

JULY/AUGUST 2023 VOL. 9, NO. 4

VALUE & OUTCOMES SPOTLIGHT

A magazine for the global HEOR community.



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 **ISPOR**
Improving healthcare decisions

VALUE & OUTCOMES SPOTLIGHT

JULY/AUGUST 2023
VOL. 9, NO. 4

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The mission of *Value & Outcomes Spotlight* is to foster dialogue within the global health economics and outcomes research (HEOR) community by reviewing the impact of HEOR methodologies on health policy and healthcare delivery to ultimately improve decision making for health globally.

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VALUE & OUTCOMES SPOTLIGHT PUBLISHING, SUBSCRIPTION, AND ADVERTISING OFFICE:

Value & Outcomes Spotlight
Online: ISSN 2375-8678
Published bimonthly by:
ISPOR

505 Lawrence Square Blvd, S
Lawrenceville, NJ 08648 USA

Direct photocopy permission and reprint
requests to Director, Publications.

Cover photo courtesy of iStockphoto/dvarg

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Pharmacoeconomics and Outcomes Research.

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FROM THE EDITOR

Health Impacts of Climate Change

The body of evidence that climate change is real—whether caused by humans or by natural regulation—continues to mount, shedding little doubt that it is a phenomenon having a detrimental global impact and can no longer be ignored. As evidence, the global average temperature of the planet has increased since 1901, which may be causing the observed dangerous climate and weather shifts. Some clear examples of climate change on weather include extreme heat waves; rainfall shifts leading to increased flooding and/or intense rain in some areas and draughts in others; warming of the oceans; melting of ice caps; and rising of sea levels.

In recent years, scientists have made significant advances in our understanding of the effects of climate change on increased risk to human health.

Many of the recent extreme weather events occurring around the planet are part of that mounting evidence of global climate change. For example:

- Many US states (eg, Arizona, Louisiana, Mississippi, New Mexico, and Texas) are setting records for extreme heat and high temperatures. Much of the eastern United States is facing daily severe thunderstorms that render hail, heavy rainfall, wind gusts, and even tornadoes which have resulted in deaths.
- In Canada, more than 900 wildfires are currently burning which has resulted in horrendous and life-threatening air quality not only in Canada, but also in some parts of the northeastern United States, including Pennsylvania, New Jersey, and New York.
- In Italy, Rome had record-high temperatures resulting in an approximately 20% increase in emergency room visits.
- In Greece, wildfires are raging in Athens and in other parts of the country.
- In France, new record-high temperatures were recorded.
- In India, water flooding from the Yamuna River overflowed into New Delhi and even reached the compound walls of the famous Taj Mahal.

The extreme heat, very poor air quality, and environmental catastrophes resulting from changes in rainfall patterns pose a dangerous threat and health risk to many individuals worldwide, especially the vulnerable.

In recent years, scientists have made significant advances in our understanding of the effects of climate change on increased risk to human health. We know that climate change affects the food supply, air quality, the availability of potable water, and adequate shelter against these ever-changing forces of nature. A population's health and well-being can be impacted through climate change by altering the frequency and/or intensity of weather and spreading disease by the proliferation of certain pests that carry these diseases. Researchers also now better understand the long-term impact heat waves have on health. Links between sustained heat exposure and chronic health conditions such as diabetes, kidney stones, cardiovascular disease, and obesity are being established. The health effects of climate change include increased diagnoses of respiratory and heart diseases, greater prevalence of pest-related diseases like Lyme disease and West Nile Virus, elevated numbers of environmental-related illnesses, and heightened injuries and mortality. Increases in overall poor mental health have also been linked to climate change. For example, climate disasters may result in damage to homes, vehicles, and loss of loved ones which in turn increase the likelihood of mental health disorders, such as anxiety, depression, and posttraumatic stress.

All of us face some sort of health impact risk resulting from climate change. However, many face potentially higher risks depending on their exposure to these hazards, sensitivity to these exposed hazards, and ability to cope and adapt to climate-related stress. These health impact effects also do not happen in isolation, as people may face multiple threats at the same time or at different stages in their lives that accumulate over their lifetime leading to the detriment of their health. As people are exposed to multiple environmental health threats, the risk an individual has for developing a climate-related

As health economists and researchers, we should develop more evidence on climate change and health outcomes such as forecasting and prediction models to address the gaps and uncertainties.

disease may increase. For example, extreme heat can not only directly result in increased heat-related illness but can facilitate poor air quality leading to other illnesses such as respiratory diseases. Additionally, changes in factors such as an individual's personal habits, living conditions, and access to medical care can influence whether a person is exposed to health threats and whether or not they become ill. Examples of vulnerable groups that may be impacted by climate change include: low-income populations that may not have access to air conditioning in extreme heat, certain occupational groups such as construction workers who are exposed to extreme heat and disease carrying insects, pregnant women who may experience mental health issues and/or low birthweight or preterm birth, people with preexisting medical conditions such as asthma, children particularly those more sensitive to respiratory hazards, people with disabilities who have challenges in preparing and responding to extreme weather events, older adults who are at increased risk of heat-related deaths, and people living in certain locations that may be prone to flooding and hurricanes.

As highlighted in our feature article in this issue, climate change is expected to cause approximately 250,000 additional deaths per year from malnutrition, malaria, diarrhea, and heat stress

according to the World Health Organization. The direct damage cost to health is estimated to be between \$2 billion to \$4 billion a year by 2030.

Looking ahead, we need to work together to address the health impacts of climate change. It starts with raising **awareness** of the issue, as many people are not even aware of the impact on human health due to climate change. **Education** will increase our collective understanding and appreciation of climate change and its impact on health and should be taught to all healthcare professionals early in and continually throughout their careers. These professionals should also be provided with the tools and skills to effectively communicate the health impacts of climate change to patients. **Partnering** with community organizations, including profit and nonprofit organizations, churches, governments, etc to **communicate** to the broader community key messages about health risks associated with climate change and other environmental factors is also important. As health economists and researchers, we should **develop more evidence** on climate change and health outcomes such as forecasting and prediction models to address the gaps and uncertainties. By having more data and evidence, we can make an impact on policy changes for the betterment of society. As individuals, we can all do our part to reduce the effects of climate change by making minor changes to our everyday life, such as saving energy, using cleaner energy, reducing waste, reducing the environmental impact of fuel emissions, conserving water, and addressing disparities in healthcare as part of environmental justice initiatives. By working together, we can improve health outcomes related to climate change and the environment and make a change for a better tomorrow.

As always, I welcome input from our readers. Please feel free to email me at zeba.m.khan@hotmail.com.

Zeba M. Khan, RPh, PhD
Editor-in-Chief, *Value & Outcomes Spotlight*



FROM THE CEO

Why Climate Change Matters to Global Health

Rob Abbott, ISPOR CEO and Executive Director

The end of things happens in two ways: slowly, and not so slowly. The 6000-year experiment that is recorded human history is in danger of collapse—we just haven't accepted it yet. We continue to believe cultural messaging that we can carry on as before and mitigate any negative impacts. This is willful blindness, reinforced by the fact that we have always been able to either redeem our mistakes or walk away from them, to heal the past with the future, never imagining that we would run out of new frontiers, that we would run out of the future.

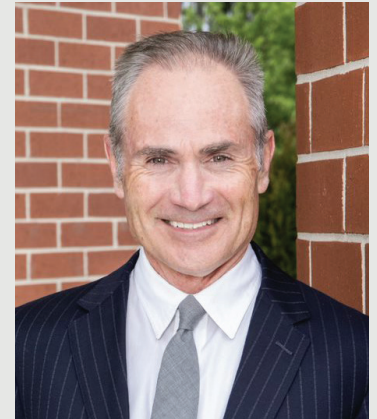
The “collapse” I allude to above is being accelerated by climate change. I am therefore gratified that this special issue of *Value & Outcomes Spotlight* is centered on the topic. I have had the rare privilege of working on 6 continents and so I have also borne witness to the cascading impacts of climate change around the world. While the focus of much reporting on climate change has centered on ecological impacts, it is important to remember that there is ultimately no separation of human life from nature; we do not live at a remove from the manifold changes in the natural world—we are very squarely in the picture. Nowhere is this more evident than in disease management.

The 6000-year experiment that is recorded human history is in danger of collapse—we just haven't accepted it yet.

A recent study of the economics of biodiversity commissioned by the UK Treasury and published in February of 2021 reports that biodiversity is declining faster than at any time in human history. Climate change is an important driver of this decline. Sir Partha Dasgupta, an Emeritus Professor of Economics at Cambridge University and lead author of the study, was blunt in his appraisal of humanity's capacity to live on Earth sustainably:

Our demands far exceed nature's capacity to supply us with the goods and services we all rely on. We would require 1.6 Earths to maintain the world's current living standards. Humanity faces an urgent choice. Continuing down our current path presents extreme risks and uncertainty for our economies. Choosing a

sustainable path will require transformative change, underpinned by levels of ambition, coordination and political will akin to, or even greater than, those of the Marshall Planⁱ.



Released against the backdrop of the COVID-19 pandemic, the study sounded an ominous chord with its warning that this disease could be “just the tip of the iceberg” of pandemic diseases driven by the destruction of nature. As humans take over or change the habitats of wild animals, many species are driven to extinction but those that remain— bats, rodents, and various primates—are far more likely to host dangerous pathogens that can make the jump to humans and ignite disease. Most efforts to prevent the spread of diseases focus on vaccine development, early diagnosis, and containment, but these well-intentioned efforts are akin to treating the symptoms without addressing the underlying cause: the driver of the disease. The discovery and confirmation of monkeypox (a viral disease) in the United Kingdom in May of 2022—the first time this disease had spread outside Central and West Africa—only confirms this point. From mid-May onward, cases of monkeypox were reported around the world, and on July 23rd, the Director-General of the World Health Organization, for the second time in 2 years, declared the outbreak a public health emergency of international concern.

Throughout the second half of 2018, much of California (the most populous state in the United States and the world's 4th largest economy) was on fire, literally—a million acres turned to ash—and yet there was collective denial that climate change, and therefore human behavior, was a contributing factorⁱⁱ. Worse, there was a belief that we can carry on making the same bad choices and mitigate the impacts. This is what psychologists refer to as *cognitive dissonance*, the mental discomfort of a person who simultaneously holds two or more contradictory beliefs. We may believe that the fires consuming large swaths of California are not linked to climate change, but in the face of evidence that suggests this is exactly what is happening, we will

ⁱ The Marshall Plan, named for United States Secretary of State, George C. Marshall (and known officially as the European Recovery Program) was an American initiative passed in 1948 to facilitate the provision of foreign aid to Western Europe. Under the program, the United States transferred over \$13 billion in economic recovery programs to Western European economies after the end of World War II.

ⁱⁱ The summer of 2021 may one day be viewed as a turning point, a moment when the true nature of climate change, the human nature at the heart of it, began to take a firmer hold in our collective consciousness. Both Greenville and Paradise, California were “lost” to wildfires, the towns utterly consumed by wildfires that were beyond human control.

ⁱⁱⁱ In psychology, magical thinking is the belief that one's thoughts can trigger effects in the world or that thinking something is the same as doing it. In psychiatry, magical thinking is a disorder of thought content; it denotes the false belief that one's thoughts, actions, or words will cause or prevent a specific consequence in some way that defies or circumvents commonly understood laws of causality.

find a way to resolve the contradiction to reduce our discomfort. Sadly, too many people are reducing their discomfort by practicing magical thinkingⁱⁱⁱ or retreating into complacency. In a revealing editorial published on February 16, 2019 in *The New York Times*, David Wallace-Wells, author of *The Uninhabitable Earth*, acknowledged as much:

I know the science is true, I know the threat is all encompassing, and I know its effects, should emissions continue unabated, will be terrifying. And yet, when I imagine my life 3 decades from now, or the life of my daughter 5 decades from now, I have to admit that I am not imagining a world on fire but one similar to the one we have now. That is how hard it is to shake complacency. We are all living in delusion, unable to really process the news from science that climate change amounts to an all-encompassing threat. Indeed, a threat the size of life itself.

There is such pathos embedded in the delusion that Wallace-Wells describes. A substantial percentage of the human literati know that if we continue on our present course, we will author our ecological—and by extension, civilizational—doom, and yet we continue. We have burned so much carbon into the atmosphere that CO₂ levels are higher than they have been in 3 million years; each day the extra heat that is trapped near our planet is equivalent to 400,000 Hiroshima bombs. There are

no known technologies that can be deployed at world scale to reverse such warming. It is with this in mind that I welcome an exploration of how climate change affects human health—and perhaps more pointedly, what ISPOR can do to help shape a new direction in the discourse on climate change. It seems clear, for instance, that an increased exploration of the social determinants of health, including climate change, and the

Throughout the second half of 2018, much of California was on fire, literally—a million acres turned to ash—and yet there was collective denial that climate change, and therefore human behavior, was a contributing factor.

need to appropriately value these is something our society could undertake. Equally, examining the evidence and offering commentary on the value of interventions that address the spread of disease from animals to humans may be an important area of future discussion. I welcome input from our members on where and how they believe ISPOR can contribute to maximum impact on the human health implications of climate change.

ISPOR SPEAKS

Reimagining a New Strategic Vision for ISPOR

Brian O'Rourke, PharmD, President, Brian O'Rourke Health Care Consulting, Inc, Ottawa, Canada; and ISPOR President (2023-2024), Lawrenceville, NJ, USA

I am honored to serve as your President. Thank you for trusting me with this considerable responsibility. The future is exciting—for our Society, for our careers as health economics and outcomes research (HEOR) professionals, and for the impact that HEOR continues to have on healthcare globally.

ISPOR's global reach is wide, representing members from 110 countries including 19,000 individual and chapter members with 84 regional chapters and 143 student chapters. Members involved in our student chapters represent some of the best and brightest scientists, clinicians, and health economists—meaning our future is secure.

It is an incredibly exciting time for ISPOR. As the pandemic subsided, we gathered again in person in Boston, MA, USA this May with more than 4500 participants representing stakeholders from academia, pharmaceutical and medical device companies, consultancies, governments, payers, health technology assessment agencies, patient organizations, and others. We are back!

It is also a time of enormous opportunity for ISPOR and the broader HEOR community as we promote early and equitable access to innovative and affordable pharmaceuticals and health technologies—all with the goal of improving global health.

We recently welcomed Robert Abbott to the ISPOR family as our new CEO and Executive Director. As someone who was involved in the CEO selection, I am confident Rob will bring his passion for science, his knowledge and experience, his creativity, and his exceptional leadership skills to propel ISPOR successfully into the future.

It is also a time of enormous opportunity for ISPOR and the broader HEOR community as we support implementation of complex legislation; as we strive to better understand the role of digital health solutions; as we continue to advance our HEOR methods and processes; and as we promote early and equitable access to innovative and affordable pharmaceuticals and health technologies—all with the goal of improving global health.



Reimagining HEOR will take a combination of evolutionary and revolutionary thinking and it will require increased collaboration and harmonization of our methods.

Over the coming months, the ISPOR Board of Directors will work with Rob Abbott and his incredible ISPOR staff to reimagine a new strategic vision for ISPOR. We will consult broadly and leverage past learnings, while capitalizing on new thinking. For example, the "Amplify HEOR" initiative that was recently launched will help to spread and scale the voice of HEOR with decision makers at all levels. We will also continue to elevate the science and practice of HEOR and look for ways to build health equity principles into everything we do.

Reimagining HEOR will take a combination of evolutionary and revolutionary thinking and will require increased collaboration and harmonization of our methods. I look forward to sharing details on our emerging strategic vision as we review, evaluate, and rewrite our strategic plan. Very exciting times are ahead!

HEOR NEWS

1 AWS Launches New Healthcare-Focused Services, Powered by Generative AI (TechCrunch)

Amazon has expanded its range of health-focused apps and services with the launch of HealthScribe, a platform that offers artificial intelligence (AI) tools to help clinicians transcribe and analyze their conversations with patients. The platform creates transcripts, extracts details, and creates summaries from doctor-patient discussions that can be entered into an electronic health record system.

[Read more](#)

2 Research Method Reveals Health Impacts of Heat and Air Quality (Open Access Government)

Researchers from the University of Waterloo and Toronto Metropolitan University collaborated on an innovative data collection method to understand the implications of rising temperatures and declining air quality. The study published in *Environmental Research* revealed that even moderate temperature increases, such as nighttime temperatures starting at 18.4° Celsius, can trigger a surge in hospital visits and fatalities, especially among older adults and individuals with cardiorespiratory conditions.

[Read more](#)

3 More Evidence Needed to Recommend Type 2 Diabetes Treatment Tirzepatide (NICE)

NICE issued a draft guidance against the recommendation of Eli Lilly's Mounjaro (tirzepatide) injection for the treatment of type 2 diabetes, with experts saying while clinical trial evidence showed that any dose of the once-weekly injected drug resulted in better glucose control and lower weight compared with semaglutide or insulin therapy, they want Lilly to provide more data to address the uncertainties in the clinical evidence when compared to all relevant alternative treatments.

[Read more](#)

4 Early OxyContin Marketing Linked to Long-Term Spread of Infectious Diseases Associated With Injection Drug Use (Health Affairs)

A study evaluating the effects of exposure to initial OxyContin marketing on the long-term trajectories of injection drug use-related outcomes in the United States found that OxyContin marketing decisions from the mid-1990s increased viral and bacterial complications of injection drug use and illicit opioid-related overdose deaths 25 years later.

[Read more](#)

5 WHO Endorses Landmark Public Health Decisions on Essential Medicines for Multiple Sclerosis (World Health Organization)

The new editions of the Model Lists of Essential Medicines (EML) now include cladribine, glatiramer acetate, and rituximab—3 medicines that can delay or slow the progression of multiple

sclerosis (MS). The inclusion of these drugs is aimed at facilitating improved access to treatment for people living with MS around the world.

[Read more](#)

6 The Rise and Fall of Underemployment: Implications for Workers' Health (Health Affairs)

Underemployment—particularly in the form of working part-time involuntarily rather than voluntarily—is associated with reduced self-reported general health and antecedents to it, such as greater work stress, work-life imbalance, and financial insecurity.

[Read more](#)

7 Africa CDC, WHO, and RKI Launch a Health Security Partnership to Strengthen Disease Surveillance in Africa (World Health Organization)

The intent of the partnership, which will initially be launched in The Gambia, Mali, Morocco, Namibia, Tunisia, and South Africa, is to strengthen Africa's health security capabilities in the areas of biosecurity, integrated disease surveillance, event-based surveillance, genomic surveillance, and epidemic intelligence.

[Read more](#)

8 A New Vision for US Healthcare (MIT News)

In her new book, *We've Got You Covered: Rebooting American Health Care*, MIT Professor Amy Finkelstein and her coauthor, Liran Einav, posit that the solution to address the United States' patchwork health insurance system is to provide free, basic healthcare for everyone, with automatic enrollment, no charges for basic care, and no losing insurance with a job switch or climbing above the poverty line.

[Read more](#)

9 Institute for Clinical and Economic Review Announces Leadership Transition (ICER)

Steven Pearson, MD is stepping down from the organization after 17 years. Sarah K. Emond, MPP, most recently executive Vice President and Chief Operating Officer of ICER, is being promoted to serve as president-elect. Following the transition, Pearson will remain at ICER as an advisor through the end of 2024.

[Read more](#)

10 How Healthcare May Be Affected by the High Court's Affirmative Action Ruling

US doctors are concerned that the Supreme Court's affirmative action will have far-reaching effects not only on the diversity of doctors and other care providers in training but ultimately also on patient care, with an analysis of bans in 6 states finding that medical school enrollment of students of color who were members of underrepresented groups fell roughly 17% after the bans were instituted.

[Read more](#)

FROM THE REGIONS

Making an Impact and Advancing the Science in the Region: ISPOR's 2023 Outstanding Chapter Award Winners



SMALL CHAPTER AWARDEE

Daniela Paredes, RM, MPH
 Instituto de Salud Pública ISPAB
 Universidad Andrés Bello
 Health Economics and Reimbursement
 Manager, Medtronic SouthLatam

ISPOR Chile Chapter President

Could you describe a particularly successful event or initiative organized by your Chapter and its impact on the HEOR community?

ISPOR Chile co-organized the 6th HEOR Workshop for payers to ensure an up-to-date and evidence-based discussion. The workshop also aimed to address the concerns of key opinion leaders and decision makers, such as national payers, superintendency, ministry of health leaders, and key public providers. The 2-day workshop discussed the implementation of Diagnosis-Related Groups (DRG) payment reform, barriers for undertaking risk-sharing agreements, and the urgent need to move toward a structured and formal health technology assessment (HTA). In this regard, ISPOR members have also actively participated in the national discussion to enact an HTA law.

The ISPOR Chapter also facilitated the DRG implementation in Chile by disseminating best practices, providing economic analysis derived from coding, and following-up add-on payment funds. As an example of this effort, ISPOR Chile co-organized a nationwide online seminar to revise the DRG's implementation from a payment mechanism perspective in collaboration with an academic partner and medical devices industry, with a reach of 400+ attendees and more than 3000 visits from public providers.

As an ISPOR chapter outstanding awardee, what initiatives or projects do you plan to pursue in the future to further advance the HEOR science?

Aligned with our strategy to promote HEOR instruments at the providers' level beyond academia, we must recognize local efforts using economic tools applied to day-to-day healthcare management.

As an innovation, we are planning the first National Best HEOR Practices Ranking. The Ranking will award diverse initiatives carried out by providers, industry, patients, and other stakeholders, in the areas of HTA, DRGs, and economic evaluations, among others.

How have you fostered inclusivity and diversity within your Chapter to ensure representation and equitable opportunities for all members?

The composition of our Board of Directors and Presidents is diverse and ensures the representation of the stakeholders in the healthcare system. Our members come from the pharmaceutical and medical devices industry, academia, and public and private providers. This composition also responds to a local strategy to foster the HEOR discipline beyond academia and to be able to export the benefits of HEOR to more stakeholders in the healthcare environment. In our vision, both public and private systems contribute to the healthcare sector and their interaction is a key component to our success.

Furthermore, the Chilean Chapter has promoted incorporating more female talent, with 4 members in the positions of President (Daniela Paredes), President-Elect (Paula Zamorano), Secretary (Carla Campaña), and Director (Magda Gutiérrez).



MEDIUM CHAPTER AWARDEE

Marie-Therese Estephan Sawaya, MD
 Head of Public Affairs and Market Access
 – Levant and Iraq

ISPOR Lebanon Chapter President

As an ISPOR chapter outstanding awardee, what initiatives or projects do you plan to pursue in the future to further advance the HEOR science?

Lebanon is going through the most significant economic and financial crisis of its history. Our healthcare system and governmental bodies are in most need to accelerate and advance HEOR science to enable cost optimization while maintaining patients' access to appropriate care management. Our chapter remains committed supporting authorities in advancing HEOR knowledge through education, collaboration, consultation, and partnership. Moreover, we wish to integrate the patient voice in the decision-making process by including patient advocacy groups in our chapter and providing them with an opportunity to be more visible, coordinated, and further exposed to the science of the HEOR assessment. Last but not least, we are committed to developing young generations of academia talents on the HEOR science through the creation of the student chapter and supporting the inclusivity and diversity of new members.

Could you describe a particularly successful event or initiative organized by your chapter and its impact on the HEOR community?

The local ISPOR chapter has been conducting annual educational meetings on different HEOR topics. Our 2022 event, "Moving Towards Sustainable Health System in Lebanon," was inspired by the local emerging crisis and the need to provide decision makers with a framework and forum to exchange learnings from global or regional experiences. The meeting discussed the economic depression and funding landscape challenges to be a rare window of opportunity for the health system in Lebanon. We listened to the local experiences and the challenges faced by the Minister of Health and former General Directorate of the Ministry. Relevant learnings were shared from global and regional experiences. A concrete example on the transformation of the healthcare system in Turkey was exposed by the former Minister of Health in Turkey, Mr. Recep Akdag, with extremely insightful discussions and exchanges. A position paper was submitted later by the ISPOR board to the Minister of Health supporting the transformation strategy and implementation journey. Finally, the ISPOR local chapter was pleased to sponsor and support the thorough educational/research project of Dr Karam and her team to develop pharmacoeconomic evaluation guidelines in Lebanon.

How have you fostered inclusivity and diversity within your chapter to ensure representation and equitable opportunities for all members?

Inclusivity and diversity are cornerstones of our values. Member selection in the chapter ensures an equitable mix of private and public as well as academia, governmental, pharmaceutical, payers, and consultants. This was further emphasized during our general assembly elections in 2022, whereby by majority voting we opted to have the new board of ISPOR voted at 50% from academia and public payers versus 50% from the private and pharmaceutical industries, aiming to maintain a balance and equal opportunity to all point of views to be well-represented and addressed. This balance will be further enforced in the bylaws as we strongly believe that the sustainability of the local chapter will be based on an equitable balance among different healthcare partners and inclusivity of all, driven by a common goal and science to enhance patients' outcomes and optimize the value offering across all sectors of the healthcare value chain.



LARGE CHAPTER AWARDEE

Pier Luigi Canonico, MD
University of Piemonte Orientale

ISPOR Italy Rome Chapter President

As an ISPOR chapter outstanding awardee, what initiatives or projects do you plan to pursue in the future to further advance the HEOR science?

Our chapter is working hard on future initiatives and projects focused on HEOR science. First of all, we are working to reinforce the connection with young members by offering free

membership for those under 35 years of age and involving them in new initiatives and programs together with senior HTA professionals for mentoring and coordination.

In addition, 5 projects are ongoing involving more than 60-chapter members (young and senior) representatives from government institutions, academia, consulting agencies and manufacturers. The projects investigate: (1) costing of resources in health economics in Italy, (2) use of real-world Evidence for pricing and reimbursement negotiations, (3) identification of standardized cost parameters for economic models from an Italian perspective, (4) use and future perspective of early access programs in Italy, and (5) working on the second edition of the EXPLORARE Project (Rare Disease Access Deep-dive).

During 2023, the ISPOR Italy Rome Chapter also planned the first training course (Bologna – Naples) to improve the practice of budget impact analysis and cost-effectiveness analysis.

Could you describe a particularly successful event or initiative organized by your chapter and its impact on the HEOR community?

Our Chapter supports 2 main events every year. The first one is the national conference that in 2022 was held in Rome (8th edition), involving more than 180 in-person participants from national and regional authorities, healthcare organizations, academic institutions, consulting agencies, and manufacturers of drugs and medical devices. It was held as a plenary meeting and hosted more than 5 sessions about the past and future projects promoted by the Chapter. The second main event is the Congress of ISPOR Rome for Future Group. The Chapter brought together all young ISPOR members under the age of 35, where the Congress served as a multidisciplinary network for new professionals in HEOR. The first event was held in 2022, involved more than 80 young members from national and regional authorities, healthcare organizations, academic institutions, consulting societies, universities, and pharmaceutical companies. The Congress was held as a plenary meeting, with an opening Lectio Magistralis followed by 3 sessions and was entirely organized by ISPOR young members. Both events will be repeated in 2023 and will facilitate networking among members and increase the Chapter's visibility.

How have you fostered inclusivity and diversity within your chapter to ensure representation and equitable opportunities for all members?

As already discussed, one of the main aims of our chapter was to involve young people and maximize collaboration to ensure representation and equitable opportunities. Our members increased from 146 members in 2020 to 407 in 2023. Of these, 145 (36%) are under the age of 35 years and 54% are female. All the stakeholders are equally invited to participate in our projects and we encourage individuals from different backgrounds and identities to take on leadership roles and participate in the decision-making processes.

RESEARCH ROUNDUP

Section Editor: **Aakash Bipin Gandhi, BPharm, PhD**, Methodologist Expert, RWD, Sanofi, Cambridge, MA, USA

Climate Change and Health: Three Grand Challenges.

Campbell-Lendrum D, Neville T, Schweizer C, Neira M. *Nat Med*. 2023;29(7):1631-1638.

Summary

The article by Campbell-Lendrum et al summarizes 3 key directions that society can undertake to mitigate the impact of climate change on health. First, actions that have a direct effect on reducing carbon emissions that can, in turn, improve health should be promoted. Second, future health systems should be built in a manner that ensures climate resilience and low carbon emission. Third, public health measures and interventions should be in place to mitigate and protect individuals from the health-related climate risks. Overall, the article highlights the role that the health community can play in providing leadership and advocacy to guide the transformation of health systems into climate-resilient and low-carbon emitting settings. Further, efforts by healthcare community can serve as a model of excellence for other sectors whose actions may also negatively influence climate change.

Relevance

The negative impacts of climate change on public health continue to increase at a rapid pace. Major societal changes that have associated financial implications are required to mitigate the adverse consequences of climate change on public health. However, the financial implications are outweighed by the resulting positive health benefits and long-term economic gains through the creation of a suitable environment where humans can continue to thrive.

Circular Economy Strategies for Combating Climate Change and Other Environmental Issues.

Yang M, Chen L, Wang J, et al. *Environ Chem Lett*. 2023;21(1): 55-80.

Summary

The article by Yang et al provides an overview of various circular economy strategies that help reduce carbon emissions keeping in mind aspects such as waste management, climate change, energy, air and water quality, land use, food production, and lifecycle assessment. In their findings, the authors observed that there are increasing challenges associated with the use of bio-based materials especially in terms of land use and cover. Further, the implementation of carbon removing technologies is extremely expensive ranging from \$100 to \$1200 per ton of carbon dioxide. Consequently, only a small number of companies have pledged to climate change goals as part of their

future strategy and growth. In summary, the authors state that while circular economies can be introduced in various sectors, a high degree of system optimization is required to guide its implementation. To this effect, the authors propose a theoretical foundation which can guide the implementation of cost-effective routes that result in circular economies in industrial, agricultural, and commercial fields.

Relevance

With an ever-increasing need for global industrialization and resultant dependence on nonrenewable energy sources, there has been a substantial production of solid waste and pollution which has adversely affected the climate. Implementation of circular economies are projected to help achieve carbon neutrality through decreasing carbon emissions by 45% by 2030.

Thinking Health-Related Behaviors in a Climate Change Context: A Narrative Review.

Chevance G, Fresán U, Hekler E, et al. *Ann Behav Med*. 2023;57(3):193-204.

Summary

The objective of this article was to identify the bidirectional relationship between climate change and health-related behaviors. Further, based on the findings, the authors also propose key actions that can be followed by the behavioral medicine community to mitigate the adverse effects of climate change on health behaviors. Specifically, the authors investigated 2 primary concerns. First, the impact of climate change events such as increasing temperatures, air pollution levels, and rising sea-levels on health-related behaviors such as eating, physical activity, sleep, substance abuse, and preventive care. Second, the authors also studied the inverse relationship where they explored the positive and negative impact of health-related behaviors on climate change.

Relevance

Past evidence has displayed that climate change substantially increases the current and future risks of unhealthy behaviors. Health behaviors that accelerate climate change may be considered as unhealthy behaviors and need to be addressed with suitable interventions in a timely manner to mitigate any adverse consequences.

Note from the Section Editor: Views, thoughts, and opinions expressed in this section are my own and not those of any organization, committee, group, or individual that I am affiliated with.

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September 20 / 10:00AM – 11:00AM EDT

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- Introduce the foundational data available in the US to conduct DCEA.
- Learn how to gather data for a DCEA and develop a DCEA in the US setting through a case study in Alzheimer's disease.

September 26 / 10:00AM – 11:00AM EDT

How to Drive Value in the Digital Transformation Era?

What you will learn in this webinar:

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Growing the Body of Evidence for **Climate Change's Impact on Health**

By Christiane Truelove

Type the words “climate change” into Google and hundreds of news headlines pop up. On July 27th, the United Nations warned that the “era of global boiling” has started, with UN Secretary-General António Guterres saying that “short of a mini-Ice Age,” July 2023 would likely “shatter records across the board.”

“Climate change is here. It is terrifying. And it is just the beginning,” the UN chief said in a statement, warning of consequences such as “children swept away by monsoon rains, families running from the flames, (and) workers collapsing in scorching heat.” Scientists from the World Meteorological Organization (WMO) and the European Commission’s Copernicus Climate Change Service stated that new data showed that so far, July has seen the hottest 3-week period ever recorded and the 3 hottest days on record.

The possibility that the world will only get warmer is real, as ocean temperatures are at their highest-ever recorded levels for this time of year. According to WMO’s Director of Climate Services Chris Hewitt, 2015 to 2022 saw the 8 warmest years on record, based on a 173-year dataset. The La Niña sea-cooling phenomenon towards the end of that period in the Pacific region reined in global average temperatures slightly, Hewitt says, but now has been replaced by the sea-warming El Niño effect, which is beginning to heat up in the tropical Pacific and brings the “almost certain likelihood that 1 of the next 5 years will be the warmest on record.”

“The climate crisis threatens to undo the last 50 years of progress in development, global health, and poverty reduction, and to further widen existing health inequalities between and within populations.”

– World Health Organization

What does this mean for human health? According to the World Health Organization’s (WHO) fact sheet on climate change and health from October 2021, between 2030 and 2050, climate change is expected to cause approximately 250,000 additional deaths per year from malnutrition, malaria, diarrhea, and heat stress. The direct damage costs to health, excluding costs in health-determining sectors such as agriculture and water and sanitation, is estimated to be between \$2 billion to \$4 billion a year by 2030. And areas with weak health infrastructure — mostly in developing countries—will be the least able to cope without assistance to prepare and respond.

“The climate crisis threatens to undo the last 50 years of progress in development, global health, and poverty reduction, and to further widen existing health inequalities between and within populations,” WHO says. “It severely jeopardizes the realization of universal health coverage (UHC) in various ways—by compounding the existing burden of disease and by exacerbating existing barriers to accessing health services, often at the times when they are most needed. Over 930 million people (approximately 12% of the world’s population) spend at least 10% of their household budget to pay for healthcare. With the poorest people largely uninsured, health shocks and stresses already push nearly 100 million people into poverty every year, with the impacts of climate change worsening this trend.”

Linking Health Conditions to Environment

There are a growing number of studies generating data to tie environmental conditions such as excessive heat to an adverse impact on human health, especially in regions that have not been subject to such heat before. A study by Sahani et al in the May 2022 issue of *Sustainable Cities and Society* attempted to correlate daily maximum temperature and mortality using the distributed lag non-linear model (DLNM) in 2 areas of the United Kingdom, Southeast England and Aberdeenshire. The goal of the study was to examine the effect of heat on those living in bucolic areas, since earlier studies had focused on more urban, developed areas. In their modeling, researchers found heat waves are making more people in rural areas of England severely ill today than they were in the 1980s.

“Heat waves’ impact is well known to be more pronounced in urban and built areas but how the risk varies in semi-urban, suburban, and rural areas is not vastly explored,” these researchers say. “Across the globe, hot days are getting hotter and more frequent, while experiencing fewer cold days. As a result, heat waves are becoming a more common challenge in small cities, towns, and in the landscape areas too.”

On July 27, the University of Waterloo announced that researchers from there and Toronto Metropolitan University in Canada have refined and expanded a method of data collection to assess the health impacts of extreme heat. The study, “Heat and Air Quality Related Cause-Based Elderly Mortalities and Emergency Visits,” appears in the journal *Environmental Research*. These researchers discovered that even moderate temperature increases, for example, nighttime temperatures starting at 18.4° Celsius, can lead to increased hospital visits and death for older adults and those with cardiorespiratory conditions.

Researchers say the new method will help municipalities make a strong case for choosing which mitigation and adaptation measures to pursue to effectively respond to climate changes. The options could include planting more trees for shade, investing in emergency warning programs, or planning to have more staff available to run ambulances and support hospitals and long-term care homes.

“Communication is very important, especially in less well-educated or disadvantaged populations, climate change isn’t something that’s on their radar.”

– Jun Wu, PhD

“Heat waves cause more deaths in Canada than any other climate hazard,” stated Mohamed Dardir, PhD, MSc, postdoctoral researcher in the School of Environment, Enterprise and Development at the University of Waterloo. “We are getting better at being proactive and planning for climate emergencies, but we still aren’t responding to temperatures

in the same way we respond to big weather events, such as floods and fires.”

The study analyzed the spring and summer in Mississauga and Brampton, Ontario. By integrating data on air quality and heat, the researchers achieved the most detailed picture of the short-term health risks impacting the vulnerable population on a municipal level. The findings confirm there was an increase in the total deaths and hospital visits in these areas with the highest impact happening on the day of the heat and poor air quality and extending 2 days after these events.

In the future, the team plans to expand its analysis to include more environmental hazards, such as storms and floods, and factors including ambulatory calls across municipalities in Ontario and other provinces. The researchers say that this work will help civil society and policy makers grasp the magnitude of these climate events and equip decision makers to justify investments in climate resiliency.

Jun Wu, PhD is codirector of the UCI Center for Environmental Health Disparities Research at the University of California at Irvine that focuses on environmental health, including exposure assessment of various environmental agents, health impacts of environmental exposures, and environmental justice/environmental health disparity. In 2022, a team of researchers including Wu received a \$3.2 million R01 grant from the National Institute of Aging to study the impact of climate change on life expectancy in a multi-ethnic population. The goal of the study is understanding the contribution of long-term extreme heat and wildfire smoke on life expectancy.

“Our estimates are that roughly 1400 people a year, adults 20 years of age and older, are dying related to extreme heat.”

– Sameed Khatana, PhD

Wu has also examined the impact of exposure to green space on maternal postpartum depression. The [study](#), published online in the journal *The Lancet Regional Health – Americas*, determined that exposure to green space and tree coverage was associated with a decreased risk of postpartum depression among mothers, and suggests that researchers, city planners, and public health professionals should work together to develop policies and interventions that increase the amount of tree coverage to create a beneficial environment for community members—especially new mothers who are at risk of postpartum depression.

In her research, Wu says she is increasingly interested in environmental health and how research can help improve public health, particularly through actual practical interventions with communities.

“Throughout the years of research, we have been focusing on the impacts of air pollution,” she says. “We found a number of health risks and maternal health pregnancy complications from air pollution, such as gestational diabetes, preterm birth, low birth weight, etc.” Wu and her colleagues also have found that extreme heat can increase the risk of preterm birth.

The impetus for the wildfires and health impacts research is while there is existing research linking wildfires to adverse effects on health, it is difficult to distinguish whether the impact is from the smoke or just the stress of the wildfire event, especially for people living nearby. Wu and her colleagues are building models to estimate wildfire-specific air pollution and then further examine the health impact using data in California.

“A lot of our patients aren’t really aware that extreme heat is a health issue. I would say many healthcare providers probably aren’t aware of this issue either.”

– Sameed Khatana, PhD

Wu says clinicians and others engaged in healthcare outcomes research, who are mostly focused on the health side or disease side of the problem, may not be well educated on climate change’s impact on health. Although there have been increasingly more severe, higher frequency extreme climate events happening in recent years, “there’s always a lag between what you start to be aware of and how much you really know,” she says.

Education about climate change and its impact on health should be established for medical students, doctors, and nurses, and healthcare workers should be taught about how to share this information with patients, Wu says. For example, when hospital patients are discharged, their notes should include explanations of the risks of wildfires and heat waves, and patients should be more aware of their actual risk and understand how they can reduce risk to their health.

Wu says the healthcare sector should work closely with community organizations to deliver these messages as well as to set up mobile clinics. Additionally, because there is more community trust for physicians than government, physicians can be very helpful in delivering information about the health risks of environmental factors.

“Communication is very important, especially in less well-educated or disadvantaged populations,” Wu says. “Those subpopulations are usually at a higher risk for climate change” especially since they have greater worries such as job security and high costs of housing and food—“climate change isn’t something that’s on their radar.”

A Clinician’s View of Environmental Impacts

Sameed Khatana, PhD, of the University of Pennsylvania is a practicing cardiologist at the Philadelphia Veterans Affairs

Medical Center who has done research on the impact of extreme heat on patient health. “It’s been known for some time that the effect of extreme heat on individual’s health is related to their preexisting medical conditions, and for people who already have things like heart disease and risk factors for heart disease like diabetes, they might be at some of the highest risk for adverse health effects related to extreme heat,” Khatana says.

The work of Khatana and his colleagues—“[Association of Extreme Heat With All-Cause Mortality in the Contiguous US, 2008-2017](#),” published in *JAMA Network Open* in May 2022, and “[Association of Extreme Heat and Cardiovascular Mortality in the United States: A County-Level Longitudinal Analysis From 2008 to 2017](#),” published in *Circulation* in June 2022—explores the burden of extreme heat-related deaths. In looking at both all-cause mortality and then cardiovascular mortality, Khatana and his colleagues found that extreme heat was associated with higher levels of mortality, both for all-cause and cardiovascular disease.

“There are a lot of data out there, and scientists need to be cautious about using it without understanding the proper context of what is the source of these data and how best to apply it.”

– Sameed Khatana, PhD

“Our estimates are that roughly 1400 people a year, adults 20 years of age and older, are dying related to extreme heat, with about half of these deaths associated with cardiovascular disease specifically,” Khatana says.

Khatana observes that in comparing all studies looking at the health impact of heat, it is difficult to see what the exact burden is because the definition of extreme heat varies from study to study and different regulatory bodies have different definitions of extreme heat. “But the bottom line is that that people are dying due to this issue,” he says.

He and his colleagues also wanted to determine which populations are particularly impacted by extreme heat. “We found that older individuals are the ones that were more likely to be affected by extreme heat exposure. Then looking at race and ethnicity subgroups, we found that non-Hispanic Black adults had a disproportionately greater increase in mortality when exposed to extreme heat compared to non-Hispanic White adults,” Khatana says, probably due to differences both in the burden of preexisting medical conditions and differences in the lived environment.

The researchers also found some regional differences in the burden of extreme heat-related deaths. In particular, they determined that in areas that traditionally have fewer extreme heat days, when extreme heat does occur, people had a disproportionately greater increase in cardiovascular mortality.

This suggests, Khatana says, areas such as the Northeast or the Mid-Atlantic might be less well prepared for extreme heat when it does occur. “This may be due to lower access to air conditioning or people culturally not used to thinking of heat as being a health issue.”

Like Wu, Khatana believes that in terms of next steps, providers and researchers need to be thinking about work around awareness. “A lot of our patients aren’t really aware that extreme heat is a health issue,” Khatana says. “I would say many healthcare providers probably aren’t aware of this issue either. I think it’s becoming more and more notable, something that people are talking about a lot more in the past couple of years, so I’m assuming awareness will increase.”

The problem is many people, policy makers included, still think of extreme heat as more of a nuisance than a health issue. This means researchers should be advocating for patients, Khatana says, adding that the people who suffer health impacts from extreme heat are usually some of the most marginalized people in society—the homeless and people who are socially isolated. “Many of these people might not be able to be able to advocate for themselves, and I think they rely on researchers and healthcare workers to speak up for them.”

Khatana says extreme heat is not the only health impact of climate change that researchers need to look at. “It causes floods, it causes crop failures, it causes mass migration,” he says. Because of this, researchers need to start thinking about how these different impacts of climate change subsequently impact human health. “I think any true understanding will need to account for all of these different factors.”

While the federal government is trying to put additional policies into place to lower the greenhouse effect, “the health impacts are already here,” Khatana says. “So, now our society and our government need to start thinking about mitigation and how we can lessen the impact of extreme heat as well as other extreme weather conditions that occur due to climate change.”

Because climate change impacts virtually every aspect of society, any research on climate-related health impacts requires a multidisciplinary approach, Khatana states. “If an economist is using satellite data that is mapping either temperature or humidity, it perhaps makes sense to be working with researchers in those fields to really understand where the data are coming from, what the limitations of the data are, and how would it best be applicable for the question that the researcher is trying to answer,” he says. “There are a lot of data out there, and scientists need to be cautious about using it without understanding the proper context of what is the source of these data and how best to apply it. Obviously, people in the climate science community have been working on this for decades. And now researchers such as health services researchers like myself, perhaps health economists in the near future, are going to start working on these issues. But I think it’s good to come from a position of humility and to think really deeply about having a multidisciplinary approach to research.”

By the Numbers: Global Threats from Climate Change

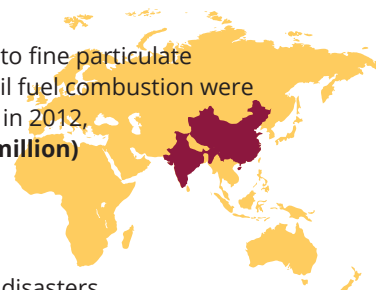
Section Editor: The ISPOR Student Network

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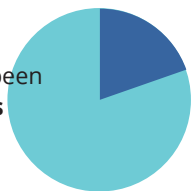
Mother Nature's Hot Flash: Climate Change Effects Around the World

3x Natural disasters have tripled since 1960, resulting in more than 60,000 deaths annually, projected to increase to at least 250,000 deaths annually by 2030.

Global deaths attributed to fine particulate matter (PM2.5) from fossil fuel combustion were estimated at 10.2 million in 2012, with 62% in China (3.9 million) and India (2.5 million).

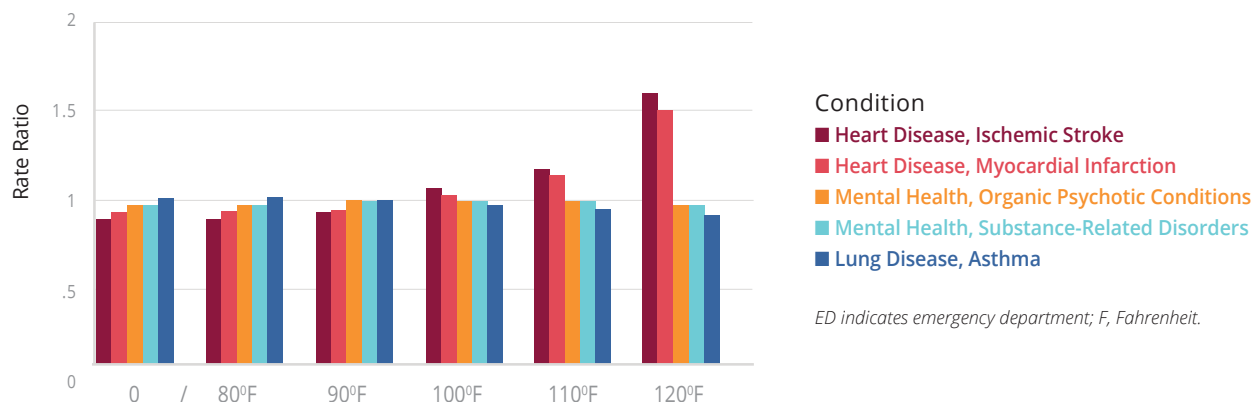


Air pollution in Ukraine has been linked to 21% of all illnesses affecting women & children.

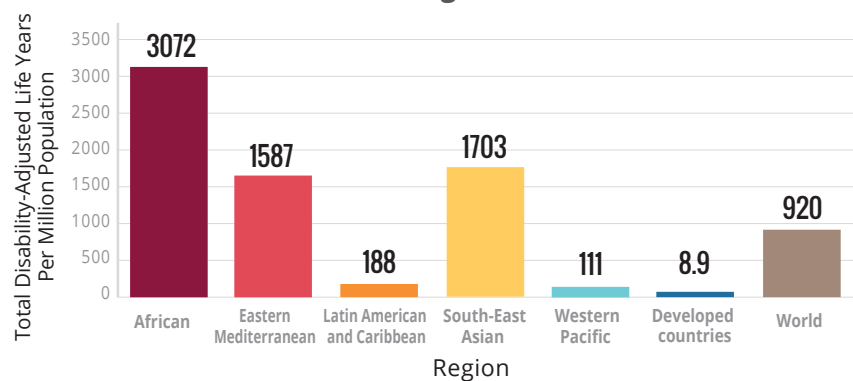


4x Death rates from disasters are four-fold higher in under-resourced countries.

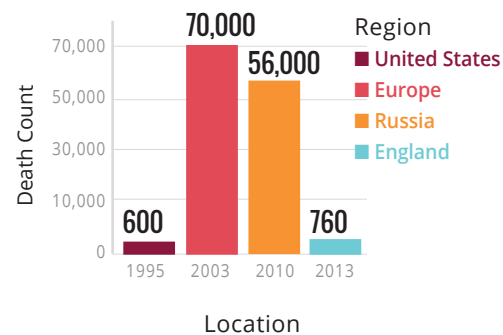
The Impact of Increasing Heat Index on US Patients With Different Disease States and Illnesses: Heat Index and Associated Rate Ratios for ED visits



Global Burden of Climate Change



Historical Heat Waves and Associated Death Burden



Study to Investigate the Adoption of Digital Media by Global Payer Audiences in Their Assessment of Evidence

Sue O'Leary, BSc Pharmacy, Jenny Blackham, MPH, George Miles, BSc, and Michelle Collins, BA; Prime Global, Knutsford, England, United Kingdom

Digital media presents a valuable enhancement to traditional payer communications and can be used to demonstrate differentiation and value for products.

Traditional publications for evidence exchange are still considered a key vehicle by payers. There is a level of apprehension to fully adopt digital media.

As payer audiences look to adopt digital resources to engage with evidence, a multichannel approach will ensure optimum scientific exchange with this evolving stakeholder group.

Background

The healthcare industry has seen a significant increase in the development of new technologies aimed at providing targeted therapies for specific patient populations. For instance, in just 1 year, there was a 47% increase in global research and development (R&D) products for gene therapy and 78% growth in R&D products for cell therapy.¹

This quick pace in new technology advancement has presented a challenge for payers in understanding the value of such interventions. To address this challenge, the industry has been using a combination of traditional channels (publications and PowerPoint) and novel digital media (podcasts and videos)

We have also seen a shift in the adoption of communication channels, moving from traditional channels only, to increasing engagement with emerging digital communication platforms, including social media networks.

to explain and demonstrate how new science is addressing an unmet need. When the scientific foundation of a new complex mechanism of action is articulated in a compelling and informative way in publications and beyond, it builds the fundamental knowledge needed to be able to digest the product value story, which is essential for obtaining optimal market access. Alongside these therapeutic and diagnostic developments, we have also seen a shift in the adoption of communication channels, moving from traditional channels only, such as publications and evidence dossiers, to increasing engagement with emerging digital communication platforms, including social media networks.

Previously, digital channels have not been considered typical for value and evidence communication exchange between market access and health economics and outcomes research (HEOR) teams, payers, policy makers, and health technology assessment (HTA) bodies. However, the restrictions on traditional interaction surrounding the COVID-19 pandemic accelerated the adoption rates of these digital channels as people sought virtual alternatives to review evidence. This shift in how scientific value is now being exchanged among various stakeholders is creating a new window of opportunity for innovative digital engagement.

Our study sought to evaluate the openness of payer audiences to receiving information via digital and social media compared with traditional methods, and their future preferences for receiving communications.

Methods

Two third-party payer recruiters with networks of more than 100 participants were used to recruit payers across Europe and the United States. The payers were able to enroll into the study if an opening was available based on predefined payer types/roles: **United States** (types: national, regional, and integrated delivery network; roles: pharmacy and medical directors) and **Europe** (national, regional, and local). The respondents in the study were determined by a first-to-respond method. The payers were asked to complete an online survey via the third-party platforms made up of 10 questions focused on digital media, social media, and the types of evidence and dissemination channels that they used at the time of the survey and expected to use in the future. The question formats were a mixture of open-ended and multiple-choice answers.

Between June and September 2021, 40 payer decision makers across Europe and the United States took part in the survey. Twenty respondents were based in Europe, representing national, regional, and local payers across Germany, Italy,

and the United Kingdom, and 20 were from the United States (10 medical directors and 10 pharmacy directors) (Figure 1).

Summary of Results

In Europe and the United States, 80% of payer respondents were comfortable using digital media to gather information/data for professional reasons (Figure 2). Half of payer respondents in Europe indicated they used digital media more frequently since the onset of the COVID-19 pandemic, compared with a 20% increase reported by US payer respondents, who indicated that usage was already high (Figures 3 and Figure 4).

Payers received a variety of different information from pharmaceutical companies in 2021, most commonly through a combination of traditional and digital channels (Figures 5 and 6), as opposed to one channel alone, and payers considered podcasts and short videos effective and informative resources in preparing for future decision making (Figure 7).

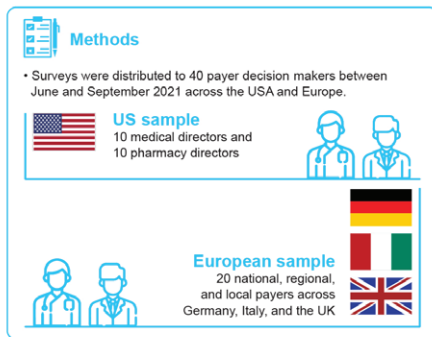
When looking at channels for future communication, traditional publications continued to be regarded as a priority (ranked in the top 3) for 72% of respondents. In addition, there was interest in a range of alternative media, including short videos (54%), PowerPoint

decks (54%), interactive PDFs (44%)—which incorporate different types of media content, such as links, audio and video files, images, clickable buttons, and fillable forms—and podcasts (28%; Figure 8).

Of the social media platforms currently available, LinkedIn was ranked the highest information resource used by payers for professional purposes (Figure 9). Social media platforms ranked included Instagram, YouTube, Facebook, Twitter, and LinkedIn.

We investigated whether digital media was more suitable for specific types of information and our survey found

Figure 1. Overview of research methods



UK indicates United Kingdom; USA, United States of America; US, United States.

Figure 2. Changes in social media and digital behaviors

Q1. Over the past year, has your preference to access resources, such as social media and digital (video and podcasts) channels, to gather information/data for professional reasons stayed the same or changed?

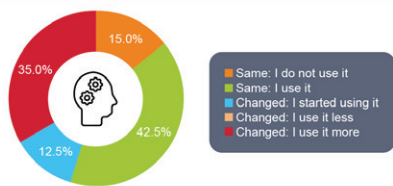
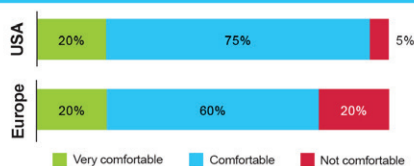


Figure 3. Payer comfort with digital channels and social media

Q2. How comfortable are you using digital and social channels for gathering information/data for professional reasons?



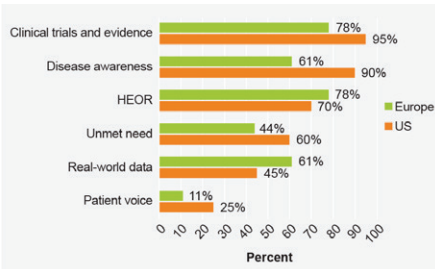
USA indicates United States of America.

Figure 4. Changes in social digital media channels as a result of fewer face-to-face interactions

Q3. Has your comfort level for using digital and social channels increased as a result of fewer face-to-face interactions?



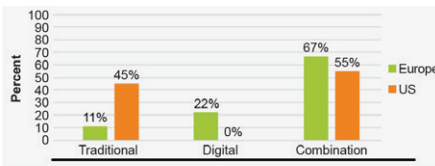
Figure 5. Type of evidence payers were receiving from the industry in 2021



Q5. In 2021, what type of information have you received from field pharma/biotech?

HEOR indicates health economics and outcomes research; US, United States.

Figure 6. Through which channels payers received evidence from the industry



Q6. How have you received this information?

US indicates United States.

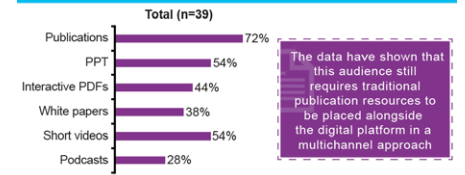
Figure 7. Podcast and short videos as effective and informative resources for payers

Q7 and 8. For podcasts and short videos, did you find the information informative and effective in preparing for future decision making?



Figure 8. Preferred payer channels for communication

Q9. Moving into the future, select your top 3 methods of how you would like to receive information from field pharma/biotech relevant to your future decision making.



PDF indicates portable document format; PPT, PowerPoint.

Figure 9. Payers top engagement with digital and social media channels

	% ranked first (Europe)	% ranked first (US)
SOCIAL MEDIA		
LinkedIn	60	30
Instagram	5	5
Facebook	0	5
YouTube	5	0
Twitter	0	0
OTHER DIGITAL MEDIA		
Search engine or pharma sponsored website	35	60

Global results. Respondents were able to rank multiple or no options in first place.

Q4. Please rank in order of engagement which digital and social channels you use as an information resource for professional purposes.

that while publications remained the preferred source for conveying clinical trial evidence (84%) and real-world data (64%), information on disease awareness, unmet need, and health economics might preferentially be communicated via a range of different digital media formats (Figure 10).

Country Variations:

- Half of payer respondents in Europe indicated they used digital media more frequently since the onset of the COVID-19 pandemic versus 20% in the United States.
- Short videos were the second most popular format for European payer respondents after traditional publications (voted in the top 3 by 63% respondents in Europe compared with 40% in the United States).

Limitations:

- The relatively small sample size, particularly within specific countries and types of US payers, may limit extrapolation to diverse types of payers.
- There is a potential recruitment bias of digitally focused payers as the study was conducted online via a survey and was determined by first to respond.

Discussion

As introduced above, we know that the COVID-19 pandemic caused information and digital fatigue and sped up the adoption of digital and social media in our industry. Pharmaceutical stakeholders are turning to online

methods for communication: McKinsey reported that there was a 70% reduction of personal promotion in September 2020 from before the COVID-19 pandemic.² We have seen that healthcare professionals can be active on Twitter, particularly for medical specialties where new evidence is being released at lightning pace. Meanwhile, patients are forming groups on Facebook to share and learn from their peers who live with the same conditions. This leads

Half of payer respondents in Europe indicated they used digital media more frequently since the onset of the COVID-19 pandemic, payers considered podcasts and short videos effective and informative resources in preparing for future decision making

us to ask: “Where are the payers?” We learned from this research that payers do not have an established social media home like healthcare professionals and patients, but if they were going to engage with a channel, it would be LinkedIn.

This lack of a social media home may be because many countries have rigidly structured processes and templates for formal HTA submissions and hospital pharmacy and therapeutics committee reviews. Furthermore, market access teams may be apprehensive to foray into new, legally uncharted domains, given the uncertainty around social media from an internal and external viewpoint.

However, there are broader opportunities to utilize digital communications with certain payer stakeholders across markets. While information exchange in some countries follows regulatory approvals, there are policies in some countries to communicate ahead of launch, such as the US Food and Drug Administration pre-approval information exchange³ and the UK PharmaScan system.⁴

Social media is only one avenue we explored in this research. We also explored digital formats, such as podcasts, interactive PDFs, and short videos. For digital formats the type of evidence shared via these media did matter. For example, using video technology coupled with a creative thought process can be an effective way to bring the payer on the journey from identifying the eligible patient to how the mechanism of action, when used in the right patient, translates to positive efficacy outcomes and manageable safety profiles.

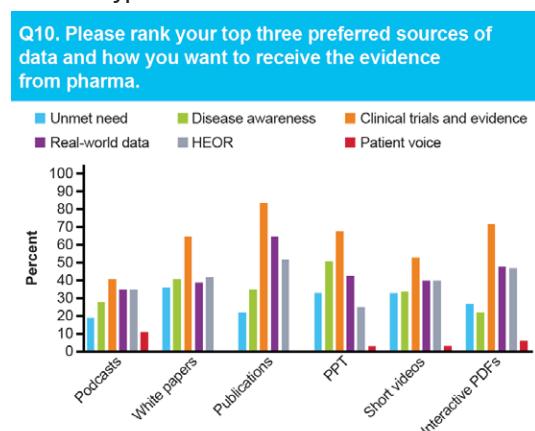
With the rise in popularity of podcasts, we found that this digital medium can be leveraged to share new evidence, particularly around disease awareness, unmet need, and health economics. Payers are people and learning styles are not one-size-fits-all so employing a range of media formats has the potential to enhance communication with a diverse payer audience.

Based on our experience working with affiliates across markets, it is important to understand local compliance guidelines to ensure that appropriate channels are able to be leveraged. Also, new evidence disseminated from market access and HEOR digital initiatives needs to be aligned with industry guidance and national policy, as well as appropriate messages for the stage of the product life cycle. Lastly, we have learned that if the evidence being shared via a podcast or video is derived from a publication, which the payer can access to go deeper into the data, then the medium and content have more credibility.

There are broader opportunities to utilize digital communications with certain payer stakeholders across markets.

Therefore, it is vital that digital media is nimble and flexible to ensure the right value story is being presented to the right decision maker at the right time, leading to positive patient access, which in turn will drive improved patient outcomes.

Figure 10. Preferred payer channels for different types of evidence



HEOR indicates health economics and outcomes research; PDF, portable document format; PPT, PowerPoint.

Conclusions

The study demonstrated that payer audiences saw value in receiving information via a variety of digital media alongside more traditional formats. Within each of the countries represented, there was a notable variation in the preferences of payers for the type of media, demonstrating that a multichannel communication approach is required to meet the preferences of a broad audience. Across all countries surveyed, the United States and the United Kingdom showed the most favorable response to digital media, and Germany was the least favorable.

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Disclosures

All authors are employees of Prime Global, a market access and medical communications agency. Recruitment of payers was conducted by DeFacto Research Ltd in Europe and InCrowd Inc in the United States.

Leveraging Electronic Health Records and Artificial Intelligence for Automated Health Outcome Analysis

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The digitization of medical data is growing rapidly, with more diagnostic tools and medical devices connected to patients, records, along with wearables and health apps that record patient data at home.

The data used in artificial intelligence algorithms include both structured data (categorical and continuous variables) and unstructured data (medical notes), with codes like ICD and CPT helping to standardize data collection.

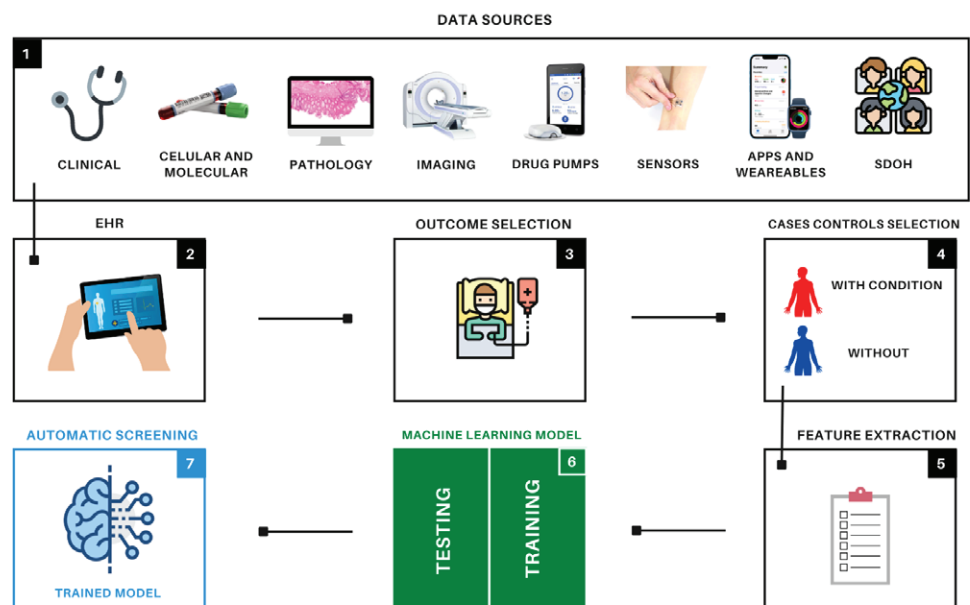
The application of machine learning to electronic health record data has the potential to improve health outcomes and reduce healthcare costs by enabling more accurate predictions of disease risk, earlier diagnosis, and more personalized treatment plans.

Introduction

The digitization of medical-related data has experienced substantial growth in recent years.¹ An increasing number of diagnostic tools and medical devices are connected to patients' records, transferring data to a network or cloud for monitoring and treatment purposes (Figure 1). Additionally, wearables and digital health apps that can record patient vital signs at home have added to the amount of data that can be transferred to databases.² This large collection of medical data represents a valuable resource for finding patient populations that share a particular condition. Clustering techniques can be used to group patients within the same pathology and artificial intelligence (AI) algorithms, specifically machine learning (ML), can then be applied to automatically identify

new patients.³ Upon the admission of new patients, diagnostic tests are conducted and the results are added to their electronic health records (EHRs). This enables the algorithm to analyze the available information and predict the probability of the patient exhibiting the condition.^{3,4} With this capability, it is possible to analyze hundreds of patients swiftly and efficiently across different medical institutions and create a patient care plan that is organized according to the severity of their condition. Additionally, the models can determine the most influential factors in a patient's classification by analyzing the data, thereby facilitating the identification of crucial diagnostic testing to determine the patient's disease severity.^{5,6} The implementation of these algorithms has the potential to speed up the patient

Figure 1. Graphical representation of the process of building and training artificial intelligence algorithms, specifically machine learning, for automatic patient screening. 1, represents all medical data sources that can integrate EHRs, SDOHs; 2, 3, and 4 represent clinical processing: outcome and case-control selection; 5 and 6 represent the computational part of the process: feature extraction and model construction. Model construction includes the training and testing phase with selection of best hyperparameters; 7 represents the operational part of the trained model in the clinical environment.



Adapted from Cossio.⁸
EHR indicates electronic health record; SDOH, social determinants of health.

care process, leading to shorter wait times and improved quality of care. Additionally, the automatic analysis of data may provide insights into other areas of healthcare, such as the level of integration between diagnostic units and treatment facilities.

How Are the Algorithms Trained?

To begin the process, the desired outcome of interest, such as renal disease, is selected. Access to a database is then obtained and all patients with the specified outcome are filtered while ensuring anonymization to safeguard private information (Figure 1). There are also pre-existing anonymized public databases, such as Clinical Practice Research Datalink (CPRD), which contain data on more than 40 million patients. Next, data analysis is performed to clean the data and address any issues, such as missing values. Medical experts can manually choose the outcome-related variables or the model can autonomously determine the most relevant variables without expert input. Control subjects without the outcome are also selected. Finally, a suitable machine learning model, such as a support vector machine, is selected and the input variables are fed into it with the outcome as the label. The model parameters are iteratively adjusted until the best accuracy is achieved (Figure 1). The trained model is then exported and tested on unseen data.^{3,5-7}

Origins of the Data

There are several data sources. EHR systems gather patient data at countrywide or regional level in public and private healthcare systems (eg, centralized EHR in some European countries).⁴ Databases can also be made from the systems due to their widespread implementation in all the hospitals across the regions. These databases offer a high level of anonymity to enable data use without endangering patient confidentiality. The SAIL databank in the United Kingdom,⁹ which has made it possible to create a wide range of ML applications using EHR data, serves as an example. Finally, we have closed EHR systems, such as those in the United States, that typically combine networks of hospitals run by the same company or private health insurers. To enable the creation of digital applications, these systems have also created their own

databases, although given the number of patients they serve, they are typically smaller than others.¹⁰

Medical Specialties With Higher Development Rates

The leading medical specialties are cardiovascular, psychiatry, oncology, diabetes, and neurology. The most common conditions in those specialties are type 2 diabetes, suicide attempts, acute kidney injury, depression, and heart failure.^{5,6}

The utilization of artificial intelligence models, specifically those incorporating machine learning, has many effects on healthcare outcome assessment.

The primary objective behind the development of these applications was to determine which variables within the algorithm had the greatest impact on the outcome. Variable ranking, population screening programs, and automatic diagnostic tools were among the remaining motivations for the development of early detection systems. A promising application of these algorithms is predicting complications in patients undergoing surgical procedures.⁷

Structure and Data Types

There are 2 configurations when it comes to the structure. The first type of data is structured data, which includes predetermined categorical and continuous variables. The second type of data is unstructured data and comes in the form of medical notes.¹¹ These notes must be processed using natural language programming techniques to extract variables that algorithms can use. These methods enable the extraction of data, such as medication or patient symptoms.⁵ Along with clinical data, the inclusion of social determinants of health (SDOH) in EHR is becoming increasingly important and plays a key role in the analysis of population-level findings.^{5,6,11}

Codes for Data Classification

Two of the most widely utilized coding systems are the *International*

Classification of Diseases (ICD) and *Current Procedural Terminology* (CPT) codes. The ICD codes play a critical role in defining the desired outcome and identifying comorbid conditions,¹² while CPT codes provide information about a patient's resource use.¹³ The significance of these codes lies in their ability to standardize data collection across international systems through their specificity.

Impact of the Models on Outcomes Analysis

The utilization of AI models, specifically those incorporating ML, has many effects on healthcare outcome assessment. The initial step in the development of these models is a thorough examination of data, which enables the identification of the most crucial variables relevant to outcomes.³ This prioritization streamlines decision making and reduces the financial burden on healthcare. Additionally, the data analysis can uncover variables with missing information and trigger a probe into the reason behind these gaps. One solution to this issue is to group patients with a high number of missing values and examine their SDOH. Research has demonstrated that there is a correlation between SDOH and outcomes, revealing that Black patients in the US healthcare system tend to receive substandard care compared to White patients.¹⁴ The models can also be trained to predict the likelihood of complications postsurgery, providing value in ensuring optimal medical care for patients and lowering the cost of managing postoperative complications.⁷ Furthermore, the models can be trained to identify common coexisting conditions linked to diseases. This recognition allows for the anticipation of complications during treatment and the implementation of effective preventive measures, leading to a delay in the onset of comorbidities, enhancing the patient's quality of life, and having a positive impact on the healthcare system.

Promising Roles of Deployed Models

Models that are trained with EHR data also have a significant impact on clinical trials and the production of real-world evidence (RWE).¹⁵ Regarding the first aspect, models can assist in selecting crucial variables for screening trial participants. The role of SDOH is also crucial here, as it contributes to

the inclusiveness of the process and ensures that all patients, regardless of their socioeconomic status, are equally considered. As for the second aspect, the automation of RWE generation is critical for real-time data analysis and the maintenance of updated database variables.¹⁶ In this regard,

It is imperative to consider the privacy implications when working with a substantial amount of patient information.

natural language processing (NLP) data extraction plays a significant role. A large portion of the information obtained from medical visits is in the form of free text, making it crucial to extract concise information that can be transformed into variable instances.^{5,17}

Data Privacy and Identity Protection

It is imperative to consider the privacy implications when working with a substantial amount of patient information. Before embarking on a project to develop an AI model for patient data analysis, it must undergo review and evaluation by an ethics committee. The committee assesses the impact of the project and considers the cost-benefit tradeoff. Subsequently, the project and its prototype must be evaluated by data protection experts, who will consider questions such as the location of data storage, access permissions, and server locations. To further safeguard privacy, various techniques, such as homomorphic encryption, the interplanetary file system (IPFS), and blockchain technology, can be employed to anonymize patient data and maintain data integrity without

compromising confidentiality.¹⁸ These privacy protection measures enhance patient trust and encourage the donation of data, ultimately advancing AI and ML applications in the healthcare field.

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Critical Considerations in Assessing the Value of Medical Devices: Are Health Technology Assessment Bodies Falling Behind?

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Scarcity of high-quality trial data and confounding factors may impact a manufacturer's ability to demonstrate a medical device's benefit on clinical outcomes.

Changes to regulatory laws across jurisdictions will likely impact how a medical device is evaluated by health technology assessment bodies, resulting in methodological changes in evidence requirements for reimbursement submissions.

It is vital that reimbursement decision makers and other payers consider the development of device-specific assessment frameworks that truly represent the potential of a medical device to improve patient outcomes and contribute to healthcare sustainability.

Introduction

Evidence generation activities and healthcare decision making for medical devices (MDs) are associated with unique challenges. Scarcity of high-quality trial data and confounding factors may impact a manufacturer's ability to demonstrate an MD's benefit on clinical outcomes.

There has been a recent shift toward higher evidentiary standards in the regulatory setting for MDs. For example, in 2021, the European Union (EU)'s Medical Devices Regulation (MDR) restricted the use of evidence from existing devices, switched to a formal evaluation of the new device, and established increased MD assessment requirements.¹

The gap in the availability and quality of clinical evidence to support medical device claims compared to pharmaceuticals has not been formally recognized by decision makers.

Changes to regulatory laws across jurisdictions will likely impact how an MD is evaluated by health technology assessment (HTA) bodies, resulting in methodological changes in evidence requirements for reimbursement submissions. The EU's Joint Clinical

Assessment (JCA) Programme is one prominent example of how reimbursement processes are being updated to follow suit with regulatory changes.²⁻⁴

The recent regulatory and reimbursement trend for MDs to increasingly align with those for pharmaceuticals ignores the fundamental differences in the way MDs and pharmaceuticals are developed and used (Figure 1). This puts manufacturers at risk of being unable to meet these requirements, potentially barring patient access to effective and safe MDs.

Unique challenges for MD evidence generation

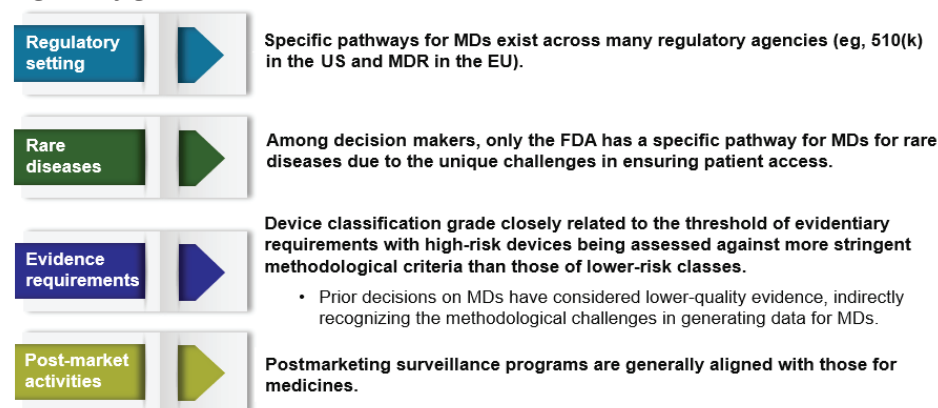
Regulatory bodies agree that evidence generation activities for MDs face unique challenges such as the inability to blind trials, how to assess investigator bias in outcome reporting due to increased training and experience of staff with the device, and the rapid development of software inherent to most high-risk devices that conflict with the time needed to conduct clinical trials. A less explored factor is the impact of continuous recalibration of programmable devices and its influence on clinical outcomes.

Current regulatory frameworks in the United States,^{5,6} European Union,¹ United Kingdom,⁷⁻⁹ and Canada^{10,11} provide clear guidance (although the level of detail varies) on evidence requirements and considerations of the challenges

Figure 1. Challenge of generating evidence for medical devices



Figure 2. Main themes of medical device evidentiary requirements across regulatory guidance documents



EU indicates European Union; FDA, US Food and Drug Administration; MDs, medical devices; MDR, Medical Devices Regulation; US, United States.

in generating reliable outcomes for MDs and the impact in decision making (Figure 2). Generally, these guidelines are specifically aimed at high-risk MDs (ie, class III or above), yet they share many similarities with requirements for pharmaceuticals. For example, it is recommended that evidence should be identified from different sources and be further collected as needed. However, it is recognized that conducting randomized controlled trials (RCT) for MDs can be difficult due to ethical and practical reasons; therefore, US and EU frameworks specifically allow for submission of other evidence (eg, uncontrolled studies if safety and effectiveness of the MD can be reasonably established). Data from another manufacturer's device with similar operational technicalities and mode of action can also be used as supporting evidence if equivalence can be established (although results of a recent study showed that class I recalls in devices seem to beget class I recalls in descendant devices).¹²

Similar challenges exist in reimbursement settings, with HTA bodies rarely distinguishing between MDs and pharmaceuticals in evidence and submission requirements. However, some positive steps have started emerging; for example, recent UK strategy acknowledges many of the evidence-generation challenges highlighted in this paper to ensure timely access to safe and effective medical technologies.¹³ An overview of some of these themes in MD evidence generation is discussed below.

1. Timely MD access requires high-quality clinical data

The gap in the availability and quality of clinical evidence to support MD claims compared to pharmaceuticals has not been formally recognized by decision makers. MD manufacturers are generally required to conduct thorough literature reviews and robust primary trial data collection following a similar evidence hierarchy typically used for pharmaceuticals, with emphasis on the need for RCTs. However, considerable challenges in conducting RCTs or real-world studies for MDs may affect the quality and confidence in the clinical data outputs: the inability to follow blinding processes, need for informed consent about invasive devices, or difficulties in protocol standardization between hospital settings. The increase in support of evidence outside RCTs and the development of MD-specific guidance documents are progress; in rare cases, expert opinion and patient testimonies can inform decision making.^{14,15} MD-specific quality tools are also needed to provide transparency in the bias assessment.

2. Data collection should aim for clinical relevance

The traditional focus on RCT data and the clinical relevance of MD data such as intended benefit for the targeted population, quantifiable benefit linked to product performance, or assessing the direct impact of device-user interaction to patient-relevant outcomes may disregard the nature of research (effectiveness and safety) questions for MDs. For example, MD-specific guidance does not

account for continuous improvement to MD specifications and models, unclear target population (devices may be used across different indications), and parallel use of different MDs in clinical practice. Differences in practice across countries, and even between medical centers, are difficult to fully address through a clinical trial. Issues around data transportability and recent methodologies to account for these differences such as linked analysis accounting for product performance have rarely been applied in MD assessments. Therefore, the expansion of real-world evidence (RWE) frameworks for MDs with emphasis on issues around data storage, collection, and analysis will guide manufacturers to sufficiently account for differences in data sources and explore biases that will support manufacturers in demonstrating a device's clinical relevance for decision making.

3. Overcoming current operational obstacles related to submission timelines and clearer guidelines may improve data quality

Without clear expectations about the accepted quality level for MD assessment, manufacturers may struggle to provide timely, robust evidence at such an early stage in the MD's lifecycle. Some HTA agencies require submission of the full evidence dossiers for MDs within 2 to 6 weeks following publication of the final scope, whereas timelines for pharmaceuticals tend to be longer (eg, around 60 days in the United Kingdom).¹⁶

The expansion of real-world evidence frameworks for medical devices will support manufacturers in demonstrating a device's clinical relevance for decision making.

The need for evidence generation through continuous data collection in the postmarketing setting is higher for MDs due to challenges in data collection through the first assessment. This reassessment schedule may be triggered by the risks and benefits associated with each new device. However, current processes do not provide coherent, time-sensitive plans for proactive

evaluation of new MD evidence. As part of the MDR, the European Database on MDs (EUDAMED) is being expanded to strengthen surveillance, transparency, and monitoring the safety and performance of available MDs; however, it appears behind schedule in terms of capturing all devices (independent of class).¹⁷ Agencies in other jurisdictions need to update processes to address MD-specific considerations, using EUDAMED as an example.¹⁸

4. Increasing transparency in decision making will elevate MD evidentiary standards and safeguard consistency in the process

MD evaluation processes vary greatly within and between countries. Given the lack of clarity in decision-making requirements and challenges in generating and robustly synthesizing MD evidence, it is not surprising that HTA and payer decisions lack transparency.

Clarity around the type of evidence needed will streamline the HTA process, allowing manufacturers to weigh evidence generation activities as early as the study design phase which, in turn, will eliminate some uncertainties later. Likewise, with the increased acceptance of RWE in HTA submissions, manufacturers could plan for data collection methods (eg, MD registries, data linkage) that aim to improve the quality of the evidence from these study types, help address MD performance evolution, and capture real-life patient experience. Novel methodologies, such as living systematic reviews, will

Given the lack of clarity in decision-making requirements and challenges in generating and robustly synthesizing medical device evidence, it is not surprising that HTA and payer decisions lack transparency.

transparently present the evidence generated across the lifecycle of an MD and its comparators, eliminating the traditional, more static assessment of an MD. Results from pilot programs that

encourage an innovative assessment approach for promising MDs (such as the early value assessment in the United Kingdom) may help showcase the potential of gathering RWE for MDs within a live environment while enabling greater access to patients.¹⁹ Recognizing and addressing these challenges for MDs will be vital for efforts like the EU JCA to provide acceptable, timely access for patients and incentivize evidence generation for MDs.

Conclusion

There is a recognition that MDs and pharmaceuticals have little in common regarding evidence generation from operational and methodological standpoints. Regulatory agencies have provided clear guidance to reflect this situation, but HTA bodies are lagging in this regard. It is therefore vital that reimbursement decision makers and other payers consider the development of MD-specific assessment frameworks that truly represent the potential of an MD to improve patient outcomes and contribute to healthcare sustainability.

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Disability and Health State Utility Values: A Framework for Assessing Ableism and Equity

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Disabled people have expressed numerous ethical concerns about the use of quality-adjusted life years in healthcare decision making. One concern involves methods of health state utility value measurement that privilege the perspectives of nondisabled people.

Little has been published about the ways in which these measurement methods meet the definition of ableism and how they may contribute to inequities in cost utility analysis and healthcare decision making.

This article introduces a framework to guide scientists in identifying ableism and assessing equity in health state utility value measurement.

Over recent decades, scientists in the field of health economics and outcomes research have debated the measurement of health state utility values (HSUVs) for the calculation of quality-adjusted life years (QALYs) with little input from disabled people.¹ QALYs are calculated by multiplying HSUVs by the amount of time spent in a particular health state. HSUVs are scores that are typically reported on a scale from 0 to 1 to reflect the extent to which impairment reduces quality of life. Quality of life is defined by the World Health Organization as “an individual’s perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns.”¹ While some HSUVs are generated by asking disabled people about the impact of impairment on their quality of life and their preferences around impairment, many HSUVs are measured at least in part by asking nondisabled people to state their preferences for impairment by imagining its potential impact on their quality of life.^{2,3}

Increasingly, disabled people have expressed concerns about the ethics

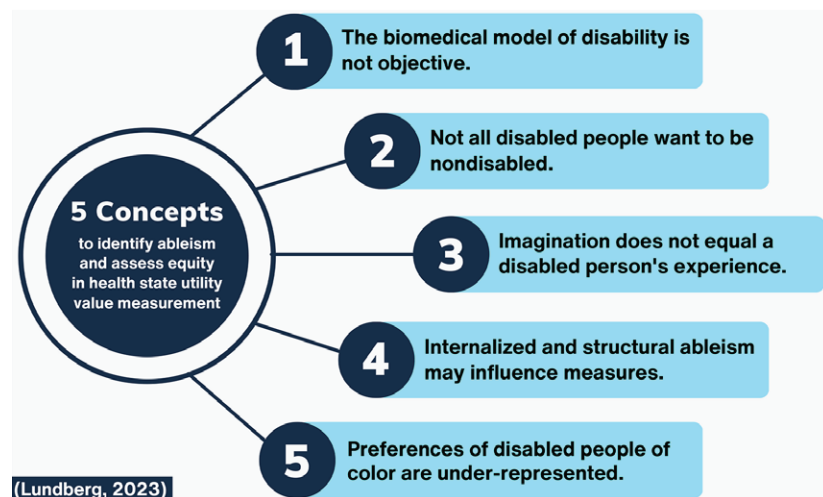
of HSUV measurement methods that are based largely on the perspectives of nondisabled people.³ Despite the growing criticism of QALYs, little has been published about the ways in which these measurement methods meet the definition of ableism and how they may contribute to inequities in cost utility analysis and healthcare decision making. Ableism refers to beliefs, practices, and forms of systemic discrimination that privilege the nondisabled body and mind and frame them as ideal.⁴

This article proposes a framework—“The Ableism and Equity in Measuring Health State Utility Values Framework”—to guide researchers in identifying ableism and assessing equity in their approaches to HSUV measurement. The framework includes 5 concepts to be considered, followed by companion questions that scientists can reflect on as they work to measure HSUVs and apply them in practice and policy settings. The framework is summarized in **Figure 1**.

1. The Biomedical Model of Disability Is Not Objective.

Many of the concerns expressed by disabled people concerning HSUVs have

Figure 1. The Ableism and Equity in Measuring Health State Utility Values Framework



* I use identity-first language (ie, disabled person) instead of person-first language (ie, person with a disability) to emphasize disability as a social, cultural, and political identity in addition to an experience of living with impairment. While this intentional choice reflects my own language preferences as a disabled person and the preferences of many disabled people, there are diverse views about language within disabled communities.

their origins in the reliance of these methods on the biomedical model of disability.³ This model views disability as a deficiency or abnormality of the individual person that requires a cure to remedy it.⁵ Despite suggestions of its objectivity, the biomedical model is a subjective approach to understanding disability that reflects specific Western cultural values.⁶ An alternative model, the social model of disability, views disability as bodily difference that is disabling primarily because of physical, social, and structural barriers that limit activities and access to resources.⁵

HSUV measurement does not currently distinguish between quality-of-life impacts resulting from impairment and impacts resulting from physical and social barriers. If impacts relate to the latter, this has implications for healthcare decision making. It suggests that more resources should be devoted to community and structural-level interventions that eliminate barriers for disabled people rather than to individual-level interventions that seek to cure disability. This is not intended as an argument for large-scale disinvestments in medical interventions for disabled people but to question if prioritization of medical interventions is always appropriate to advance health equity.

Increasingly, disabled people have expressed concerns about the ethics of health state utility value measurement methods that are based largely on the perspectives of nondisabled people.

To explore this concept, researchers should critically ask: “What evidence do I have that a health condition is the problem affecting quality of life rather than physical, social, or structural barriers that limit activities?”

2. Not All Disabled People Want to Be Nondisabled.

An assumption embedded in HSUV measurement is that impairment reduces quality of life. Because of this, it is assumed that all disabled people

would prefer a nondisabled life. This assumption is not well-supported by current literature. Studies have demonstrated that many disabled people would choose to be disabled if given the opportunity to be nondisabled.^{7,8} In practice, this assumption can bias researchers and cause them to adopt a deficit-based lens that leads them to overlook domains where disability may enhance quality of life. For example, a disabled person may develop relationships with other disabled people that improve their psychosocial health. While impairment does sometimes have negative impacts on quality of life and can warrant intervention, in cases where it does not, researchers may waste resources developing interventions that disabled people do not want. While it has been suggested that disabled people typically rate their quality of life higher than nondisabled people would expect them to, this finding actually varies across populations and domains.^{9,10}

To explore this concept, researchers should critically ask: “To what extent do I consider the nondisabled body and mind ideal and desirable?”

3. Imagination Does Not Equal a Disabled Person’s Experience.

HSUVs are commonly generated using methods that involve asking the general population to imagine they have an impairment and provide their preferences for it. This is in opposition to methods that survey people living with impairment about their experiences and preferences. According to a systematic review, the majority of QALYs are calculated using HSUVs derived using data from the general population.² This practice warrants scrutiny. Just as a study interviewing a majority group about the experiences of a minority group would be considered invalid, there is no evidence that nondisabled people can accurately report the experiences of disabled people. Some researchers have argued that surveying the general population includes disabled people, but this is flawed as well.³ A minority group’s perspectives are not going to be well-represented in a study where they are the minority. While some ethicists have argued that the general population’s preferences around health states should be prioritized in cost utility analysis because the public pays for

healthcare, a major goal of contemporary healthcare is to reduce health inequities and allocate resources to populations with the most need. If this is the goal, it seems unreliable to assess the impact of an intervention on a minority group’s quality of life using a majority group’s imagination of the minority group’s experiences.

While impairment does sometimes have negative impacts on quality of life and can warrant intervention, in cases where it does not, researchers may waste resources developing interventions that disabled people do not want.

To explore this concept, researchers should critically ask: “Does my approach to measurement equate nondisabled people’s imaginations about disability with disabled people’s lived experiences?”

4. Internalized and Structural Ableism May Influence Measures.

When a disabled or nondisabled person is asked to provide their preferences around impairment, internalized ableism and exposure to structural ableism may influence their responses. In a community where inaccessibility and discrimination against disabled people are prevalent, respondents may be less likely to believe disabled people can have a high quality of life. They may also have implicit or explicit biases about disability. Since inaccessibility and discrimination vary by location and over time, generalizability of HSUV measurements may be limited. This is especially true if the population where valuation occurs is not representative of the population where the values are applied.

To explore this concept, researchers should critically ask: “Could the generalizability of my measurements be limited by geographic or temporal differences in internalized ableism or exposure to structural ableism?”

5. Preferences of Disabled People of Color Are Under-Represented.

The barriers that make impairment disabling have the greatest impact on disabled people who live at the intersection of structural ableism with structural racism and other systems of oppression.¹¹⁻¹³ Due to these systems, in the United States for example, disability is more common among Black and American Indian and Alaska Native populations.¹⁴ However, studies that value health states often do not consider racialized identity in their sampling. If they do, they often have samples that over-represent White people. This raises concerns that disabled communities of color, who have unique experiences and values around disability, are not being adequately represented.

To explore this concept, researchers should critically ask: “Does my approach to valuing impairment and disability equitably involve the perspectives of disabled people of color and disabled people with multiple marginalized identities?”

Concluding Remarks

In summary, this article introduces a framework to assist researchers in identifying ableism and assessing equity in their approaches to measuring HSUVs. Reflection questions are also offered, which are summarized in **Figure 2**.

Determining whose experiences and preferences are valued in quality-of-life measurement is an important consideration for increasing equity in healthcare decision making.

This article helps bridge the gap between disability justice advocates concerned about ableism in healthcare and health economics and outcomes researchers who believe cost-utility analysis is an important tool for healthcare decision making. This work is particularly relevant given congressional legislation in 2023 to prevent the use of QALYs in federal healthcare coverage and

Figure 2: Companion Questions for the Ableism and Equity in Measuring Health State Utility Values Framework

Reflection Questions

(Lundberg, 2023)

for researchers as they work to measure health state utility values and apply them in practice and policy settings

- 1 What evidence do I have that a health condition is the problem affecting quality of life rather than physical, social, or structural barriers that limit activities?
- 2 To what extent do I consider the nondisabled body and mind ideal and desirable?
- 3 Does my approach to measurement equate nondisabled people's imaginations about disability with disabled people's lived experiences?
- 4 Could the generalizability of my measurements be limited by geographic or temporal differences in internalized ableism or exposure to structural ableism?
- 5 Does my approach to valuing disability equitably involve the perspectives of disabled people of color and disabled people with multiple marginalized identities?

payment decisions in the United States. Regardless of the QALY's future, the concepts and questions raised in this framework will remain relevant to the broader project of reducing ableism in quality-of-life measurement.

While the framework proposed here is most relevant to considering equity concerns in HSUV measurement for disabled people, some of the ideas may also be applicable to other populations.[†] Experiences and preferences around quality of life are likely to differ by gender, race and ethnicity, nationality, geographic location, and other dimensions of human diversity. Determining whose experiences and preferences are valued in quality-of-life measurement is an important consideration for increasing equity in healthcare decision making. New dialogue is needed around how the perspectives of marginalized and multiply marginalized people are included in quality-of-life measurement processes.

Ultimately, QALYs and HSUVs would be less of a concern for disabled people if disabled people were adequately represented in healthcare decision making.¹⁵ If disabled people are not at the table when measurement approaches are selected and when healthcare decision making occurs, choices can be made that are not in line with disabled people's needs. This may cause harm and be counterproductive

to advancing health equity. In this way, increased representation of disabled people in research and health policy is the ultimate structural solution to most of the issues raised in this article.

Funding/Support

This project was supported by grant number T32HS013853 from the Agency for Healthcare Research and Quality. The content is solely the responsibility of the author and does not necessarily represent the official views of the Agency for Healthcare Research and Quality.

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[†] The issues raised in this article are likely to also hold relevance for disability-adjacent populations (ie, those who are not disabled but are neurodivergent or chronically ill).

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Impact of Climate Change on Human Health and Health Economics

An Interview With Wendy Janssens

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Q&A

“At every single one of my research sites, I see how the people we are working with are affected directly by climate change.”

Although climate change isn't a new phenomenon, its impact on global health and health outcomes is only now making mainstream news headlines. This issue of Value & Outcomes Spotlight examines global threats from climate change through an HEOR lens, which presented a unique opportunity for me to speak to Wendy Janssens, PhD, a Professor in Development Economics at the School of Business and Economics at Vrije Universiteit, Amsterdam, The Netherlands. She is an Academic Board member of the Amsterdam Institute for Global Health and Development (AIGHD), in the Health Economics Research Amsterdam (HERA) management team, and research fellow at the Tinbergen Institute. She is also research advisor for PharmAccess Foundation.

Currently, she is leading an interdisciplinary research program on mobile technology and universal health coverage for mothers and children in Kenya, including the evaluation of maternal mental health interventions.

Value & Outcomes Spotlight: Climate change has been ongoing for a few decades now. Several of the consequences of rising temperatures and rising CO2 levels are already being experienced: there are severe droughts, flash floods, melting ice, and forest fires reported across the world with multiple health consequences.

You are a development economist. What made you interested in the topic of the impact of global climate change on health?

Wendy Janssens: My work focuses mostly on global health. In the past 10-15 years I've been working on access to healthcare and sexual and reproductive health, as well as on maternal and child health. At every single one of my research sites, I see how the people we are working with are affected directly by climate change. Let me provide a few examples.

In Pakistan (where we are doing a research study on child marriages), monsoon floods occurred at a large scale last year, with the poorest segment of the population—who were most likely to live in the areas with the greatest risk of flooding—were impacted most severely. About 1500 people died during the initial weeks. In addition to death risks, flooding also causes a lot of other health-related problems, such as infectious diseases outbreaks, mental health stress, or malnutrition due to damage to crops and livestock.

In Malawi, we witnessed a significant impact from an intense tropical cyclone Freddy that hit between February and March 2023. It was the most long-lasting cyclone ever recorded, persisting continuously for 5 weeks, going back and forth across Southern Africa. Malawi was the hardest hit, with 500 deaths and 500,000 people displaced. In the pediatric hospitals [where we were conducting our research at the time], children affected by flooding and mudslides were brought in with various injuries. There were also cases of cholera outbreaks.

The devastating impact of climate change is going to overrule all the other health measures that we are undertaking if we do not manage to turn the tide now.

Kenya and the entire region of the Horn of Africa (region including Kenya, Somalia, and Ethiopia) have been affected by a very severe drought over the past couple of years. As we were monitoring different infectious diseases in the West of Kenya, we noticed a real-time increase in the number of children being brought in with malnutrition symptoms. In the north of Kenya, the problem was even more severe.

In the current situation, my colleagues and I feel that it is crucial to incorporate climate change in our work on health and development because we are already in the middle of it. The devastating impact of climate change is going to overrule all the other health measures that we are undertaking if we do not manage to turn the tide now.

VOS: Much of your work is focused on health problems in the low- and middle-income countries in the Global South. What do you see for these regions in terms of the impact of climate change on population health in addition to the examples that you have given?

WJ: A major problem is that a lot of the countries in the Global South have had very little to do with causing climate change. For example, Africa has only contributed to 3% of the global carbon emissions. The contribution of most low- and middle-income countries to global climate change is small, but at the same time the impact on these countries is the largest. They are also the most vulnerable, as they possess limited resources to mitigate the consequences and to adapt to climate change. In addition, the poorest states are also the ones with the youngest population, who will be affected most by the impact in the future.

VOS: This resonates with the [study published in *The Lancet Planetary Health*](#) that suggests larger anxiety caused by global climate change among young people aged 16 to 25 years.

WJ: Yes, I find the results of this study concerning. For this study, 10,000 young people (including children and adolescents) were interviewed in 8-10 countries. So far, there is very limited quantitative evidence about the perception of global climate change among young people. This was an online survey, meaning that their respondents had access to the Internet and were generally involved in current affairs, so in that sense there is a selection bias; however, the size of the study population

is large. In this study, 60% of the respondents reported being “very”, or “extremely worried” about climate change—a substantial number.

It was clear from the comparison between the participating countries that the youth from countries in the Global South were most worried. These concerns were also related to the extent of help they were expecting from their government to cope with the effects. In countries like The Philippines, where an increase in the number of floods and cyclones is already being felt, this is reflected in an increased pressure on mental health and elevated stress and anxiety levels among young people. Similarly, pandemics may become more prevalent as well. In a [recent study in *PLOS Medicine*](#), we show how COVID-19 significantly increased depressive symptoms in eight different low- and middle-income countries.

VOS: So far, only individual studies report data on consequences of these impacts of climate changes on human health. Coincidentally, on June 6, 2023, the WHO launched a consultation on the matter ([REACH 2035](#)). In addition, the Royal Netherlands Academy of Arts and Sciences (KNAW) released a report on the [Planetary Health: An Emerging Field to Be Developed](#). The report is a step ahead as it provides a list of research topics and questions. One of the issues raised there was the carbon footprint of healthcare itself. Do you think it would make sense to include environmental impact of healthcare in health technology assessments?

WJ: A 2022 paper in [The Lancet Planetary Health](#) suggested that the environmental impact of the healthcare sector is about 5% of the total carbon footprint, similar to that for the airline industry; within The Netherlands, this figure is even higher at 8%. The healthcare sector contributes a lot to water consumption, pollution, and waste generation, while less polluting solutions are available.

Africa has only contributed to 3% of the global carbon emissions. The contribution of most low- and middle-income countries to global climate change is small, but at the same time the impact on these countries is the largest.

VOS: What ongoing research do you have in this area (ie, carbon footprint and global warming)?

WJ: At the moment, a large research consortium is being set up across Africa to investigate the impact of heat-related stress on pregnancy and birth outcomes for pregnant women and newborn babies. This project will use [data from my previous studies](#) (among others) that assessed risk factors during pregnancy for maternal and child health and the potential of value-based healthcare in improving outcomes.

We are also developing a research program that will link fine-grained meteorological data on rainfall, droughts, and temperature to the occurrence of a large range of health outcomes, including both infectious and noncommunicable diseases. From existing studies, we know that these impacts

may be large. For example, in Indonesia, a [paper in the journal *Health Economics*](#) found that on the days when the temperature reaches 30° Celsius or higher, visits to healthcare centers or hospitals increased by 8%. Visits associated with diabetes increased by even 25% and visits of patients with cardiovascular diseases increased by 14%.

With global warming, higher temperatures will become more prevalent, especially in tropical areas. Rates of noncommunicable diseases are also increasing, which means there will be a lot of additional pressure on healthcare systems due to climate change. In many countries, healthcare systems are highly vulnerable and urgently need strengthening.

VO: Are there any issues you see there that have been exacerbated by climate changes in the last decade?

WJ: A critical issue to highlight is malnutrition that occurs due to the increasing rates of droughts and floods, but also during epidemic outbreaks such as when COVID-19 hit. Malnutrition has a long-lasting impact throughout an individual's life. Children who experience chronic malnutrition at a young age may later suffer from cognitive delays, which will hinder their academic performance and attendance at school. This may also affect their productivity as an adult and result in a greater proportion of individuals with low income-generating capacity in the future. It thus creates a cycle of intergenerational poverty. Economic research has shown that even in-utero malnutrition can have long-lasting and severe impacts -- leading to weaker immune systems, physical and cognitive impairments, and greater susceptibility to non-communicable diseases as an adult.

A lot of progress that has been achieved in reducing malnutrition rates over the past decades may now be reversed due to the negative impact of climate change. How to mitigate these effects, for example by changing to more drought-resilient crops, is something we want to look into further.

VO: There are several digital health interventions being tested by a non-governmental organization, PharmAccess Foundation, that you are partnering with. Could these be used to create an alert system that would send out notifications about approaching heatwaves and provide instructions on protective measures for people to undertake?

WJ: In high-income countries, these alert systems are well established. Especially for the more vulnerable populations (such as the elderly, pregnant women, and young children), there are plans in place that also activate various measures, including the opening of community centers equipped with air conditioning and ensuring sufficient water supply in towns during a heatwave.

In many low- or middle-income countries, meteorological alert systems do not yet exist. However, implementing health-alert systems, even in a simplified form, could already benefit vulnerable populations. For instance, providing simple tips

such as staying in shaded areas, drinking sufficient water, and avoiding strenuous activity during the hottest hours can go a long way in mitigating the effects of hot weather without requiring significant financial resources. It all begins with timely alerts to the population.

As we document in several recent publications, mobile technology can be of great value in this respect. For example, during the COVID pandemic, PharmAccess was running a [digital maternal care program](#) that registered pregnant women via their mobile phones. This program proved particularly beneficial during lockdowns as it enabled healthcare staff to easily contact women as required at each stage of their pregnancy. They could provide timely advice, and guidance on what to do or avoid. The convenience of this approach was helpful in supporting expectant mothers. Similarly, digital dashboards were developed that supported local governments in tracking and localizing outbreaks and vaccine uptake.

There is a gap in our understanding of how different aspects of climate change impact health. While we are gaining knowledge in this area, we still lack a clear understanding of how to effectively address these effects.

Nowadays, mobile phones are in widespread use and many individuals have access to mobile money applications. Digital tools can provide outreach and health services, and governments can leverage mobile technology to transfer cash and rapidly establish a social safety net for those in need. Mobile money eliminates the need for recipients to travel or possess a bank account, reaching people even in remote locations.

Still, there is a lot that remains for us to investigate. There is a gap in our understanding of how different aspects of climate change impact health. While we are gaining knowledge in this area, we still lack a clear understanding of how to effectively address these effects. Global warming is now increasing towards 1.5° Celsius and countries will increasingly encounter its consequences. What actions should countries take? Which interventions will have the greatest impact and will be at the same time cost-effective? Given limited resources, countries must strategically focus their efforts to address the vast problems at hand. There is much work to be done within a relatively short time frame, as time is running out to allocate resources towards interventions that will bring the greatest impact at the lowest cost.



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