait and be vaccinated for free or to pay for immediate vaccination. The levels for the attributes that describe the vaccines that respondents were asked to choose between varied across the choice tasks.

Our initial sample was 475. We excluded observations with an unrealistic pattern of always choosing the option on the left ($n=22$) and missing demographic information such as age, race, income, or education ($n=1$) for a final sample size of 452.

ANALYTIC APPROACH ADDRESSING HEALTH DISPARITIES

Pursuing health equity means pursuing the elimination of health disparities between all groups in a given category.¹² Typical value assessment methods in health, including cost-effectiveness and health outcomes, generally account for health disparities by using observed differences between the most advantaged group in a given category (income, race, etc) and disadvantaged groups. Standard analysis of a “representative” sample—including underrepresented populations—yields average effects across the entire population.

There are a number of methodological approaches available that incorporate differences in individual preferences. In particular, notwithstanding extensions to nonlinear specifications, the utility for a given alternative

TABLE 1 Sample Descriptive Statistics

	Population %	Sample mean n (%) (N=387)
Sex		
Male	49.2	191 (49.4)
Female	50.8	196 (50.6)
Age (years)^a		
Younger than 30	22.9	82 (21.2)
31-40	17.1	69 (17.8)
41-50	15.8	113 (29.2)
51-60	16.7	48 (12.4)
Older than 60	27.5	75 (19.4)
Race^b		
White	76.3	294 (76.0)
Black	13.4	37 (9.6)
Asian	5.9	22 (5.7)
Mixed	2.8	18 (4.7)
Other	1.6	10 (2.6)
Prefer not to say/missing	-	6 (1.6)
Income (USD)		
Less than \$20,000	13.1	56 (14.5)
\$20,000-\$40,000	15.9	72 (18.6)
\$40,001-\$75,000	24.6	89 (23.0)
More than \$75,000	46.4	155 (40.1)
Prefer not to say/missing	-	15 (3.9)

continued on next page

(say *i*) is typically given as a linear in attributes specification, such that

$$(1) V_{i,n,t} = \beta_n' x_{i,n,t} = \sum_{k=1}^K \beta_{n,k} x_{i,n,t,k} \quad V_{i,n,t} = \beta_n' x_{i,n,t} = \sum_{k=1}^K \beta_{n,k} x_{i,n,t,k}$$

In this notation, $x_{i,n,t,k}$ is a specific attribute (the *k*th attribute of *K*) of alternative *i*, as seen by person *n* in choice situation *t*. The parameter $\beta_{n,k}$ captures the marginal utility for person *n* in response to this attribute. Imagine for example that attribute *k* relates to the efficacy of a vaccine. We would then expect that $\beta_{n,k}$ is positive, ie, that, as efficacy of a vaccine increases, so does its utility. The subscript *n* on $\beta_{n,k}$ reflects the fact that different individuals will have different sensitivities to changes in the attributes.

In the simplest type of random utility model, the multinomial logit (MNL) model, which serves as the starting

point for what follows, the probability of person *n* choosing option *i* in task *t* is given by

$$(2) P_{n,t}(i | x_{n,t}, \Omega) = \frac{e^{V_{i,n,t}}}{\sum_{j=1}^J e^{V_{j,n,t}}} P_{n,t}(i | x_{n,t}, \Omega) = \frac{e^{V_{i,n,t}}}{\sum_{j=1}^J e^{V_{j,n,t}}}$$

where Ω groups together the different model parameters. Returning to the above example of efficacy increasing for vaccine *i* (of *J* vaccines), this would imply that $V_{i,n,t}$ increases too, and as a result, the probability of person *n* choosing that vaccine becomes larger.

In the simplest approach, interaction terms can be used to allow differences in preferences across different groups. As long as the differences in preferences relate to differences in observed decision maker characteristics, this will be an effective approach.

A more subtle problem is the inclusion of unobserved preferences. Mixed logit models rely on using continuous statistical distributions to represent unobserved heterogeneity.

Unobserved factors that affect preferences such as personality traits (eg, extraversion)¹³; personal values such as universalism, spirituality, and moral values¹⁴; and distressing uncertainty, emotional distress, or religious affiliation or beliefs are often ignored, although there are models available that can account for such differences. For example, “mixed” multinomial logit models (MMNL) allow variation in preferences based on both observed and unobserved characteristics. Applications of MMNL in health include, but are certainly not limited to, estimating switching costs for health insurance,¹⁵ analyzing patient preferences for provider choice,¹⁶ and analyzing patients’ responsiveness to quality when choosing hospitals. There have also been numerous studies using MMNL models to analyze preferences for specific treatments or health services, such as for diabetes care,¹⁷ men’s preferences and trade-offs for prostate cancer screening, and patient preferences for managing asthma.¹⁸

A different approach is to use discrete (rather than continuous) distributions and probabilistically segmenting a sample population into different segments, such as latent class analysis (LCA). LCA explores deterministic heterogeneity by incorporating explanatory variables as multiplicative interaction terms. In a model with *S* different classes, each class would then be characterized by a different vector of parameters, say Ω_s for class *s*. This could, for example, capture the existence of one class of individuals who are particularly sensitive to efficacy, whereas another

TABLE 1 Sample Descriptive Statistics (continued)

	Population %	Sample mean n (%) (N=387)
Education^a		
None	0.3	–
Less than high school	10.3	4 (1.0)
High school graduate/GED	28.3	137 (35.4)
Associate degree	9.8	71 (18.3)
Bachelor's degree	21.3	114 (29.5)
Professional/graduate degree	12.0	61 (15.8)
Smoking status^b		
Nonsmoker	86.0	309 (79.8)
Current smoker	14.0	78 (20.2)
Health status		
No chronic health conditions	–	252 (65.1)
Chronic health conditions	–	135 (34.9)
Risk-taking behavior		
I don't take more risks than others	–	138 (35.7)
I take more risks than others	–	249 (64.3)
Physical health pre-COVID		
Excellent	–	61 (15.8)
Very good	–	133 (34.4)
Good	–	131 (33.9)
Fair	–	53 (13.7)
Poor	–	9 (2.3)

^aP value is 0.01.

^bP value is 0.05.

GED = graduate equivalency degree; USD = US dollars.

class is more sensitive to side effects. If we knew with certainty that person n falls into class s, then the choice probability would simply be given by

$$(3) P_{n,t,s}(j | x_{n,t}, z_n, \Omega_s) P_{n,t,s}(j | x_{n,t}, z_n, \Omega_s),$$

where this would be given by equation (2) when using an underlying MNL model inside each class. However, the actual class allocation is not observed deterministically, and a latent class structure consequently uses a class allocation model, where respondent n belongs to class s (of a total of S classes) with probability

$$(4) \pi_{n,s}, \text{ where } 0 \leq \pi_{n,s} \leq 1 \forall k \text{ and } \sum_{s=1}^S \pi_{n,s} = 1, \forall s \sum_{n=1}^N \pi_{n,s} = 1, \forall s.$$

These class allocation probabilities can vary across individual decision makers as a function of their observed

TABLE 2 Predicted Vaccine Uptake

Vaccine uptake ^a	No vaccine, %	Wait for free vaccine, %	Pay for immediate access, %
All respondents	10.6	59.9	29.5
Self-reported race			
White	11.8	59.2	28.9
Black	7.6	62.6	29.8
Asian	7.6	62.4	30.0
Mixed	7.5	62.4	30.1
Other	12.0	58.6	29.4

^aBased on latent class analysis.

characteristics, ie, $\pi_{n,s} = h(z_n, \gamma) \pi_{n,s} = h(z_n, \gamma)$, where γ is an additional vector of estimated parameters, and z_n are characteristics of the decision maker. Returning to the previously described example, this model component might, for example, explain that patients with preexisting health conditions are more likely to fall into the class that is more sensitive to side effects, whereas respondents with higher education levels might be more likely to fall into the class that is more sensitive to efficacy.

In contrast with the simple MNL model, the log-likelihood function uses a weighted average across separate submodels (1 for each class), with the weights given by the class allocation probabilities, such that

$$(5) LL(x, z, \Omega, \gamma) = \sum_{n=1}^N \log \sum_{s=1}^S \pi_{n,s} \left[\prod_{t=1}^T P_{n,t,s}(Y_{n,t} | x_{n,t}, \Omega_s) \right] LL(x, z, \Omega, \gamma) = \sum_{n=1}^N \log \sum_{s=1}^S \pi_{n,s} \left[\prod_{t=1}^T P_{n,t,s}(Y_{n,t} | x_{n,t}, \Omega_s) \right]$$

where this is now also a function of the vector of parameters γ used in the class allocation model, where $\Omega = \langle \Omega_1, \dots, \Omega_S \rangle$ and where $Y_{n,t}$ is the observed choice for person n in task t.

Latent class models capture both observed and unobserved heterogeneity in preferences and are relatively new in health.¹⁹ LCA has been used to examine differential health preferences such as pharmaceutical preferences^{20,21}; physician preferences^{19,22}; patient-centered care²³; language used in palliative care consultations¹⁴; and specific treatments or diseases such as tuberculosis infection preventive treatment,²⁴ community pharmacy asthma services,²⁵ and human papillomavirus vaccines among adolescent girls.²⁶

Traditionally, subgroup analysis in health aims to determine heterogeneous treatment effects. In many applications, the subgroups will be homogeneous in their response, but it is possible to also allow for further heterogeneity within a class. Crucially, membership in the subgroup may differ by

TABLE 3 Sociodemographic Make-Up of Individual Classes

	Latent class difference from sample mean (posterior estimation)		
	Class 1: Anxious, %	Class 2: Evaluative, %	Class 3: Cost-conscious, %
No vaccine	1.2	51.5	4.1
Wait for free vaccine	36.8	36.2	89.3
Pay for immediate access	61.8	12.3	6.6
Sex			
Male (reference)			
Female	-4	-7	6
Age (years)^a			
Under 30	26	-2	-20
31-40	-29	-18	30
41-50	-6	18	-2
51-60	3	7	-5
Over 60	5	-13	1
Race^b			
White	0	7	-2
Black	8	-2	-5
Asian	-10	-42	24
Mixed	-10	-8	11
Other	1	-33	11
Prefer not to say/missing	41	-97	3
Income (USD)			
Less than \$20,000	13	21	-18
\$20,000-\$40,000	40	-31	-21
\$40,001-\$75,000	-19	-21	23
More than \$75,000	-14	17	5
Prefer not to say/missing	-	-	-
Education^a			
None	-	-	-
Less than high school	-96	193	5
High school graduate/GED	14	-11	-7
Associate's degree	2	4	-3
Bachelor's degree	-1	-10	5
Professional/graduate degree	-26	25	11
Smoking status^b			
Not a smoker	-	-	-
Current smoker	4	-14	2
Drinking status			
Not a drinker	-	-	-
Current drinker	-24	11	16

continued on next page

health disparities. For example, there could be a subgroup of individuals who are hesitant to receive a COVID-19 vaccine. That group will act similarly—not based on health disparities—but membership within the group could be more likely for disadvantaged populations.²⁷ The application of these methods in health can be valuable to support policy development and clinical practice, especially to account for individual drivers of health disparities.

The key analytic problem is thus the need to include in our model unobserved factors that affect preferences. To do this, we used a LCA, which addresses the issue of unobserved preferences by probabilistically segmenting a sample population into different groups or “classes”.

Results

VACCINE HESITANCY

Overall, 15.7% of respondents indicated they would not accept a COVID-19 vaccine, either because of attribute levels or regardless of its attributes. Of these, 14.7% identified as White and 2.4% as non-White (ie, 1.3% Black, 0.5% mixed race, and 0.5% other). Of Black residents in the sample, 10.9% were in this group completely unwilling to consider a vaccine, regardless of any other factor. Of White respondents, 16.8% would not consider a vaccine, a higher proportion than among Blacks.

Of the 10.9% of Black respondents who indicated they would not consider a vaccine, 60% said that vaccines will need to undergo more testing before they would trust them, 20% selected “I prefer obtaining immunity naturally without vaccination,” and 20% selected “I do not believe in the benefits of vaccination.” These motivations were different among White respondents, where 37.7% answered vaccines would need to undergo more testing, 31.1% said they preferred

TABLE 3 Sociodemographic Make-Up of Individual Classes (continued)

	Latent class difference from sample mean (posterior estimation)		
	Class 1: Anxious, %	Class 2: Evaluative, %	Class 3: Cost-conscious, %
Health status			
No chronic health conditions	-	-	-
Chronic health conditions	2	-34	11
Risk-taking behavior			
I don't take more risks than others	-	-	-
I take more risks than others	3	-9	1
Physical health pre-COVID			
Excellent	-17	61	-9
Very good	4	24	-12
Good	-	-33	12
Fair	12	-54	10
Poor	-6	26	-4

^aP value is 0.01.
^bP value is 0.05.
 USD = US dollars.

obtaining immunity naturally without vaccination, 11.5% said they do not believe in the benefits of vaccination, 6.6% said the options offered were not good enough compared with not being vaccinated, 3.3% responded “enough people will accept vaccination so I will benefit from herd immunity,” and 9.8% had some other reason.

The 15.7% of respondents who indicated they would not accept a COVID-19 vaccine were excluded from the analysis.

SAMPLE CHARACTERISTICS

Table 1 reports the sample characteristics for gender, age groups, race, income, education, smoking status, whether or not respondents had a chronic condition, smoking status, drinking status, and whether they were more likely to take risks than others (self-assessed) among those

who indicated a willingness to consider a vaccine.

Our sample included 50.6% females; 21.1% of respondents aged younger than 30 years; 17.8% aged 31-40 years; 29.2% aged 41-50 years; 12.4% aged 51-60 years, and 19.4% aged older than 60 years. In our sample, 77.4% of respondents were White and 22.6% non-White; of which 13.4% were Black, 5.9% Asian, 2.8% mixed, and 1.6% “other.” We compared sample characteristics with US census data using chi-square tests and we found that the sample was representative at the 5% significance level for gender, age, race, and education ($P < 0.001$).

LATENT CLASS ANALYSIS

The LCA showed that there was the appropriate number of classes to fit our data. The model probabilistically segmented respondents into a class with an overall preference for the

paid vaccine options (Class 1); a class dominated by respondents who were most likely to choose the “no vaccine” option (Class 2); and a class that highly valued the free vaccine options (Class 3). Class 1 thus predominantly represents “anxious” individuals, Class 2 the “evaluative” individuals, and Class 3 the “cost-conscious” individuals.

Table 2 reports the predicted vaccine take-up based on the 3-class LCA, overall and by race. The results show that approximately 11% of the overall sample that would consider a vaccine would ultimately choose to forgo vaccination once they considered potential side effects, while 60% would accept a vaccine but would be unwilling to pay even \$100 for it, and 30% would like immediate access and would be willing to pay for quicker access. There was little difference in the proportions across races, except that White respondents reported a lower overall willingness to vaccinate.

Table 3 presents a more nuanced breakdown by class, and it clarifies if there are fewer or more individuals with particular characteristics in Class 1, Class 2, or Class 3. For example, there are 2% fewer individuals in Class 2 in the age group younger than 30 years and 20% fewer individuals in Class 3 than the total sample mean for that age group. In Class 1, 62% of respondents preferred a vaccine option that would require them to pay a fee, but not wait. In Class 2, 52% of respondents chose the “no vaccine” option most often, meaning that they did not like the other options given to them. In Class 3, 89% of respondents preferred vaccine options that were given for free, but with a wait time.

Table 3 also shows predictions of class membership based on sociodemographic characteristics and class differences from the survey sample mean. To get a better understanding of the sociodemographic make-up of

TABLE 4 Latent Class Nested Logit Models with Interactions

Model description	LC-NL, 3 classes, with interaction		
Number of individuals	387		
Number of observations	2,322		
Estimated parameters	51		
Log likelihood	-2,968.62		
Parameter	Class 1	Class 2	Class 3
ASC: position	0.127 ^b (0.047)	0.028 (0.048)	0.054 (0.042)
ASC: free option	0.894 (0.83)	-1.217 ^b (0.533)	0.245 (0.437)
ASC: paid option	2.148 ^b (0.821)	-1.79 ^b (0.603)	-1.675 ^c (0.489)
ASC: no vaccine	–	–	–
Risk of infection	-0.023 (0.039)	-0.013 (0.039)	-0.161 ^c (0.037)
Risk of illness	-0.071 ^c (0.02)	-0.044 ^a (0.025)	-0.077 ^c (0.02)
Unknown protection duration	–	0.097 (0.206)	–
Protection duration	0.017 ^c (0.004)	0.001 (0.004)	0.022 ^c (0.004)
Mild side effects	0.013 (0.019)	-0.026 (0.02)	–
Severe side effects	-15.751 (10.367)	-29.487 ^a (16.156)	-35.872 ^c (10.756)
Wait time, months	-0.006 (0.012)	-0.026 ^b (0.013)	-0.013 ^a (0.008)
Fee, USD	-0.003 ^c (0.001)	-0.002 ^a (0.001)	-0.003 ^b (0.001)
Population coverage, %	0.028 (0.026)	0.008 (0.005)	0.021 (0.013)
Lambda: vaccination nest	–	0.502 ^b (0.195)	–
Exempt status from travel restrictions ^a , no recent travel	–	–	–
Exempt status from travel restrictions ^a , recent travel	-1.273 (1.138)	-0.027 (0.34)	0.294 (1.182)
Delta	–	-0.723 ^c (0.186)	0.295 ^a (0.165)
Fee ^a , non-White status	–	-0.908 ^b (0.753)	1.785 (0.934)
Risk of illness ^a , aged <60 years	–	1.299 (0.47)	0.932 (0.384)
Risk of illness ^a , non-White status	–	1.498 (0.735)	0.954 (0.486)
Severe side effects ^a , non-White status	–	0.129 (0.57)	0.032 (0.695)
Wait time ^a , non-White status	–	-1.047 ^b (0.802)	4.057 (3.277)
Lambda: fee ^a , income		-0.127 ^a (0.072)	
Fee ^a , no reported income		1.727 (0.816)	

Note: Coefficients represent the marginal effect of a change between class 1 and other classes. Standard errors are reported in parentheses.

^aP < 0.05.

^bP < 0.01.

^cP < 0.001.

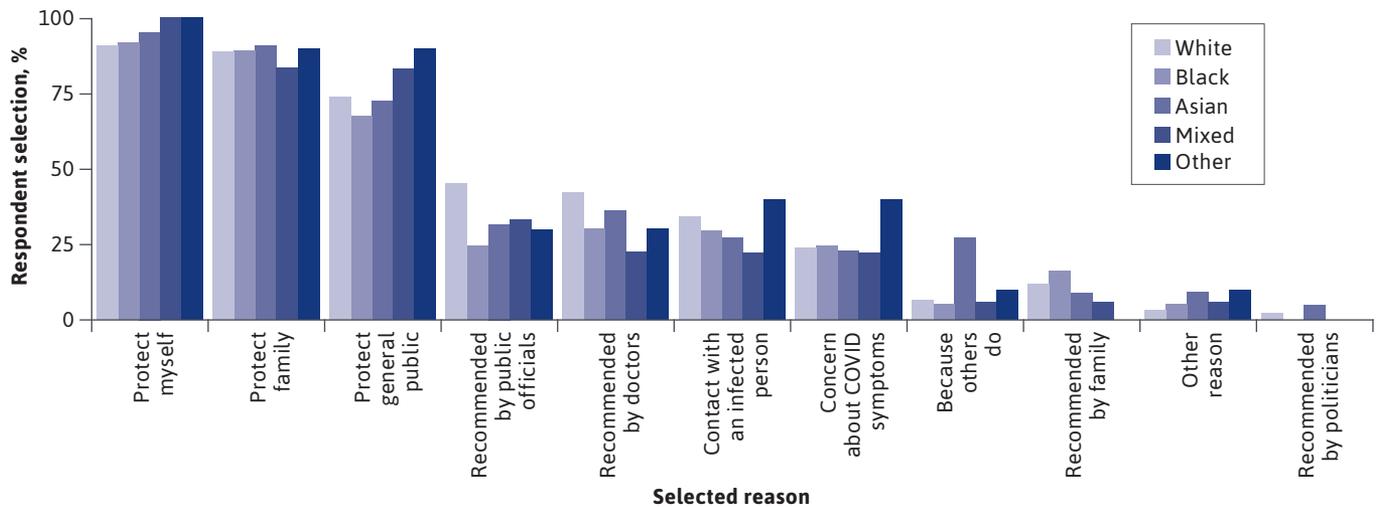
LC-NL = latent class nested logit; USD = US dollars.

individual classes, we used posterior analysis to produce a membership profile for each class. We found that there were 8% more Black respondents in Class 1, compared with the sample mean, but 2% fewer in Class 2 and 5% fewer in Class 3. In other

words, relatively more Black respondents prefer vaccine options with a fee but no wait time, and fewer Black respondents prefer free vaccine options with a wait time or “no vaccine” options.

The opposite was true for respondents identifying as Asian: there were 10% fewer Asian respondents in Class 1 than the sample mean, 42% fewer in Class 2, and 24% more in Class 3. Thus, there are relatively more Asians

FIGURE 1 Reasons for Getting Vaccinated, by Race



than the sample average to prefer free vaccine options with a longer wait time or no vaccine. We found a similar pattern for respondents with mixed or other race.

Table 4 reports the results of the latent class model including interactions with sociodemographic characteristics in the class membership model. We found that non-White respondents in Class 2 (the class with an overall preference for “no vaccine”) were less likely to choose an option that involved paying a fee than White respondents within that class ($\beta = -0.908$, $SE = 0.753$, $P < 0.001$). We found that non-White respondents in Class 3 were more likely to choose an option that involved paying a fee than White respondents in that class ($\beta = 1.785$, $SE = 0.934$), although this effect was insignificant. We also found that non-White respondents in Class 2 were significantly less likely to shift to an option with a longer wait time ($\beta = -1.047$, $SE = 0.802$, $P < 0.001$). Non-Whites respondents in Class 3 were more likely to shift to an option with a longer wait time than their White counterparts in that class, although this effect was also insignificant ($\beta = 4.057$, $SE = 3.277$). In other words: non-White participants in Class 2, the class with the strongest overall preference for the “no vaccine” option, were less willing to pay and less willing to wait for a vaccine than White respondents within that class.

Household income was considered as income elasticity for cost (ie, fee) sensitivity, with a separate interaction for missing data for income. We found that those with a higher income ($> \$75,000$) in Class 2 were less likely to be sensitive to changes in the fee for a vaccine. Respondents aged older

than 60 years in Classes 2 and 3 were more sensitive to the risk of illness attribute than those younger than 30 years, and non-White respondents were also more sensitive to this attribute than White counterparts in Classes 2 and 3. We also looked at whether non-White people were more sensitive to mild side effects, the risk of infection, and duration of protection with a vaccine, but we found no significant difference with the White population in those classes.

PREFERENCE ORDER

Respondents in the survey were also asked to select reasons for getting a COVID-19 vaccine. Figure 1 shows the reported reasons for getting vaccinated, by race. Overwhelmingly, respondents across all races answered first “to protect myself.” This was followed by “to protect my family” and “protect the general public,” although fewer Black respondents picked this answer than White, Asian, mixed, and “other” races. Fewer Black respondents than others also picked “because it was recommended by public officials” and “because it was recommended by doctors.” They were more likely to choose “because it was recommended by family” as a reason to get vaccinated.

Discussion

In this study, we sought to understand low vaccination rates among racial minorities. Overall, we found that individuals who self-report as Black had lower rates of vaccine hesitancy than those who identify as White. This was true overall,

by latent class and within latent class. This suggests that, contrary to what is currently being reported, Black people are not universally more vaccine hesitant. Combining the respondents who would not consider a vaccine (17%) with those who would consider one but ultimately choose not to vaccinate (11%), our findings indicate that more than 1 in 4 (28%) persons will not be willing to vaccinate. The no-vaccine rate is highest in White participants and lowest in Black participants.

This finding initially seems contrary to the widely reported lower vaccination rates for the Black population. What this study shows is that Black Americans, holding other factors constant, are more likely to vaccinate than White Americans. Yet other factors are not constant. Vaccine hesitancy varies by many other factors, including age, income, and education. Class 2 membership is higher among those aged between 41 and 60 years, lower income (less than \$20,000 per year), and, particularly, lower levels of education. The lower actual rates of vaccine hesitancy among Black participants are thus not necessarily a reflection of racism but rather reflect differences in preferences by income and education that cut across races, with Black Americans more likely to be in these low socioeconomic status groups. Blacks, then, are simply more prevalent within the already hesitant subgroups. Thus, to increase vaccination rates among the Black population, it will be necessary to focus attention on reasons for hesitancy among persons with less education and lower incomes.

This research also shows that grouping non-White people into broad categories like “persons of color” misses important differences among different racial groups and elements of identity intersectionality. Asian respondents were far less likely to be in the evaluative class and far more

likely to be in in the cost-conscious class. The preference structure for Asian respondents is markedly different from Black respondents.

LIMITATIONS

One limitation of the segmentation analysis is that, due to sample size, we were only able to measure “non-White” effects within classes so we cannot report the effect of Black respondents and other races within classes. The analysis thus assumes homogeneous preferences among non-White participants for the within-class analysis. It also does not consider differences in ethnicity. However, the (posterior) class profile analysis shows that Black participants generally preferred vaccine options without a wait time, whereas other races represented in our sample had overall preferences for “no fee” options or “no vaccine” options. This suggests that Black respondents within Class 2 may be even less willing to wait and less willing to vaccinate as the effects measured may be partly offset by the preferences of other non-White respondents. Another potential limitation is that some of the racial effects may be modified by income and education. Given the distribution of income, more work needs to be done to separate racial and income disparities.

Conclusions

Lower rates of vaccination among Black Americans do not reflect lower rates of racially motivated vaccine hesitancy. Instead, these lower rates reflect a higher proportion of Black people among groups with vaccine hesitancy—lower income and lower educated individuals. To reduce racial disparities in vaccination rates, it will be necessary to address vaccine hesitancy more broadly in disadvantaged populations.

DISCLOSURES

No funding was received for this study. The authors have nothing to disclose.

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Using latent class and quantum models to value equity in health care: a tale of 2 stories

Surachat Ngorsuraches, PhD

ABSTRACT

Cost-effectiveness analysis (CEA) with quality-adjusted life-year (QALY) was introduced to address health equity concerns in value assessment. However, QALY fails to capture patient preference. Stated preference methods (eg, discrete choice experiment [DCE]) have been increasingly used to incorporate patient preference into the value assessment framework in health care. Still, ones with a moral dimension such as health equity do not exist.

The objective of this paper was to describe 2 stated preference approaches that can empirically value health equity.

First, the decision-maker perceptions of the prevalence of equity dimensions in DCE choice tasks are identified. A latent class model based on random utility theory is proposed to derive the value of equity from the decision makers with different perceptions of the prevalence of equity dimensions. Second, equity attributes are incorporated in DCE choice tasks, and a quantum choice model, which can capture stochasticity during the decision process in the mind of the decision makers, is used to value the equity. These approaches will improve existing value assessment methods to address health equity adequately.

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J Manag Care Spec Pharm.
2021;27(9-a):S12-S16

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To love another person is to see the face of God

—Victor Hugo, *Les Misérables*.

Despite the increasing interest in developing the assessments of novel value elements identified by the International Society of Pharmacoeconomics and Outcomes Research (ISPOR) Special Task Force,¹ relatively few attempts have been made to value equity. None of the US value assessment frameworks directly defined equity or proposed an empirical measure of the equity. Only some potential elements (eg, unmet need) were considered.²

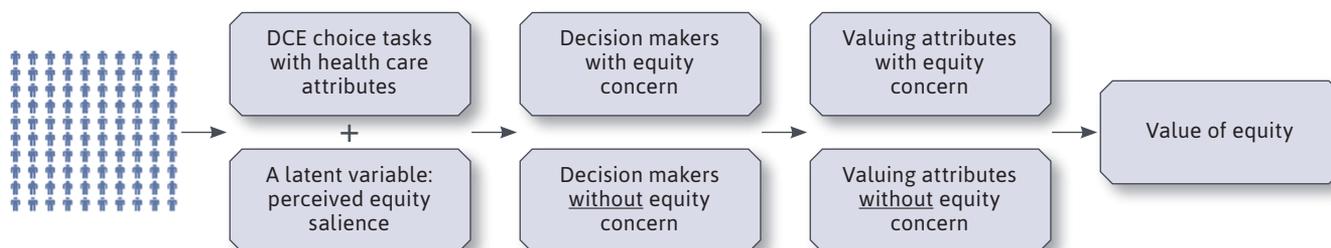
In 2017, cost-effectiveness analysis (CEA) with quality-adjusted life-year (QALY) was introduced to address health equity concerns in value assessment.³ Primarily, health economists

used 2 approaches, including equity impact analysis and equity trade-off analysis, to address these concerns.³ The equity impact analysis quantifies the distribution of costs and effects by equity relevant variables. Two examples of the equity impact analysis include extended CEA and distributional CEA.

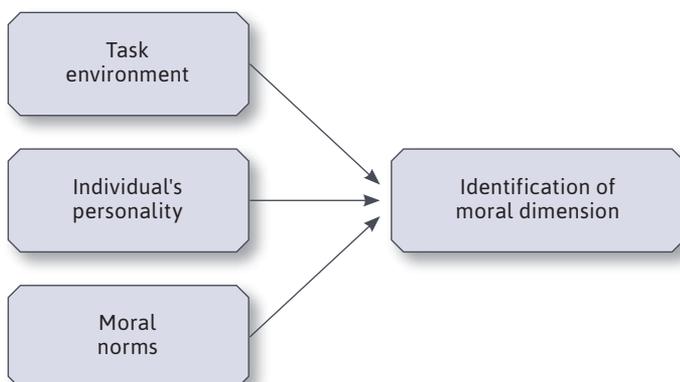
On the other hand, the equity trade-off analysis quantifies trade-offs between improving total health and other equity objectives. Two main approaches to equity trade-off analysis include equity constraint analysis and equity weighting analysis, which are counting the cost of equity and valuing the importance of equity, respectively. Similar to the equity impact analysis, CEA with QALYs has been used to capture the health loss associated with choosing a more equitable option in the equity constraint

analysis, and QALY is used as a common metric in the equity-weighting analysis.

Despite the wide use of the QALY metric in value assessment, it remains controversial because it is a single-dimensional and generic health measure. Furthermore, CEA with QALYs fails to capture patient preference and do not address the heterogeneity of patient preference. Although stated preference methods (eg, discrete choice experiment [DCE] and best-worst scaling [BWS]) have been increasingly used to incorporate patient preference into the value assessment framework in health care, the ones with a moral dimension, such as health equity, do not exist. There is, therefore, a critical need to improve existing methods that inadequately address health equity issues. Literature-suggested methods

FIGURE 1 Using a Latent Class Model to Value Equity

DCE = discrete choice experiment.

FIGURE 2 Conceptual Model of an Individual's Moral Choice Behavior^a

^aAdapted from Chorus 2015.⁵

from various disciplines should be harnessed to rigorously translate people's considered preferences to address health equity issues and to give guidance to health care decision makers.⁴

The objective of this paper is to describe 2 approaches that empirically value health equity and capture decision-maker preferences to contribute to value assessment under the realization of health equity. These approaches can be used to ensure the systematic consideration of health equity in decision making, and they will also determine how equity enters the preferences of decision makers, indicated as another challenge by ISPOR Special Task Force.¹

Proposed Approaches

Only a few stated preference studies, which explicitly acknowledged and explored the moral dimensions of choice behaviors, exist.^{4,5} One of the major challenges is that sometimes the moral choice is obvious, and, at other times, it is more latent or implicit.⁴ A moral dimension may be considered to some extent in the choice situations of these stated preference studies; however, these studies do not explicitly consider the moral dimension of the decision. This paper proposed to use 2 approaches previously developed and applied to examine the moral dimension in the transportation field to overcome this challenge and address equity concerns in health care.^{4,6}

FIRST APPROACH

This approach uses DCE with a latent class model to derive the value of equity. Figure 1 shows the steps of this approach. In general, a DCE describes various choice tasks of study treatment or health care service by its attributes (eg, efficacy, side effects, and costs). To engage patients in this approach, these attributes should be obtained from patient experiences. Each choice task contains various hypothetical alternatives with different attributes and levels, randomly combined by a rigorous method of DCE study design. Participants (eg, patients, providers, policymakers, and taxpayers) will be asked to choose 1 alternative that they prefer from each choice set. To value the equity and capture decision-maker preferences to contribute to value assessment under the consideration of equity, an individual's perception of the prevalence of equity dimensions in the choice tasks needs to be determined. Subsequently, responses to the DCE choice tasks from participants with different perceptions of the prevalence of equity dimensions are obtained.

TABLE 1 An Example of Results From the Latent Class Approach

	For underrepresented population	
	Class with equity salience	Class without equity salience
Marginal willingness to pay for health gain	\$X	\$Y

A literature review from the fields of economics and psychology was used to develop the conceptual model of an individual's moral choice behaviors and suggested to create a latent variable, "perceived moral salience," that can be used to reflect the individual's identification of moral dimension.⁴ The model identifies the task environment, the individual's personality, and moral norms as factors influencing the individual's identification of moral dimension (Figure 2). This model indicates that people can simply adjust their decision making when they encounter or identify a task environment with a moral dimension. Morality should at least to some extent be considered as a personality trait. As a result, different individuals from the same culture behave differently when encountered with the same moral situation. Many people prefer to stick with norms, even if these norms conflict with their personal preferences.

Therefore, this paper proposes to construct the perceived equity salience variable as a function of task environment (eg, the presence or absence of explicit verbal cues about health equity), individual's personality (eg, social value orientation), and prevailing moral norm of equity to determine the individual's identification of a given choice situation as having an equity dimension or not. Based on random utility theory (RUT), the perceived equity salience variable helps develop a latent class model. Individuals with different levels of

the perceived equity salience variable are assigned with different probabilities to "decision makers with equity concern" and "decision makers without equity concern" classes. These 2 classes are specified to differ in terms of preference weights or values for study attributes, based on the marginal rates of substitution between each attribute and cost. In other words, 2 value sets of treatment or health care service attributes determined with and without equity concerns are obtained. These 2 value sets can be compared to reflect the value of equity.

Preferences for the attributes under the realization of equity can be captured from the class of decision makers with equity concerns. For example, this approach can estimate social value for health gains from treatments for an underrepresented population (which can also be more specific populations). A DCE survey is designed to include health gain and cost as study attributes. Taxpayers are asked to respond to the survey. Marginal willingness-to-pay (WTP) for health gains can be calculated. Table 1 shows an example of the results. The marginal WTPs for health gains from the perspective of taxpayers with and without perceived equity salience are \$X and \$Y, respectively. Assuming \$X and \$Y to include the implicit value of equity, the difference between these amounts (\$X and \$Y) reflects the value of equity for 1 unit of health gain.

This approach can also examine how equity enters the participant

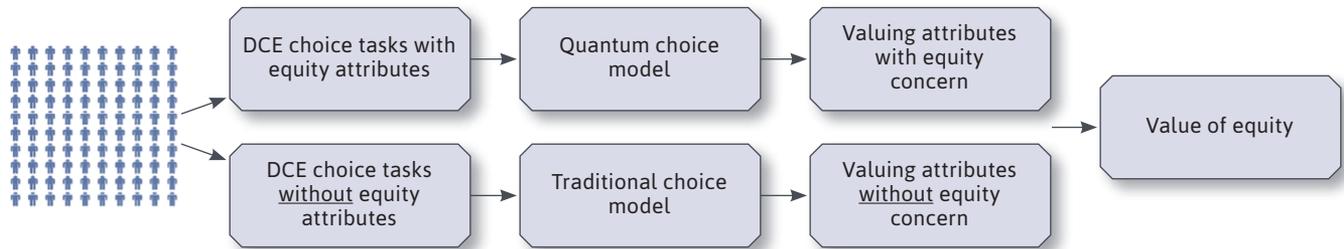
preferences identified by the ISPOR Special Task Force as an unclear issue.¹ For instance, the latent variable perceived equity salience could be modified to capture whether the participants focus equity on overall well-being or specifically on equity in health.

SECOND APPROACH

This approach uses DCE that incorporates equity attributes for individual alternatives in choice tasks to derive the value of equity. Figure 3 shows the steps of this approach. Participants (eg, patients, providers, policymakers, and taxpayers) are asked to complete 2 sets of DCE choice tasks based on an individual's preference. The first set involves trade-offs among treatment or health care attributes, including cost. Traditional choice models (eg, mixed logit model) can be used for this first set of choice tasks. The second set also includes equity attributes (eg, increased benefits and decreased risks for others in study treatment or health care) meaning that the participants need to make choices with equity concerns. An experimental study indicated that people not only preferred a resource allocation rule that most benefited them but also judged it to be fairer and more moral.⁷ In this given choice context, people may evaluate the choice tasks differently because of equity attributes. Their decisions would have changed depending on the acceptance or dismissal of the equity components. The study also suggested people could change their views about equity in a matter of minutes as they learned where their interests lay. Therefore, the stochasticity during the decision process in the mind of the individual decision maker needs to be captured to reflect behavioral realism.

RUT, which follows the classic theories of probability and has dominated the choice modeling field for decades and has been criticized as

FIGURE 3 Using the Quantum Choice Model to Value Equity



DCE = discrete choice experiment.

TABLE 2 An Example of the Results From the Quantum Approach

Observed share of an alternative under each choice task					
Choice task	Attribute changes				Observed share of alternative A, %
	Own health gain	Own cost	Others' health gain	Others' costs	
1	Included	Included	–	–	70
2	Included	Included	–	–	71
3	Included	Included	Included	Included	80
4	Included	Included	Included	Included	85
5	Included	Included	Included	Included	82

Results from a basic choice model and a quantum choice model with rotation		
Choice task	Average probability of chosen alternative A	
	Basic model, %	Quantum model with rotation, %
Choice tasks without others' health gain and cost	83	70
Choice tasks with others' health gain and cost	80	83

being inadequate in explaining moral choice behavior. It can be complex because decision makers may choose an alternative based not only on more attractive concrete attributes of the alternative but also how they believe the alternative to be an overall morally contentious option.^{6,8} Recently, quantum probability theory has been introduced in cognitive psychology.⁹ One of the key differences of the quantum theory from the classic theories of probability is that the distributivity law of “and” and “or” propositions— $A \wedge (B \vee C) = (A \wedge B) \vee (A \wedge C)$ —does not need to hold.⁹ This difference resulted in the creation of a new theory of probability, called quantum logic or quantum probability. This quantum probability can be used to efficiently reflect “changes in perspective or state of mind” of the respondents as a result of the incorporation of a moral attribute in stated

preference choice tasks. In 2020, a quantum choice model was introduced as a flexible new approach for understanding moral decision making in the field of transportation research.⁶ Given the success of using the quantum choice model in cognitive psychology and transportation, 1 possible application is to use it to address health equity.

This concept of a quantum choice model was adapted from Hancock et al.^{6,8} Conceptually, a participant would consider a choice task containing 2 alternatives. Under the quantum probability theory, the participant starts with a belief state. At this belief state, the participant may either have some underlying preference in favor of 1 alternative or feel indifferent between the 2 alternatives. When a decision is made, the belief state is projected to the chosen alternative. The alternative that has the projected vector

with a larger amplitude represents a higher probability of being chosen. However, when an equity attribute is added, it can impact the participant's choice by moving the participant's initial belief state (quantum rotation) to either "ethical answerability belief state" or "not ethical answerability belief state". As a result, the participant would start from this new state (changes in perspective or state of mind) instead of their initial belief state. Subsequently, the probabilities for choosing these 2 alternatives are altered. In other words, the quantum model can mathematically capture a change in perspective through a quantum rotation. Therefore, conceptually, the choice model is improved or fits differently when the equity attributes are considered. From this model, patients' preferences to contribute to value assessment under the realization of health equity are captured. Finally, the value of each attribute derived from the 2 sets of DCE choice tasks with and without equity attributes can be compared and used to reflect the value of equity.

For example, this approach can be used to estimate social value for health gains from treatments. Two DCE surveys are designed with and without equity attributes such as health gain for individuals from an underrepresented population. Table 2 shows an example of the results indicating the observed choice share for an alternative A and the results from choice models. If the equity attribute is considered and the observed choice share of the alternative consistently

change (eg, higher in this specific example), the results from the quantum choice model with rotation fits the data better due to its flexibility, judging from the higher average probability of chosen alternative A when including equity attributes.

On the other hand, the basic model could provide the opposite results. Similar to the first approach, how equity enters the preferences of the participants can be examined by modifying the equity attributes, for instance, focusing on equity in overall well-being or specifically on equity in health.

Conclusions

This paper describes 2 novel approaches, including latent class and quantum models, to rigorously value equity in health care. The latent class model is based on RUT with the classical theories of probability that has been widely used in choice modeling, while the quantum choice model is flexible enough to capture complex decisions as such decisions under equity. These approaches will improve existing value assessment methods that inadequately address health disparities and underrepresented populations.

DISCLOSURES

This study received no outside funding. Ngorsuraches has received research grants from Bristol Myers Squibb and through the University of Utah and PhRMA Foundation.

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“It’s Time to Represent”: shifting the paradigm to improve the quality of inputs into value assessment frameworks

Leticia R Moczygemba, PharmD, PhD; Carolyn Brown, PhD; and Michael Johnsrud, PhD, RPh

ABSTRACT

“It’s Time to Represent” integrates 2 strategies that challenge the status quo to increase the diversity of populations that participate in research and address drivers of health disparities to better inform value assessment. The first, a community-engaged campaign, proposes to develop authentic, long-term partnerships with community members, their health care providers, and researchers to

tailor recruitment and retention methods for underrepresented groups and hold researchers accountable for equitable selection of study participants. The second proposes to create an expectation for researchers to routinely collect patient-reported, actionable social determinants of health data to generate enhanced real-world evidence and thereby improve the quality of inputs utilized in value assessment frameworks.

“It’s Time to Represent” is a 2-pronged strategy to increase the diversity of populations that participate in research and address drivers of health disparities to better inform value assessment (Figure 1) with the following objectives: (1) launch a comprehensive national campaign using a community-engaged approach to inform, create buy-in, and generate excitement for participation in research, and (2) enhance information used in value assessment frameworks by expediting current methodological initiatives to require a minimum set of patient-reported social determinants of health (SDOH) elements to be collected and reported in research, including clinical trials and observational (real-world) studies.

Community-Engaged Campaign to Increase Representation

The evidence hierarchy used in value frameworks leaves large gaps in the ability to translate value when the evidence base used does not represent the economic, clinical, or patient-centric diversity of the populations that are impacted by the interventions themselves. Authentic participation and representation in research require a paradigm shift from current norms to meet underrepresented populations “where they are” in the community. Low trust, high distrust, high mistrust, and, simply, lack of opportunity are key reasons for minimal participation in research by these groups.¹ “It’s Time to Represent” recognizes that mistrust and distrust of “the system” by ethnic minorities and

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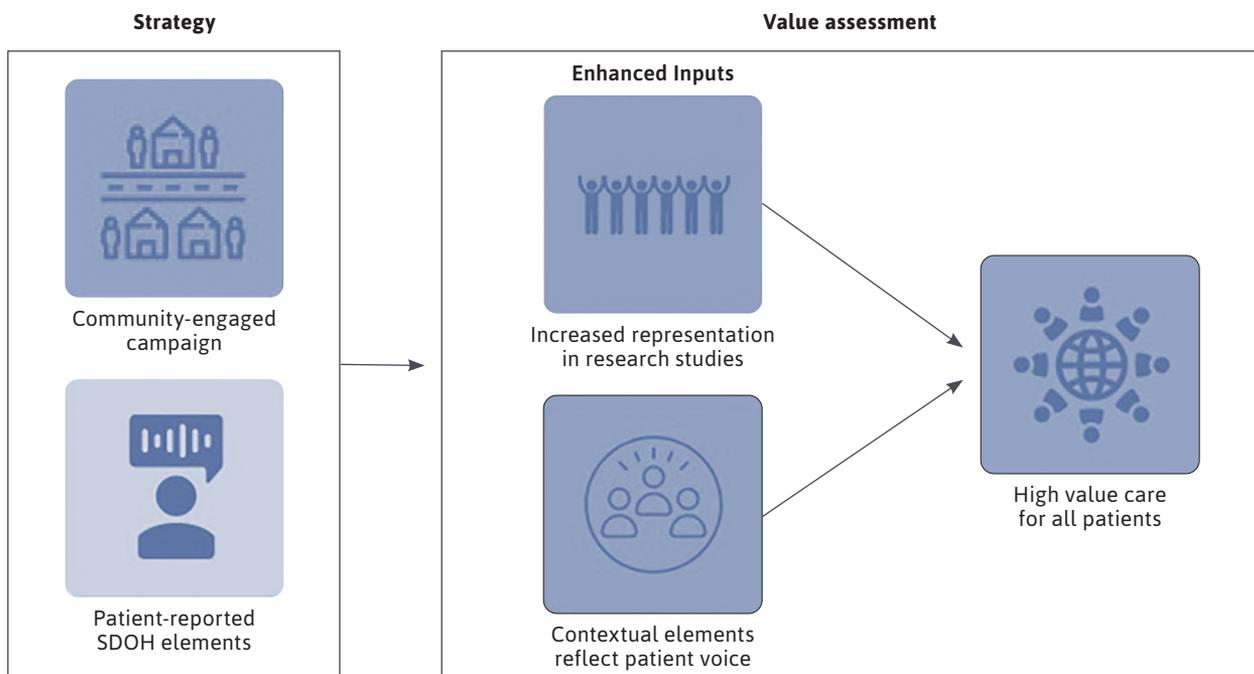
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J Manag Care Spec Pharm.
2021;27(9-a):S17-S21

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other disadvantaged groups are reasonable and valid responses to their past and present experiences and that any successful approach should also acknowledge that “the system” needs to demonstrate it is indeed trustworthy.¹ Thus, a grassroots effort with a different kind of appeal is needed to galvanize community members to evoke change as true partners, rather than subjects, to reshape views about research roles and contributions to the health of their community.

Not unlike a comprehensive “Get Out the Vote” campaign, our “It’s Time to Represent” strategy is multipronged and community-based. Community

FIGURE 1 "It's Time to Represent": Strategy Impact on Inputs to Inform Value

SDOH = social determinants of health.

members, their health care providers, and researchers should all be meaningfully engaged to increase the capacity to facilitate research participation and create community-informed best practices. Trust issues and lack of access to information are common barriers to research participation across ethnic-minority groups; however, altruistic appeals rooted in cultural and community priorities are mutual facilitators in research participation among these groups.²

Evidence shows that communities need to be engaged before and after study recruitment to legitimately increase representation and retention of underrepresented groups.³⁻⁵ Although this may seem straightforward, to do this in a meaningful way, researchers and funders must shift their thinking from *subject*, which is transactional and time-limited in that once study activities are complete the interaction is complete, to *participant*, which implies an active role as a partner.⁴ Getrich et al describes a cycle of trust whereby a relationship is being continuously cultivated before the study, during recruitment, throughout the study, and after study completion.³ Initially, the research team can build trust by communicating effectively (eg, bilingual team members), demonstrating respect and understanding of cultural norms, developing an understanding of

motivations for participation in research (eg, personal and/or community benefits, contributing to the greater good), and including community representation on the team.^{3,5,6}

Consensus building and developing shared goals for research also create a solid foundation of engagement and can lead to long-term partnerships.^{4,7} Investing the time before a study to learn about the community of focus will allow researchers to personalize recruitment and retention methods to include contextual factors relevant to a community and make potential participants feel like "more than a number."^{3,4} Equally important is continued interaction with the community upon study completion. Historically, "community-placed" research, where researchers have conducted research with no community involvement in an "up and out" fashion, has harbored deep resentment and decreased motivation of underrepresented groups to participate in research which in some cases may still exist today.⁸ Thus, strategies such as sharing study findings, co-ownership of data, and holding community forums for feedback can be used to stay engaged with communities once study participation is completed.^{4,7} To move up the ladder of participation from nonparticipation to empowered participants, commitment in the form of time

and other resources is required on the part of researchers, communities, and funders.^{7,9} The Patient Centered Outcomes Research Institute is an exemplar in upholding rigorous standards for patient engagement in research, even including patient stakeholders in funding decisions. A similar model can be used by funders and other stakeholders to ensure that authentic engagement occurs.

In parallel, researchers should be accountable to ensuring their research designs include equitable selection—without loopholes—of people who are most impacted by the outcomes being studied. As exemplified by the guidance recently released by the US Food and Drug Administration on improving diversity in clinical trials,¹⁰ and Pharmaceutical Research and Manufacturers of America's newest principle of "enhancing diversity in clinical trial participation," which has been added to the Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results,¹¹ it is critical that diverse groups be better represented in research. Often, the design of clinical trials systematically excludes the people in which they were designed to help. For example, stringent inclusion/exclusion criteria, employment constraints, cultural differences, and implementation in academic centers that may not be accessible to diverse groups are known and ongoing impediments to participation among ethnic minorities that must be addressed.^{3,12,13} A recent meta-analysis revealed that, when asked, Black patients participated in cancer clinical trials at similar rates as White patients.¹⁴ The authors noted, and we agree, that attention to modifiable structural (eg, patient access to available trials, provider resources/infrastructure for participation) and clinical (eg, broadening eligibility criteria) barriers could improve trial participation.¹⁴

Providers who are people of color need to be at the forefront of any strategy to increase research participation of their patients.¹⁵ The creation of a central repository of providers who serve communities of color, as well as other medical and health practices, and community-based organizations where people of color are cared for and accessible is a key element of this initiative. Many ethnic minority physicians would likely participate in clinical trials if trial designs were modified to accommodate their resource level and reduce participant burden.¹²

Doctors, pharmacists, other health care providers, and other community-based champions should be provided the protocol information, training, and tools to inform, engage, and activate patients and community members while building their trust, interest, and ability to participate in research studies. Implementation should be flexible and nimble because training, information, and resource needs may vary based on research experience, which will

expectedly be limited among those who primarily serve communities of color. Ultimately, investigators will have access to this rich, centralized resource for the recruitment of eligible and willing participants into clinical trials and observational research studies.

Enhancing Value Assessment Through Consideration of Social Determinants of Health Data

The approach we outline for better representation of diverse voices in value assessment frameworks targets the sources of evidence within these frameworks, namely randomized controlled trials (RCTs) and observational (real-world) data. Our "Get Out the Vote" approach is primarily directed at increasing participation in RCTs, which are often the primary source of data cited from the evidence base to make clinical and cost-effectiveness determinations that produce the judgment of a medication's value. Therefore, systems that facilitate recruitment of underrepresented patient populations into RCTs are an important mechanism to generate the needed data and evidence to better inform the value modeling processes used within most frameworks in the United States today.

In addition, an important gap within the evidence base that can provide more robust context for health equity is the integration of social determinants of health (SDOH) data into value frameworks through its collection at the point of care as observational, or real-world, data. Our approach addresses this key shortcoming in that whole-person contextual inputs are currently inadequate in current value assessment frameworks because clinical and cost-effectiveness studies that inform value determination nearly always lack appropriate risk adjustment for meaningful SDOH factors in the population. This leads to biased results that impact the interpretation of value when attempting to generalize to patient populations with higher SDOH needs. Therefore, SDOH data as a potential contributor to more robust real-world data analyses should not be overlooked. As an example, recent research has established that Medicare Advantage quality rankings related to diabetes and cholesterol control would have increased for up to 1 in 5 plans if risk adjustment that incorporated sociodemographic factors across disadvantaged populations was considered.¹⁶

The generation of real-world evidence that incorporates SDOH can be an important source of data to inform value frameworks. Recent research indicates that although the use of real-world evidence in a value framework such as the Institute for Clinical and Economic Review (ICER) has

varied in its application across the organization's published reports, ICER has provided guidance that describes opportunities for use of real-world evidence to inform coverage and formulary decisions.^{17,18}

However, our ability to leverage SDOH data within value frameworks is currently hindered by the fact that the methodologies to collect and integrate this contextual data has not fully matured, particularly patient-reported SDOH data. We must expedite our development of standards for SDOH data collection and further incentivize the use of SDOH in decision making through integration into quality and performance measures to expand available data for use in real-world evidence generation, which complements RCT data in value assessment frameworks. Integration into performance and quality measures will further serve as incentives for establishment and maintenance of standards for collecting SDOH data. The incentives will also create a proliferation of SDOH data generation that can provide the additional data elements needed for real-world evidence analyses that incorporate appropriate risk-adjustment, as described earlier. In light of this, a recent policy framework was announced by the US House Ways and Means Committee that seeks to address gaps in health equity by prioritizing approaches to standardization of metrics to measure health equity, as well as further definition of SDOH.¹⁹

A further challenge is that existing efforts to measure SDOH in research often rely upon surrogate markers (eg, ZIP code, income) that are imprecise and without the patient voice. These markers are chosen largely out of availability in current data sets, but "settling" for this approach to identifying gaps in SDOH lacks specificity and, ultimately, utility. The creation and validation of a minimum set of

patient-reported SDOH elements will begin to close the gap and address currently unmeasured confounders that exist in studies that inform value assessments.

SDOH data should be collected with the intent to be actionable. This requires pairing its collection with the meaningful development of mechanisms to actually address gaps at the individual level through the coordination of available community services by providers at the point of care. Recent guidance from the Centers for Medicare & Medicaid Services has provided a potential roadmap and examples for state Medicaid programs to broaden availability of, and access to, services to address gaps at the community level.⁶ While policymakers continue to deliberate on the structure and funding required to support these programs, this should not impede our advancement toward collection of patient-reported SDOH data; rather, it is a call to incentivize its collection in order to better identify where near-term resources can best address prioritized gaps in patient populations most effectively.

A multistakeholder approach (ie, patients, community representatives, clinicians, researchers, funders) should build on early initiatives such as the Gravity Project to continue to develop pathways for broader collection of SDOH data elements, and go further to instill an expectation for researchers to include SDOH in their study design and analyses. The focus on incorporation of SDOH enhances the richness and perspective of data and evidence used by all value assessment frameworks, regardless of therapeutic focus. The result is better informed and more equitable decisions of value being made across diverse groups and mitigation of the harmful effects of the current "one size fits all" approach.

It's Time to Represent

Our body of evidence is in dire need of better representation from diverse patient populations. The proposed 2-pronged strategy is a bold approach using authentic community engagement to increase diversity in clinical research, paired with expedited data infrastructure development that collects much needed patient-reported SDOH elements as part of real-world evidence generation, which will create a "voice" to that body of evidence. Unfortunately, this voice has been previously much too faint. Giving clear voice to the body of evidence as we move forward more authentically informs how value is determined.

Let's begin with this bold plan: It's Time to Represent!

DISCLOSURE

No specific funding was received for this manuscript. The authors report no potential conflicts of interest.

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Incorporating health equity into value assessment: frameworks, promising alternatives, and future directions

Vakaramoko Diaby, PhD; Askal Ali, PhD; Aram Babcock, PharmD, MS, MBA; Joseph Fuhr, PhD; and Dejana Braithwaite, PhD

ABSTRACT

Exploring methods that value diverse perspectives is critical to better understand the value of health equity in value assessment frameworks. In this paper, we examined emerging value assessment frameworks in the United States and present examples where evidence on outcomes and preferences for value do not take into consideration diverse perspectives. We identify possible solutions to improve existing value assess-

ment methods and illustrate—using a hypothetical shared decision-making case study—an alternative to current value-assessment frameworks, “equitable multicriteria decision analysis,” which could be implemented in the context of the value-based assessment of prevention choices for women at high risk of developing breast cancer. These proposed alternatives and solutions can be used by researchers and decision makers to incorporate health equity into value assessment.

In response to growing concerns about spiraling health care costs, the US health care system is undergoing a paradigm shift in the way it delivers and pays for care.¹ It is in this context that value assessment frameworks (VAFs) have emerged to assist different stakeholders, including clinicians and payers, in realigning health care decisions based on the most robust clinical and economic evidence. However, the use of these frameworks has sparked growing concerns, of which health equity achievement has become central, triggering a debate over the meaning of value and its measurement.² Thus, there is a critical need to identify and assess avenues to incorporate health equity measures into VAFs.

In this paper, we examined current VAFs and document examples in which available evidence on outcomes and preferences traditionally accounted for in value assessments do not consider diverse perspectives. We document processes that may inadequately address health disparities and underserved populations. Next, we propose solutions to improve existing value assessment methods. Finally, we illustrate, using a hypothetical shared decision-making case study, how an alternative to current value-assessment frameworks, equitable multicriteria decision analysis, could be implemented as part of the value-based assessment of prevention choices for women at high risk of developing breast cancer.

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J Manag Care Spec Pharm.
2021;27(9-a):S22-S29

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Overview of Value Assessment Frameworks: A Comparative Analysis

The primary goal of VAFs is to support evidence-based health care decision making using robust clinical and health economic evidence.^{1,3} Since the 1990s, the United States has fallen behind many high-income countries in relation to the benefit-cost of health care expenditures.⁴ Lately, the United States has begun shifting from a volume-based system to one based on value.³ Figure 1 shows the evolution of government and private investments in infrastructure supporting evaluation of costs and effectiveness of medicines and health care technologies in the United States.

In this context, several professional organizations such as the American Society of Clinical Oncology (ASCO),⁵ American Heart Association/the American College of Cardiology,⁶ National Comprehensive Cancer Network,⁷ Memorial Sloan Kettering Cancer Center (MSKCC [DrugAbacus])⁸ and the Institute for Clinical and Economic Review (ICER)⁹ have developed their VAFs. In this section, we examine these US VAFs according to their target audience, rationale, elements of value considered, methodological approach, and other considerations including equity attainment. Table 1 presents a summary of this comparative analysis. An initial examination of Table 1 reveals that VAFs have different rationales and perspectives. Elements of value considered in these frameworks differ based on perspectives, target audience (clinical/shared decision making versus coverage and policy), and expected outcomes, either direct or indirect.

Clinical evidence used in these frameworks is generated from population-level sources including randomized controlled trials (RCTs). As an example, the ASCO framework solely depends on RCTs to generate the net health benefit (NHB) scores and does not reflect the real-world clinical practice. Clinical trials represent the cornerstone of evidence generation when it comes to establishing treatment efficacy. Yet, it has been reported that only 5% and 1% of trial participants are Black/African American and Hispanic/Latino, despite making up 13.4%¹⁰ and 18.1%¹¹ of the US population, respectively. Knowing that participation of racial/ethnic minority groups in clinical trials is low, such evidence is not tailored to meet the needs of minority patients/communities, or underrepresented subgroups of the population including the young and the elderly.¹² Except for the ICER framework, VAFs completely ignore patient heterogeneity (eg, age, sex, race/ethnicity, socioeconomic status), complex demographic factors (eg, geography), and health care system-level factors

(eg, access to care) that are known contributors to health care disparity. This potentially leads to inefficient allocation of health care resources, coverage, and drug pricing decision making,¹³ with a huge burden on minority patients as they may not be provided with the optimal clinical services they deserve.

Similarly, equity measures (eg, unmet needs, health disparity, burden of illness) are not explicitly and quantitatively incorporated in value assessment as evidenced in Table 1. Only the MSKCC considers unmet needs and burden of illness quantitatively, whereas ICER uses an ad hoc process to include health disparity contextually, if judged feasible. Finally, the VAFs discussed in this section have previously been criticized for their limited transparency in their data aggregation processes, their ability to be reproduced,¹⁴ and the lack of decision criteria that matter the most to patients.¹

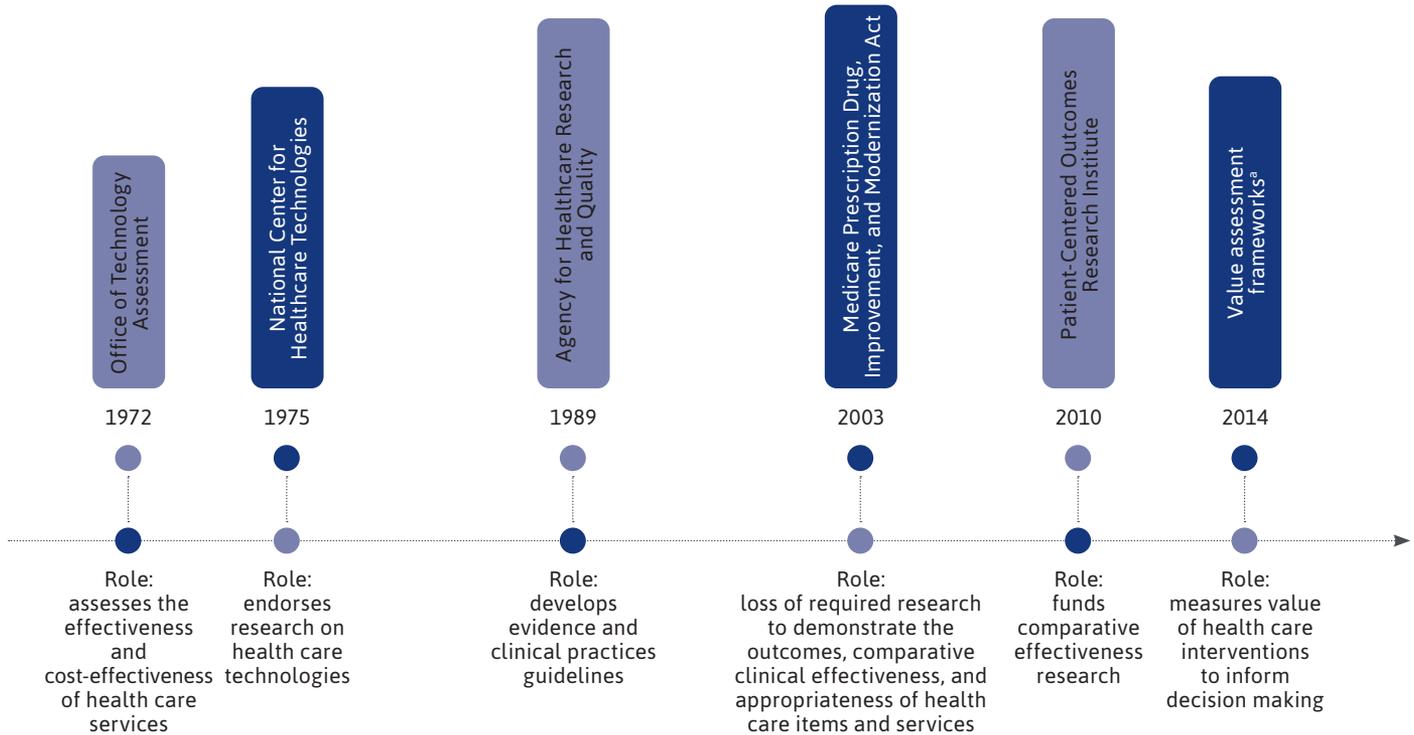
Solutions to Improve Existing Value Assessment Frameworks

In recent years, the need to curtail the spiraling of health care costs coupled with the imperative to deliver value-based care has legitimated the emergence of VAFs in the United States. With the progressive adoption of these VAFs, major limitations to VAFs have become apparent. In this section, we propose a range of solutions to address the limitations of existing VAFs, starting from the generation of appropriate elements of value, equity data specifically, to the adoption of robust data aggregation methods.

A call for action to make recruitment and inclusion of underrepresented minority groups a priority in clinical trial implementation is critical as it will ensure that RCTs contribute to the development of interventions that are responsive to the needs of a diverse population.^{15,16} Evidence obtained from these trials can then feed VAFs. Pharmaceutical companies could be incentivized to develop drugs for rare diseases and diseases that affect underrepresented minorities the most such as sickle cell disease. Including the patient voice in the clinical drug development to identify endpoints and achieve outcomes that are important to them will expand elements of value used in VAFs.

Criticized for their lack of patient centeredness while being agnostic of health equity considerations, emerging VAFs need to build on existing methodological approaches that allow for the explicit incorporation of the health inequality impacts of the health care interventions evaluated.¹⁷ We briefly present 3 approaches, 2 of which build on traditional cost-effectiveness analyses. These approaches are (1) 2-part health technology appraisal, (2) distributional

FIGURE 1 Evolution of Government and Private Investments in Infrastructure Supporting Evaluation of Costs and Effectiveness of Medicines and Health Care Technologies in the United States^a



^aAdapted from Diaby et al (2019).¹

cost-effectiveness analysis (DCEA), and (3) equitable multi-criteria decision analysis.

TWO-PART HEALTH TECHNOLOGY APPRAISAL

The goal of the 2-part health technology appraisal is to ensure patient access to health care interventions that generate extensive value to society, which is not captured by the incremental cost-effectiveness ratios traditionally used in economic evaluations.¹⁸ Specifically, the incremental cost-effectiveness ratio is used jointly with a comprehensive benefits and value (CBV) score for decision making about the value of health care interventions. The CBV score is a composite and qualitative score obtained from the aggregation performance of the interventions evaluated against expanded elements of value including innovativeness, disease severity, and unmet need.¹⁸ This approach was initially proposed as an alternative process to the National Institute for Health and Care Excellence health technology assessment.

DISTRIBUTIONAL COST-EFFECTIVENESS ANALYSIS

The term "DCEA" serves as an umbrella for economic evaluations that model distributions of health (health gains/disease burden) associated with health care interventions at both population (societal) and subgroup (eg, sex, race/ethnicity) levels.¹⁹⁻²¹ In other words, DCEA provides breakdowns of health gains and losses per equity-relevant sociodemographic variables and per disease categories. In making decisions about the value of health care technologies, decision makers make tradeoffs between improving total population health and reducing unfair health inequality.¹⁹⁻²¹

EQUITABLE MULTICRITERIA DECISION ANALYSIS

Value assessments of health care interventions are complex in nature as they involve multiple criteria of varying importance to decision makers and data from diverse sources. This conundrum calls for the development of more structured frameworks that allow for the transparent aggregation of value elements into a decision composite metric. One of the

TABLE 1 Comparative Analysis of Major Value Assessment Frameworks in the United States

	ASCO	AHA/ACC	NCCN	MSKCC (DrugAbacus)	ICER
Audience	Providers/patients	Providers/patients	Providers/patients	Payers, policymakers, providers/patients	Payers, policymakers, providers/patients
Purpose/rationale	Shared decision-making tool for patients and providers to promote access to the highest-quality care at the lowest cost	Shared decision-making tool for patients and providers to support clinical decisions regarding the adoption of health care interventions including drugs and devices	Shared decision-making tool for patients and providers to support clinical decisions regarding treatment regimens	To assess the value-based price of treatments to inform payer and policy decisions	To assess the value of treatments to support coverage and reimbursement decisions
Elements of value considered	Benefits (survival and QOL), risks, and cost	Benefits (survival and QOL) and cost	Benefits (survival and QOL) and cost	Drug price, toxicity, efficacy, novelty, research and development costs, rarity of the disease, and population health burden	Costs, benefits, opportunity cost
Approach/type of evidence used	NHB score, a combination of weighted measure of clinical benefit and side effects, with extra points assigned to bonus items including QOL. Cost information are reported separately	Value is measured qualitatively using 5 levels anchored on incremental cost-effectiveness ratio	Health benefits measured using a score (1-5, 5 being the highest) for each of 5 key measures (efficacy, safety, quality of evidence, consistency of evidence, and affordability) shown as evidence blocks. For each treatment, scores are averaged across the evidence blocks.	Value-based pricing	Incremental cost-effectiveness ratio and budget impact analysis (BIA)
Other considerations					
Equity (unmet need, health disparity, burden of illness)	No	Considers unmet need qualitatively	No	Considers unmet need and burden of illness quantitatively	Ad hoc process to include health disparity contextually "if judged feasible"
Patient heterogeneity	No explicit account of patient heterogeneity	No explicit account of patient heterogeneity	No explicit account of patient heterogeneity	No explicit account of patient heterogeneity	Subgroup analyses can be conducted
Cost/price	Yes, but costs reported separately (patient only)	Yes, costs included in traditional CEA	Yes, but costs reported separately	Yes, maximum acceptable price set	Yes, costs included in traditional CEA
Affordability	No BIA	No BIA	Affordability scale used	Yes, BIA	Yes, BIA
Stakeholders engagement	Yes	Yes	Yes	Yes	Yes

ACC=American College of Cardiology; AHA=American Heart Association; ASCO=American Society of Clinical Oncology; BIA=budget impact analysis; CEA=cost-effectiveness analysis; ICER=Institute for Clinical and Economic Review; MSKCC=Memorial Sloan Kettering Cancer Center; NCCN=National Comprehensive Cancer Network; NHB=net health benefit; QOL=quality of life.

TABLE 2 Hypothetical Performance of Each Treatment Option Against the Decision Criteria²⁶

	Out-of-pocket costs (USD) ²⁶	Safety profile	Quantification of cancer risk reduction (%)	Treatment impact on health equity
Treatment options	C ₁ (min)	C ₂ (max)	C ₃ (max)	C ₄ (max)
Low-dose tamoxifen	20	4	30	H
Tamoxifen	40	1	30	H
Exemestane	60	2	40	VH
Raloxifene	30	3	30	F
Patient preference weights for decision criteria	0.28	0.22	0.35	0.15

C₁ (min) = criterion 1 (out-of-pocket costs), to minimize; C₂ (max) = criterion 2 (safety), to maximize; C₃ (max) = criterion 3 (quantification of cancer risk reduction), to maximize; C₄ (max) = criterion 4 (treatment impact on health equity), to maximize; F = fair; H = high; USD = US dollars; VH = very high.

most comprehensive quantitative approaches to choose, rank, and select treatment options is multicriteria decision analysis (MCDA).^{22,23} The explicit consideration of criteria importance and the transparency inherent in the use of this approach ensure that the underlying process of arriving at any decision based on treatment profiles and decision criteria is consistent and clear. In this context, equitable multicriteria decision analysis can help support decision makers faced with evaluating treatment options by considering multiple criteria in an explicit manner, among which is the treatment impact on health equality.^{24,25} In the next section, we develop a hypothetical case study illustrating the application of equitable multicriteria decision analysis to the value-based assessment of prevention choices for women at high risk of developing breast cancer.

Case Study: Application of Equitable Multicriteria Decision Analysis to the Value-Based Assessment of Prevention Choices for Women at High Risk of Developing Breast Cancer

CASE STUDY PRESENTATION

Imagine that Jane Doe, a Hispanic woman at high risk of developing breast cancer, has a clinical encounter with her care provider. She is offered a choice among 4 chemoprevention alternatives: low-dose tamoxifen, tamoxifen, exemestane, and raloxifene. Treatment recommendation in this shared decision-making process is based on the performance of the treatment options (ie, how well each treatment option meets prespecified decision criteria)

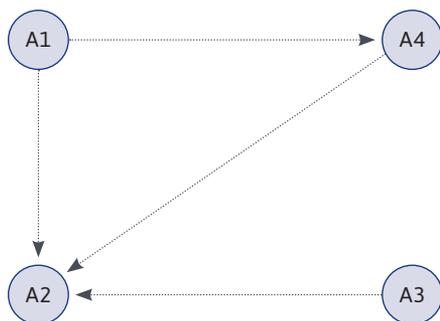
against 4 criteria that reflect the following dimensions of value: cost (out-of-pocket costs), safety (drug safety profile), clinical benefit (quantification of cancer risk reduction), and equity (treatment impact on health equity). These criteria are defined as follows:

- *Out-of-pocket costs*: Monthly co-pay expressed in dollars. This criterion is measured on a quantitative scale and needs to be minimized (ie, the lower the out-of-pocket costs, the better).
- *Safety profile*: This criterion is measured on a quantitative scale from 1 to 5, 5 being the best. This criterion needs to be maximized (ie, the higher the score, the better).
- *Quantification of cancer risk reduction*: This criterion is measured on a quantitative scale from 0 to 100 (percent), 100 being the best. This criterion needs to be maximized (ie, the higher the score, the better).
- *Treatment impact on health equity*: In this hypothetical case, the treatment impact on health equity is captured through its ability to reduce the differences in terms of cancer risk reduction among racial and ethnic groups. This criterion is measured on a qualitative scale (very low ([VL]; low [L], fair [F], high [H] and very high [VH]) and is expected to be maximized (ie, VL is the least preferred, whereas VH is the most preferred).

Table 2 summarizes the performance of each treatment option against the 4 decision criteria. It is worth noting that the data contained in this table are used for illustrative purposes. In a real-world setting, this data would be obtained from clinical trials, comparative effectiveness studies, relevant cost data sources, and experts as needed.

As part of the shared decision-making process, the provider has quantified Ms. Doe’s preferences using an approach called ELICIT,²⁷ which yielded the following weights: 0.28, 0.22 0.35, and 0.15 for out-of-pocket costs,

FIGURE 2 Dominance Relationships Among Alternatives



The arrow points towards dominated treatments. A1 = low-dose tamoxifen; A2 = tamoxifen; A3 = exemestane; A4 = raloxifene.

safety, quantification of cancer risk reduction, and treatment impact on health equity, respectively. These weights indicate the contribution of each criterion to the decision about the best chemoprevention agent. For example, the criterion safety makes up 22% of the decision while OPC makes up 28%. The weights sum to 100%.

METHODS: VALUE ASSESSMENT USING EQUITABLE MULTICRITERIA DECISION ANALYSIS

We use partial or noncompensatory MCDA methods for transparent aggregation of elements of value, notably outranking models. These models establish dominance relations among alternatives such that even if an alternative A (treatment option in our case) is as good as an alternative B on every decision criterion, a decision-maker (provider/patient) can conclude that A outranks B if a majority of the decision criteria support this assertion as long as there is no criterion on which A is worse than B. The majority rule is fulfilled when the sum of the preference weights associated to these

TABLE 3 Hypothetical Treatment Ranking by Preference Order

Alternatives	Victories ^a	Defeats ^b	Copeland score ^c	Rank
A1—Low-dose tamoxifen	2	0	2	1
A3—Exemestane	1	0	1	2
A4—Raloxifene	1	1	0	3
A2—Tamoxifen	0	3	-3	4

Note: the green highlighted row indicates the recommended treatment.

^aNumber of times a treatment is dominant over others.

^bNumber of times a treatment is dominated by others.

^cDifference between “victories” and “defeats.”

criteria are superior or equal to 55%. This is the basic principle of the Elimination and Choice Expressing Reality (ELECTRE) methods.²⁸⁻³⁰ In ELECTRE methods, alternatives are compared pairwise to establish outranking relationships by considering the weights of the criteria in favor of the outranking relation and also the possibility that an opposing criterion vetoes (“veto threshold”) that relation. Outranking relations are analyzed using an ELECTRE method to select the best alternative, rank the alternatives, or sort them into predefined categories. The issue of ELECTRE methods not yielding a single winner or best choice is circumvented by using the Copeland’s pairwise aggregation method³¹ where alternatives, treatment options in this case, are ranked by the number of pairwise “victories” (ie, number of times an alternative is dominant over others) minus the number of pairwise “defeats” (ie, number of times an alternative is dominated by others). The higher the Copeland’s score, the better the rank. Deterministic and probabilistic sensitivity analyses can be conducted to address the impact of uncertainty of the analysis results using “equitable multicriteria decision analysis.”

RESULTS: TREATMENT RECOMMENDATION FOLLOWING RANKING

Figure 2 shows the relationship among the treatment options, which translate into the ranking of these treatments by order of preference (Table 3). Each arrow represents a dominance relationship between 2 treatment options (Ax versus Ay). An arrow departing from an alternative/treatment (Ax) would suggest that Ax is dominant over Ay (Victory for Ax) while an arrow pointing towards Ax would suggest that Ax is dominated by Ay (Defeat for Ax). For example, looking at the pairwise comparison between A1—low dose tamoxifen and A2—tamoxifen in Table 1, A1 has a performance that is at least as good as A2 on all the criteria. The majority rule is fulfilled given that the sum of the weights of the criteria for which A1 is at least as good as A2 is superior to 55% (Majority weight = 0.28 + 0.22 + 0.35 + 0.15). Thus, A1 has 2 victories and 0 defeat. These dominance relationships are established for all pairwise treatment comparisons. Using equitable multicriteria decision analysis, which accounted for both patient preferences and included an equity criterion in the decision process, low-dose tamoxifen has the highest Copeland score and therefore

ranked first. As a result, low-dose tamoxifen is the treatment returning the most value.

Conclusions

Recent societal and cultural movements have helped place a spotlight on inequities that for far too long have not been addressed in our health care system. As a case in point, these inequities can be found where underrepresented communities are underserved, including VAFs. Thus, the solution is to focus resources on these communities using decision toolkits that are already available but can be adapted to ensure decision makers appropriately measure equity-efficiency tradeoffs. Innovations for improved health outcomes for marginalized groups should be appropriately incentivized to ensure the attainment of health equity. While concerns remain about VAFs, the solutions to their expansion are attainable and include fostering inclusion and diversity in clinical trials and translational research, use of appropriate value aggregation methods that can capture equity, and input from the patients on what endpoints/criteria matters most.

DISCLOSURES

No funding was received for this study. The authors have no conflicts of interest to report.

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