MIDS Communication, Coordination, and Collaboration (C3) Forum

MIDS CORs & Contractors Monthly Meeting

Wednesday
December 13, 2023
Noon – 1 PM Eastern

MIDS C3 Forum Agenda

- Partnership for Quality Measurement (PQM): Incorporating Equity and Justice into Measure Development
  - Jeff Geppert (Battelle)

Partnership for Quality Measurement

Incorporating Equity and Justice into Measure Development

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Question for Today

- Where are there opportunities in the measure lifecycle to incorporate considerations of equity and justice?
- Focus on opportunities <u>other</u> than:
  - Data collection
  - Risk adjustment
  - Stratification
- Focus on opportunities to understand the distribution of **net benefit** across population of entities and persons

Health equity means the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes.
https://www.cms.gov/pillar/health-equity

Net Benefit

- Every clinical quality measure (CQM) involves an assessment of net benefit (net benefit = benefit – harm)
- Net benefit for the individual (“meaningfulness”)
  - Person – improvement in material outcome (benefit); risk of adverse event (harm)
  - Entity – efficient allocation of resources (benefit); cost of data collection and reporting (harm)
- Net benefit for the population (“appropriateness of scale”)
  - Person – distribution of benefits and harms across subpopulations of persons (generalizability)
  - Entity – distribution of benefits and harms across subpopulations of entities (structure)

Assessment of Net Benefit - FDA

Measure Name: Measure Number:	Proposed Intended Use:	
Assessment of Benefit	Considering benefit in terms of:	
	• Type • Magnitude • Probability • Duration of effects	• Patient / person perspective • Entity perspective
1. Is there any evidence of benefit?	(yes / no). Please list.	
2. What is the extent of uncertainty for the benefits?	(complete and adequate)	
Assessment of Risk/Harms	Considering risk/harms in terms of:	
	• Type • Magnitude • Probability • Duration of effects	• Patient / person perspective • Entity perspective
3. Are the known and probable risks/harms more than minimal?	(yes / no) Please list.	
4. What is the extent of uncertainty for the risks/harms?	(complete and adequate)	
Assessment of Benefit-Risk/Harms		
5. Do the benefits outweigh the risks/harms?	(yes / no) Provide rationale.	
6. Do the benefits outweigh the risks/harms, taking into account additional considerations?	(yes / no) Provide rationale.	
7. Can the risks/harms be mitigated, so that benefits outweigh the risks/harms?	(yes / no) Provide rationale.	

Source: https://www.fda.gov/media/99769/download

Assessment of Net Benefit – CMS/AHRQ

Table 2. Comparison between Existing and Proposed Requirements as Presented to Key Informants and Rationale for Changes

Tag for Existing Requirement	Existing Requirement	Proposed Requirement	Rationale
Context	a. The principal purpose of the study is to test whether the item or service meaningfully improves health outcomes of affected beneficiaries who are represented by the enrolled subjects.	E.CMS and investigators agree upon the evidentiary threshold for the stated question. This reflects the clinically relevant difference in the key outcome(s) relative to the chosen comparator and the targeted precision.	Aimed to specifically require that the population is representative by promoting to a separate requirement.
Population	a. The principal purpose of the study is to test whether the item or service meaningfully improves health outcomes of affected beneficiaries who are represented by the enrolled subjects.	H. The studied population reflects the intended users of the product and also the racial, gender, and socio-economic diversity of the Medicare beneficiary population including older adults, individuals on dialysis, and disabled younger persons when relevant to the questions.	Split for clarity.

Source: Analysis of Requirements for Coverage With Evidence Development (CED) – Topic Refinement | Effective Health Care (EHC) Program (ahrq.gov)

Belmont Report

- Ethical principles and guidelines in the conduct of biomedical research (April 18, 1979) (The Belmont Report | HHS.gov)
- Basic principles
  1. Respect for persons – a) individuals (persons, entities) should be treated as autonomous agents, and b) persons with diminished autonomy are entitled to protection
  2. Beneficence - a) do not harm (reduce uncertainty) and b) maximize possible benefits and minimize possible harms
  3. Justice - formulation for the basis of the distribution of benefits and harms: a) to each person an equal share, b) to each person according to individual need, c) to each person according to individual effort, d) to each person according to societal contribution, and e) to each person according to merit

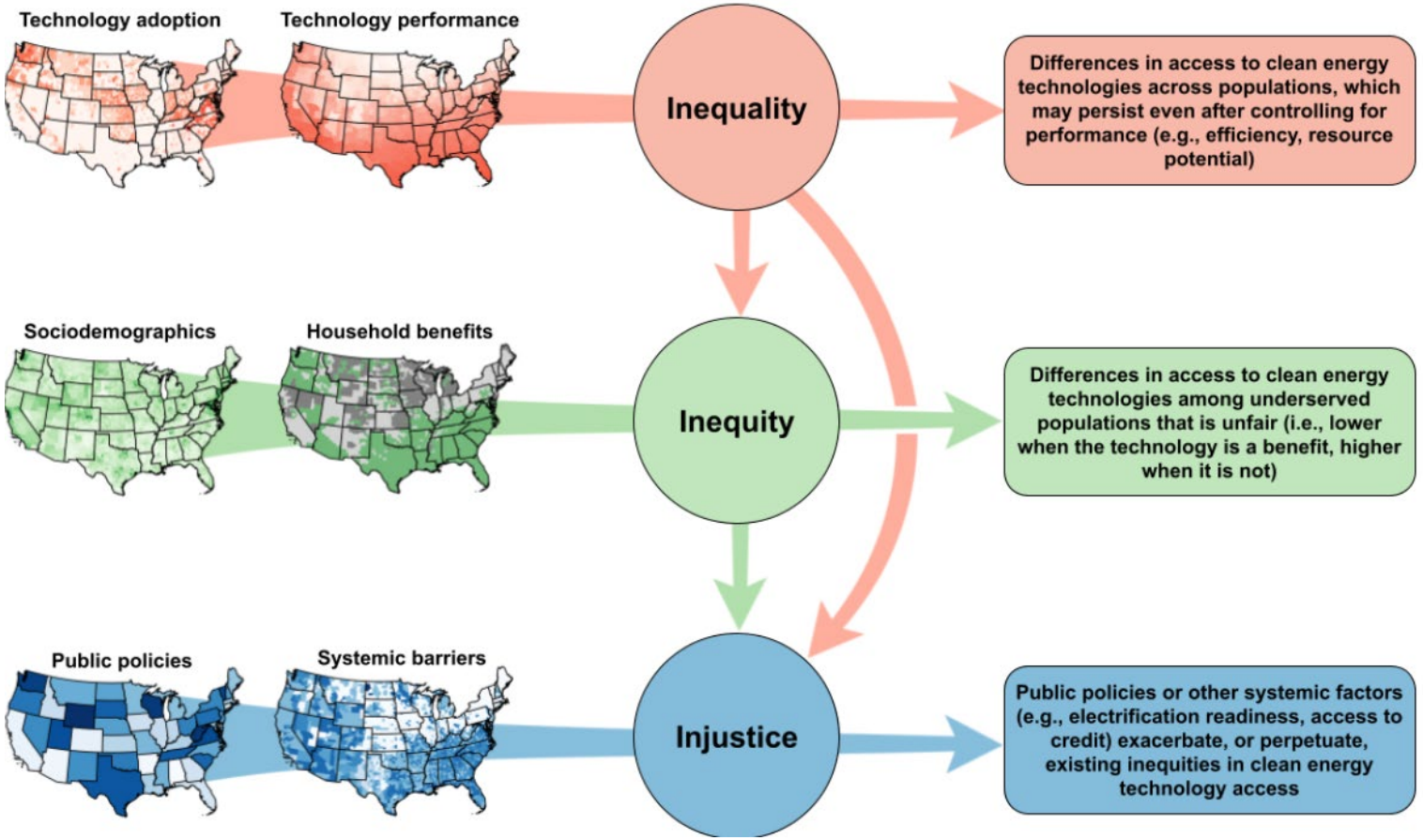
Lessons from Environmental Justice

- Health care justice calls for everyone to
  - have access to high quality, safe, affordable, and resilient health care infrastructure
  - be able to participate in health care decisions that affect them
- Underserved communities are simultaneously
  - more likely to experience the harms
  - less likely to experience the benefits
- Framework for assessing inequities in access to high quality health care explores disparities in communities' experiences by distinguishing between three concepts:
  - inequality, inequity, and injustice

Lessons from Environmental Justice

- Inequality
  - Refers to a difference in access across populations
  - Inequalities have many potential drivers and do not necessarily indicate a need for policy intervention (e.g., related to personal choice, cultural factors, disposable income)
- Inequity
  - Refers to a difference that persists even after controlling for these drivers/factors
  - Specifically, there may be lower access in underserved or under-resourced communities (e.g., rural communities, lower-income households)
- Injustice
  - Refers to cases where policies or other persistent or systematic factors exacerbate, or perpetuate, existing inequities

Lessons from Environmental Justice



Urban residents might have better access to telemedicine due to more reliable internet connectivity and greater availability of healthcare providers offering such services, compared to rural populations

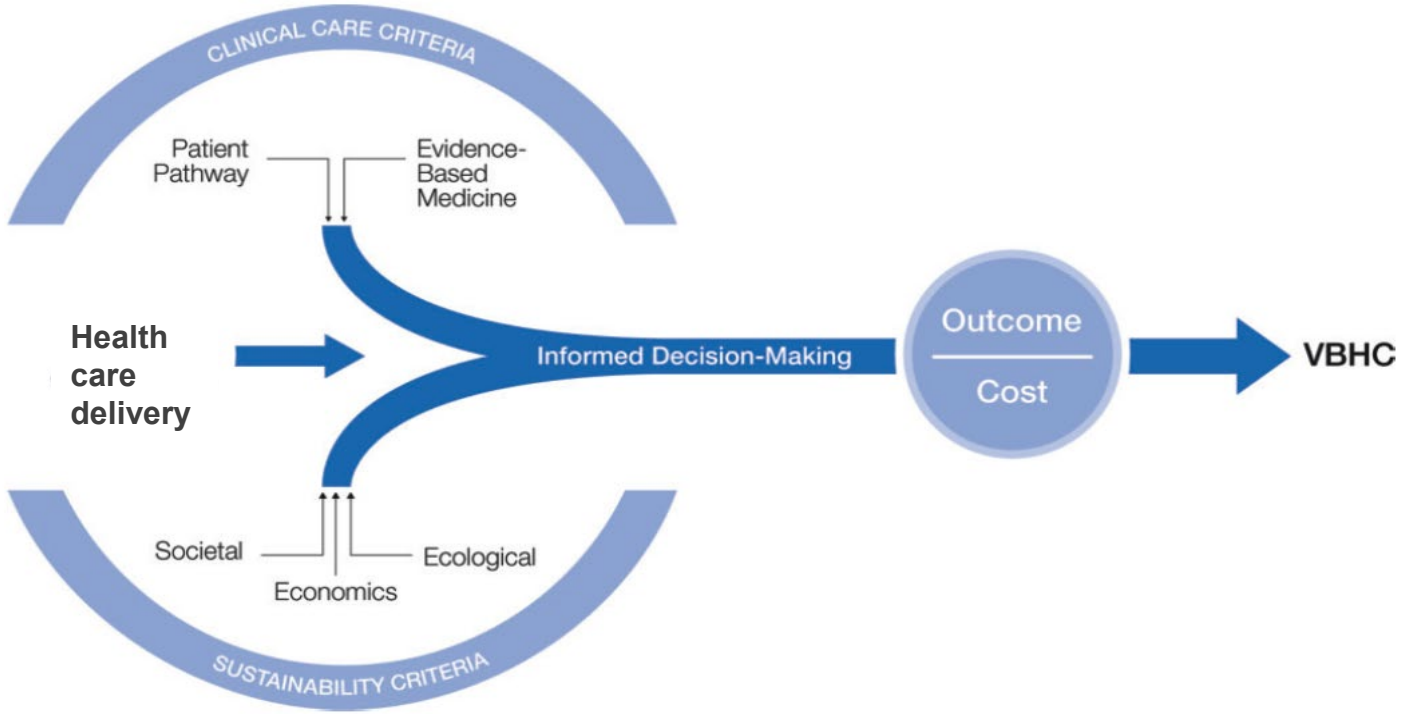
Low-income communities having less access to telemedicine because they cannot afford the necessary technology (like smartphones or computers) or lack adequate internet services.

Policies that do not fund or support broadband infrastructure in rural or impoverished areas, thereby denying these communities the benefits of telemedicine

Source: [2305.16488] Assessing inequities in electrification via heat pumps across the U.S (arxiv.org)

Sustainability

- Non-clinical sustainability criteria entail the societal and ecological implications of health care
- For resource intensive health care, concerted and fully integrated care strategies need to be urgently implemented to cope with the global demand and burden



Source: Apel, C., Hornig, C., Maddux, F. W., Ketchersid, T., Yeung, J., & Guinsburg, A. (2021). Informed decision-making in delivery of dialysis: Combining clinical outcomes with sustainability. *Clinical Kidney Journal*, *14*(Supplement_4), i98-i113.

Sustainability

- Life-cycle assessment (LCA) to evaluate potential environmental impact
  - Acquisition of resources, transportation, manufacturing, distribution, usage, and disposal

Domain	Environmental Impact	Domain	Environmental Impact
Human health preservation	Human toxicity, non-cancerous effects Human toxicity, cancerous effects Ionising radiation	Atmosphere protection	Photochemical ozone formation Particulate matter Ozone depletion Climate change
Terrestrial conservation	Acidification Terrestrial eutrophication	Resource conservation	Land use Mineral, fossil and renewable resource depletion Water resource depletion
Water protection	Freshwater eutrophication Marine eutrophication Freshwater ecotoxicity		

Source: ISO 14040/44:2006- Environmental management - Life cycle assessment - Principles and framework

Opportunities in the measure lifecycle

- Conceptualization
  - Greater use of qualitative methods – focus groups and surveys – to understand how persons and entities would respond to the measure focus
  - More effective methods to identify evidence to articulate harms in addition to benefits
  - Technical expert panels (TEPS) are better at identifying the relevant data-evidence and articulating the relevant mechanisms (e.g., association between measure focus and material outcome)
- Specification and Testing (how would the net benefit be impacted by)
  - Changes to the specifications tailored to the unique features of the specific target population or entity
  - Increases or decreases in reliability due to the number of persons per entity
  - Unique aspects of the feasibility trade-off between health benefit to patients and reporting burden to entities
  - Unique aspects of validity due to the effectiveness of evidence-based interventions in the context of population-specific characteristics, preferences, values, treatment goals, and material outcomes

Opportunities in the measure lifecycle

- Implementation and Use
  - Contribute understanding of context – four “I”s
    - The *individual* capacities of the key actors and interested parties such as interests, attitudes, knowledge, and skills
    - The *interpersonal* relationships required to support the measure, such as lines of communication, management, and administrative support, as well as professional relations and contracts
    - The *institutional* setting in which the measure is implemented, such as the culture and norms, leadership, and governance of the implementing body
    - The wider *(infra-)structural* and health care system, such as political support, the availability of funding resources, as well as competing policy priorities and influences

Source: Adapted from Durlak JA and DuPre EP (2008) Implementation matters: A review of research on the influence of implementation on program outcomes and the factors affecting implementation. American Journal of Community Psychology 41: 327–50.

Opportunities in the measure lifecycle

- Summary
  - Use of quality measurement is a potential strategy to address inequality, inequity, and injustice in health care
  - There are opportunities in the measure lifecycle to contribute better understand of the net benefit of quality measures for individuals and populations of persons and entities
  - This better understanding may inform how quality measures are conceptualized, specified, tested, implemented, and used
  - Environmental impacts and sustainability may be additional considerations along with clinical evidence as health care become more resource intensive

Discussion

Image credit: Tony Ruth for Design in Tech Report

POC

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Partnership for Quality Measurement

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