

Think locally, to let differential pricing arise globally

Mikkel Oestergaard

on behalf of the ISPOR Global Differential Pricing Working Group (WG)
Part of the ISPOR Global Access to Medical Innovation (GAMI) SIG

Co-Lead of the WG

Executive Director of HTA Statistics in MSD

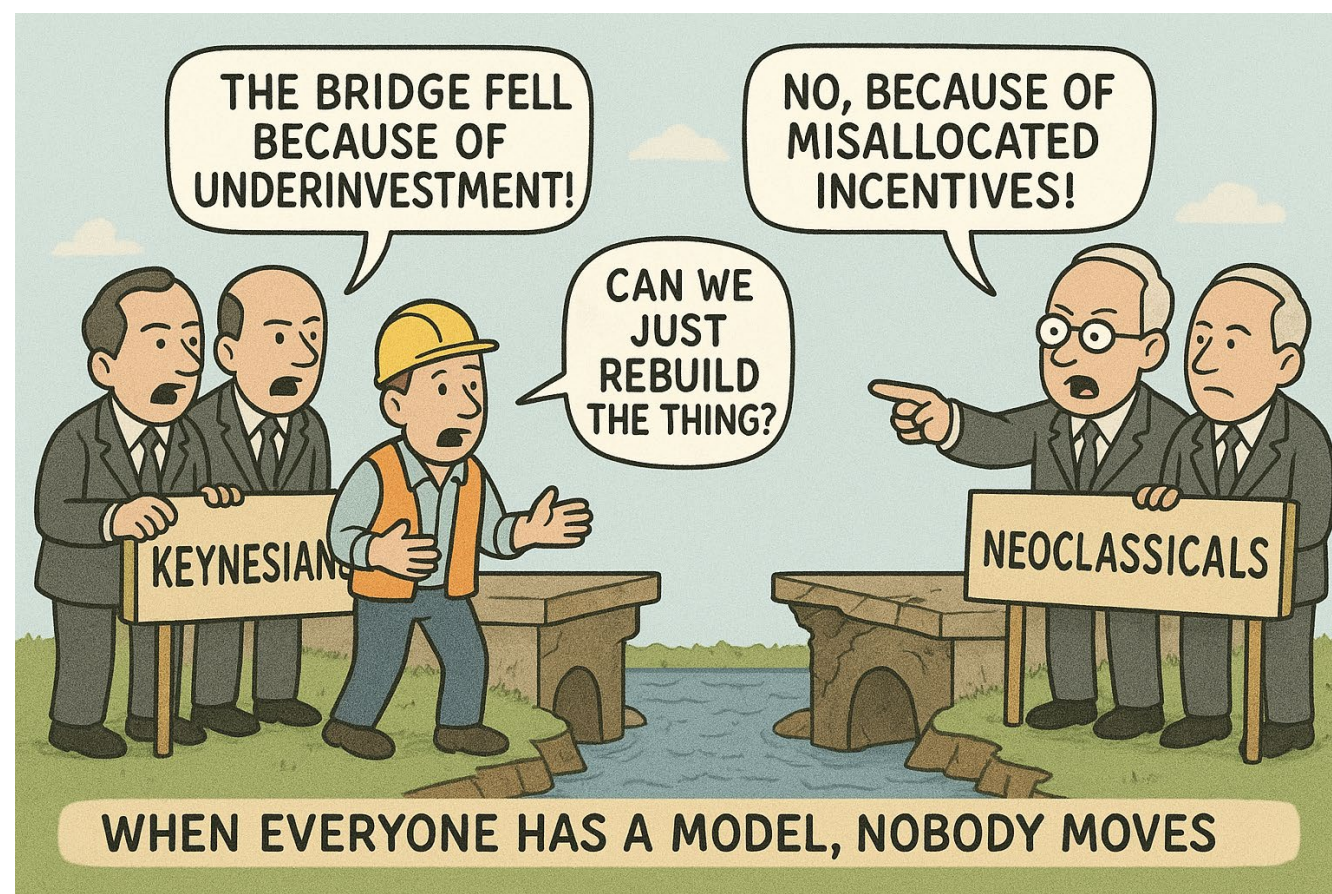
Glasgow, November 2025, ISPOR EU 25 conference

Disclaimers

- **Financial:** employee and owner of stocks in Merck & Co., Inc., Rahway, NJ, USA

- **Any perspective or opinion in this presentation...**
 - ...are presented on behalf of the ISPOR GAMI SIG's Global Differential Pricing Working Group
 - ...do not represent opinions by individual companies nor of industry

- **Not a health economist by training**
 - Trained as biochemist and genetic epidemiologist
 - Experience bias: worked in academia, at the World Health Organization (health statistics; policy), and in pharma industry (clinical development; medical affairs; HTA statistics)



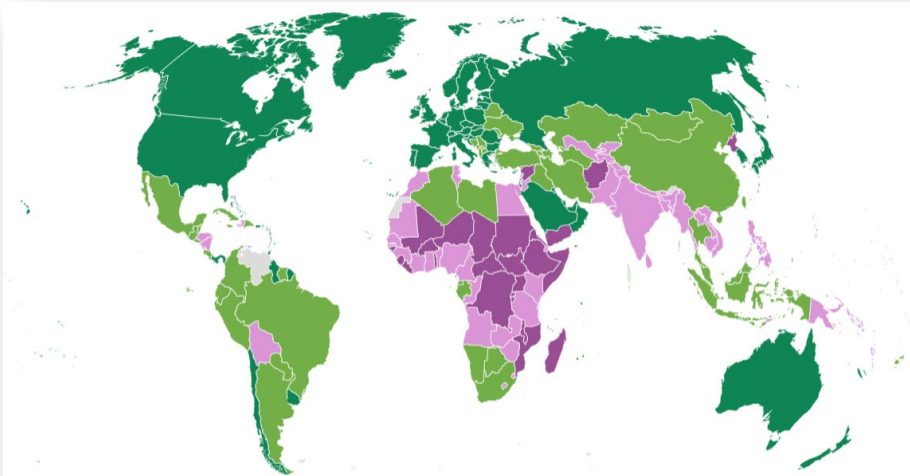
“America first need not put Africans last”



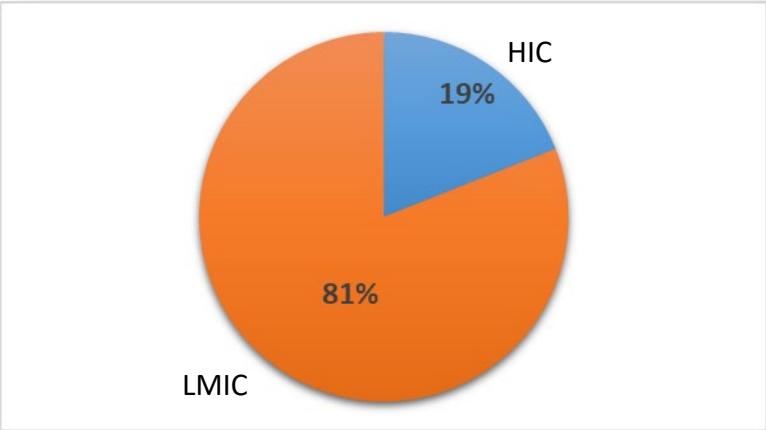
Editorial in The Economist, 30th October 2025.
In context of the US administration's global health approach

84% of the world’s population live in LMIC

81% of the global burden of disease from non-communicable diseases fall in LMIC

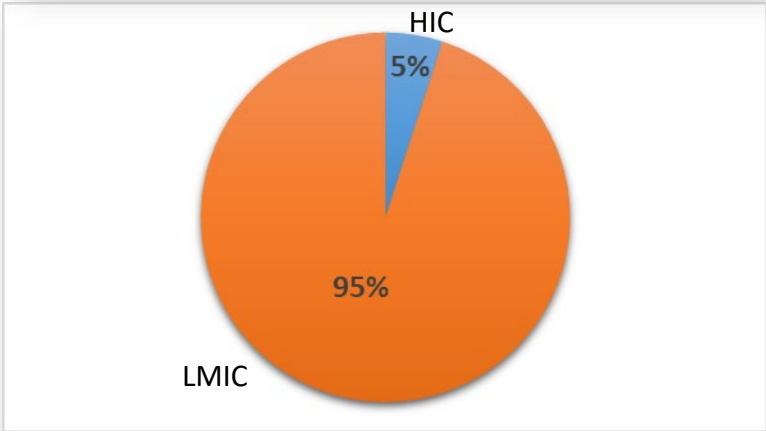


| | World Bank income group (2023) | #Countries | Population (2023) in billions |
|---|--------------------------------|------------|-------------------------------|
| ■ | High income | 86 | 1.26 |
| ■ | Upper middle income | 54 | 2.81 |
| ■ | Lower middle income | 51 | 3.25 |
| ■ | Low income | 26 | 0.74 |



Non-communicable diseases, global burden of disease¹

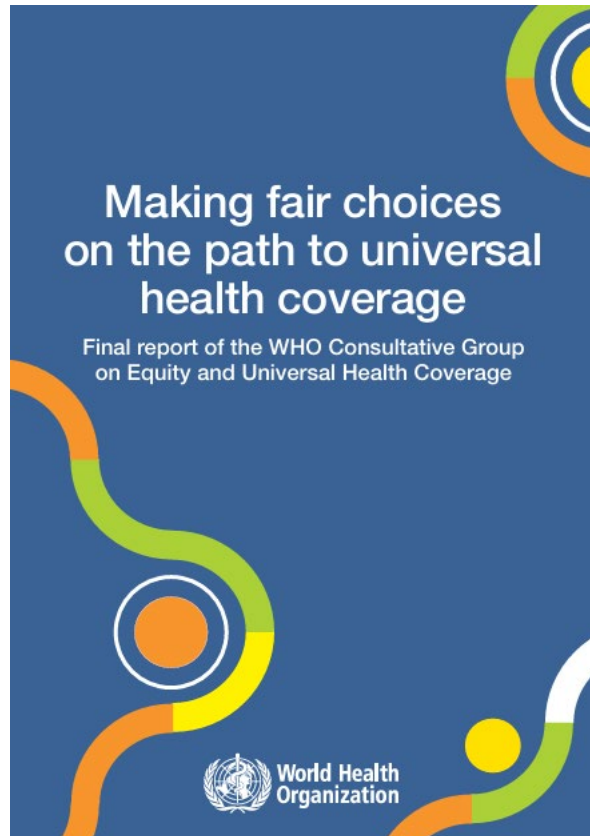
HIC: high income countries
LMIC: low- and middle-income countries



Communicable diseases², global burden of disease¹

¹ Figures developed based on the Global Burden of Disease (GBD) data from Data from IHME GBD (2024). Disease burden measured using Disability Adjusted Life Years (DALYs). Data accessed from OurWorldinData.org/burden-of-disease.

² includes: communicable, maternal, neonatal and nutritional diseases



WHO report, 2014. ISBN: 978 92 4 150715 8

Cost-effectiveness considerations argued as crucial for making fair progress toward universal health coverage together with considerations of the worse off and financial risk protection.

***Universal health coverage (UHC)** is achieved when all people receive the quality health services they need, without being exposed to financial hardship*

Polling question

How would you specify a cost-effectiveness threshold (CET)?

Decision context

- healthcare systems' assessment of innovative medicines
- other value elements are used together with the CET for decision-making

- a. Based on willingness-to-pay, that is, what expenditure ought to be for health gain (aspirational).
- b. Based on the estimated health opportunity cost in the healthcare system.
- c. Honestly, I don't understand or cannot differentiate willingness-to-pay from health opportunity cost.

“Top-down” vs. “bottom-up” approaches to global differential pricing.

Bottom-up: global differential pricing arise from local value-based assessment.



¹See e.g., www.efpia.eu/news-events/the-efpia-view/efpia-news/new-proposals-from-the-research-based-industry-can-reduce-inequalities-in-patient-access-to-medicines

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Reminder: we explored the “top-down” mechanism in past presentations by our ISPOR GAMI SIG Working Group (ISPOR 2024, ISPOR EU 2024)*

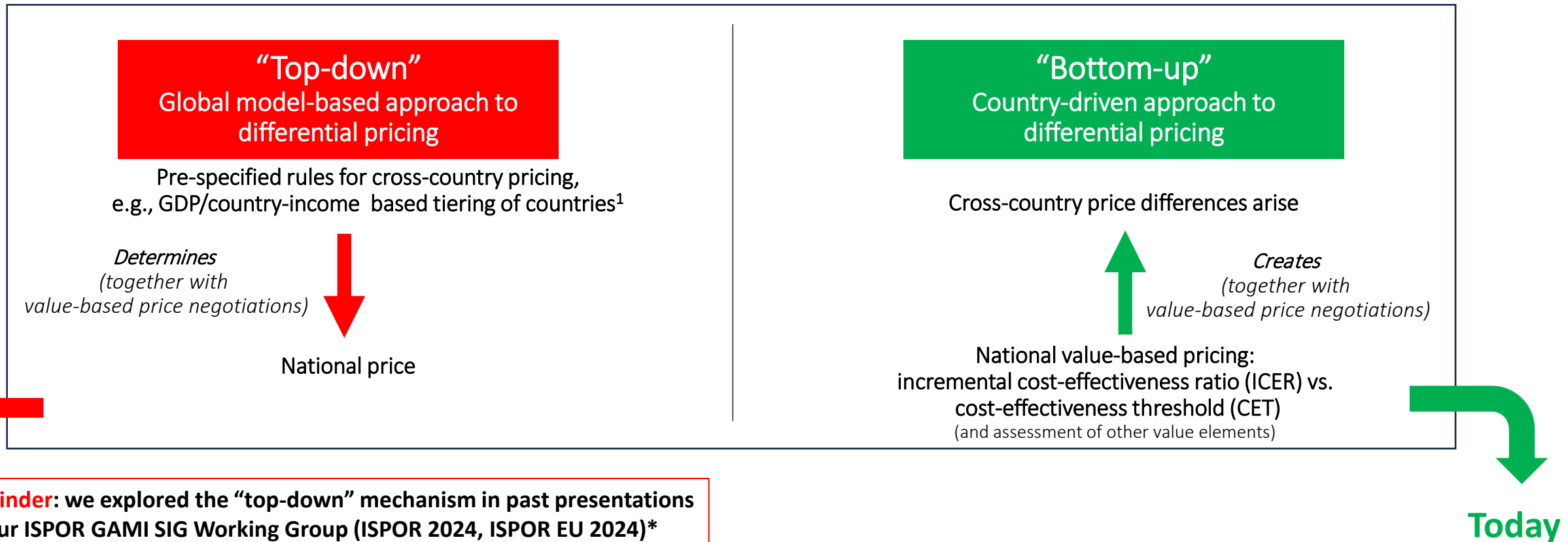
- Heavily dependent on broader societal and international political agreements, incl.: to what constitutes a fair pricing model; requires solidarity with price negotiation without ERP to lower Tiers; and requires a new international system for third-party monitoring.
- Across countries, the precise relationship between price and income levels cannot be predicted *a priori*².
- Variation per GDP (which violate a key assumption of mechanism): estimates suggest marked variation in health expenditure (% of GDP) and healthcare system efficiencies for similar income levels.

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Reminder:

conceptually, two different ways to specify the cost-effectiveness threshold (CET)

Willingness-to-Pay CET

Speaks to social value.

Reflects how much a payer or society is willing to pay per unit of health gain. Aim is to capture societal value but do not enforce budget feasibility.

Health opportunity cost CET

Enforces budget-constrained efficiency.

Reflects the health forgone when the health system (re)allocates limited budgets to fund a new intervention. A medicine is “cost-effective” if it produces more health than the health that would be displaced elsewhere*.

*In practice, as the precise intervention forgone typically unknown, estimates of health opportunity cost estimates are typically estimates of marginal productivity of healthcare expenditure

HOC vs. WTP cost-effectiveness threshold in context of LMIC

| | Health opportunity cost (HOC) | Willingness-to-pay (WTP) |
|---------|-------------------------------|--------------------------|
| Why | | |
| Why Not | | |

¹Chalkidou K et al. *Value-based tiered pricing for universal health coverage: an idea worth revisiting*. Gates Open Res. 2020. PMID: 32185365.

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⁶Edited by: Norheim et al. *Global health priority-setting. Beyond cost-effectiveness*. Oxford University Press. 2020

⁷Shafrin J, et al. *Valuing the Societal Impact of Medicines and Other Health Technologies: A User Guide to Current Best Practices*. Forum Health Econ Policy. 2024. PMID: 39512185

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ERP: external reference pricing.
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By Oestergaard, M at ISPOR EU on behalf of the ISPOR Global Differential Pricing Working Group, Nov 2025

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Why

- May better create sustainable market signals as signals (current) LMIC health need & affordability.¹
- May reduce ERP, compulsory licensing or abandonment of patents (as “countries pay what they can”).¹
- May better integrate into design of health benefit packages (HBP) with consideration of cost-effectiveness of individual/set of different services².
- If true opportunity cost known (of precise intervention replaced), may better address “low-hanging fruits” & HBP in LMIC, e.g., essential primary care, sanitation⁶.
- Within-country equity: may better protect the health of those relying on publicly financed essential service Displacing cost-effective services (often benefiting poor households) to fund expensive innovations can exacerbate inequities.
- Estimates suggest HOCs are markedly lower in LMIC vs. HIC, and at lower % of GDP than in HIC (“differential arise as needed”)³.

Why Not

- If true opportunity cost not known, HOC practice based on marginal productivity of healthcare expenditure may result in inefficient allocation, overall health reduction, and inequity.⁵
- Measurement challenges*: data, on marginal productivity often scarce/missing within LMIC, with structural and parameter uncertainties from cross-country estimates.^{3,5,6}

- May better capture dynamic considerations, e.g., new intervention may attract additional (external) funding, improve efficiency and/or catalyze economic growth.⁶
- May better capture broader societal and economic benefits/demand⁷.
- May better allow for different within-country (WTP) threshold, e.g., across diseases⁷.
- Political economy and donor funding: in settings with significant donor support, budgets are partially external. WTP—especially by donors or philanthropies—can influence feasible thresholds for specific disease area.

- WTP can be aspirational and may exceed budget envelopes⁶.
- May be more pronounced in LMIC with publicly funded health budgets that are often fixed (or slower to adjust)⁶.
- For global differential pricing, maybe more at risk of inappropriate proxies, e.g., country-income proxies, which make strong assumption, e.g., that all factors other than income and income-related preferences are invariant across countries (for second-best static and dynamic efficiency).⁴
- Estimates suggest that HOC (proxies) well below 1xGDP-per-capita for most LMIC^{3,8}.

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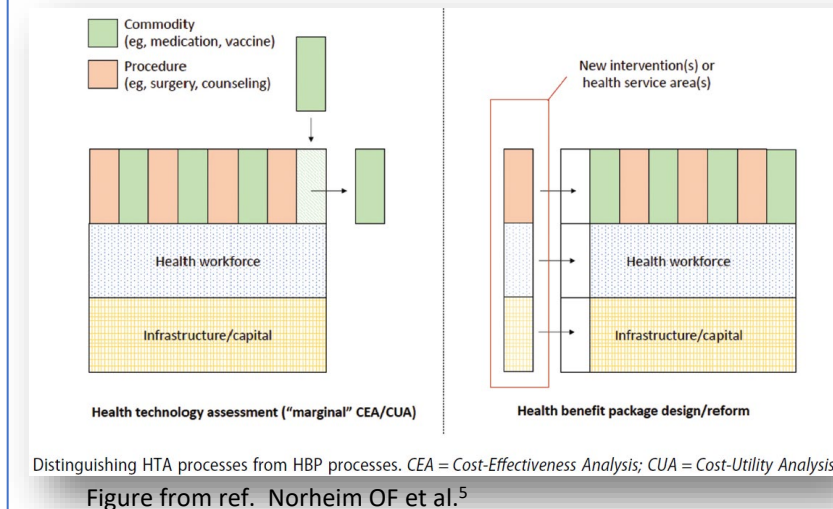
Currently, how do LMICs use HTA to assess local value of new health technologies?

Some key (global differential pricing relevant) insight from recent cross-country studies by the WHO, iDSI, and DCP-4^{1,2,3,4}

Some key Insight

- **Lack of capacity & institutionalization:** many countries lack capacity to conduct HTA or do not use HTA in their assessments to inform policy decisions
 - 53% of countries have a legislative requirement to consider HTA results in coverage decisions⁴
 - 39% of countries have a link between their decisions on health benefits package coverage and an HTA process⁴
 - 19% of countries use an officially endorsed cost-effectiveness threshold in their HTA⁴
 - The three top barriers to the use of HTA: awareness of the importance of HTA (36% of countries); institutionalization (17%); political support (11%)⁴
- **Transferability challenges:** Countries that perform HTA may use cost-effectiveness from global literature that may poorly transfer to local decision-making - partly due to different local comparator, epidemiology and pricing context¹
- **Some current trends:**
 - **Local accountability and ownership:** “aid localization” to build local institutions for health priority-setting^{2,3}
 - **Agile leap-frogging for building local HTA^{2,3}, incl.,: use of “adaptive HTA”²; and the regionalization of HTA** to tackle common cross-country limitations (incl., data scarcity, capacity, structure) and to reduce barriers to entry and lower the cost of setting up HTA (e.g., Africa CDC)^{1,2,3,.}
 - **Proposals for combining HTA and health benefit packages elements, e.g., “hybrid” or “compartmentalized”⁵**
 - **Countries encouraged/supported to move from GDP-based to opportunity cost-based cost-effectiveness²**

Health benefit packages: a set of services that can be feasibly provided given a particular country or area’s health systems characteristics and financial situation⁴



¹Alwan A, et al., eds. Vol 1: *Country-Led Priority-Setting for Health. Disease Control Priorities, Fourth Edition*. The World Bank Group 2025. <https://dcp4.w.uib.no/volumes/volume-1-country-led-priority-setting-for-health>

²Baker P, et al. *International Partnerships to Develop Evidence-informed Priority Setting Institutions: Ten Years of Experience from the International Decision Support Initiative (iDSI)*. Health Syst Reform. 2023. PMID: 38715199.

³Guzman J et al., *The Future of Health Technology Assessment in Low- and Middle-Income Countries*. Health Syst Reform. 2023. PMID: 39466901.

⁴WHO. *Health Technology Assessment and Health Benefit Package Survey 2020/2021*. www.who.int/teams/health-systems-governance-and-financing/economic-analysis/health-technology-assessment-and-benefit-package-design/survey-homepage

In WHO study, the term HTA is used to refer to any systematic, formal decision-making process regardless of whether respondents report that the process is formally named as such.

⁵Norheim OF et al. *The Role of HTA for Essential Health Benefit Package Design in Low or Middle-Income Countries*. Health Syst Reform. 2023 PMID: 37948391.

The ISPOR Global Differential Pricing Working Group

- Seeks to generate insight & dialog to improve understanding & “best-practice” for global differential pricing of innovative health technologies
- Part of the ISPOR Special Interest Group (SIG) on Global Access to Medical Innovation (GAMI)
- Currently has 10 members covering pharma, consultancies, venture capital, academia
- Complements the work of other international collaborations to improve access to medical innovation
- Key activities / deliverables shown below

QR code to access ISPOR GAMI SIG website for global differential pricing working group

Reach out (experience, suggestions, questions):
Coordinator: Maddie Shipley: mshipley@ispor.org



Current activities
in green boxes

Literature reviews

- Proposed differential pricing mechanisms
- Learnings from vaccines
- Learnings from infectious disease
- Risks, incl., ERP, product arbitrage

What are key requirements?

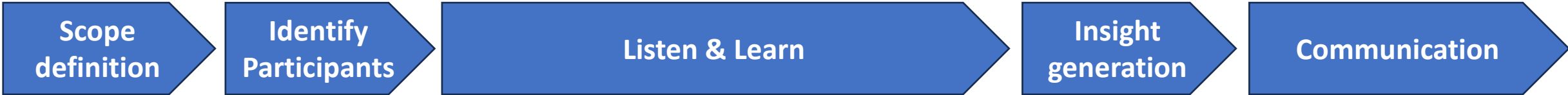
- Targeted stakeholder discussions

Survey of pharma companies

- Understand current practice & policies

Publication

- Conferences
- Manuscripts



Start of Working Group:
Q3 2024

Share early insight*, poll, create dialog, incl.,

- Conference presentations (ISPOR, Access EU)
- Conference Q&A, discussions, GAMI SIG Forums
- Polling / survey audiences at conferences

Further sharing, incl.,

- ISPOR webinars

* Focus of ISPOR 2024 Global and ISPOR EU presentations: outline of economic theory, patient access lag and need in LMIC, key challenges for global differential pricing, and outline of illustrative GDP-based tiered pricing models to stimulate dialog, and outline of key literature (please reach out if you want a copy of presentations)

Take-away messages

Making fair progress toward UHC requires consideration of cost-effectiveness, the worse off and financial risk protection⁵.
How do we integrate it into a global differential pricing mechanism?

Think locally: a global differential pricing mechanism may better arise locally (“bottom-up” over “top-down”), and be based on HOC (vs. WTP) and other relevant value elements^{1,2}

- A bottom-up mechanism is less dependent on international political agreements, structures and monitoring³.
- A top-down may not be appropriate (e.g., country-income based tiering of countries)^{4,5} given variation in LMIC healthcare systems efficiency and health spending.
- A HOC-based mechanism (vs. a WTP-based) may better address required decision context in LMIC¹, but in-country data sparsity and limitations of currently available cross-country estimates of HOC risk exacerbating efficiency, health and equity¹¹.
- The published “Value-Based Tiered Pricing”¹ and “Value-Based Differential Pricing”⁶ both start locally but differ in their anchor (HOC vs. WTP, respectively).
- Local HTA capacity and local data sparsity are (among) the key bottlenecks for use of bottom, value-based global differential pricing mechanisms⁷.
- A bottom-up mechanism is however dependent on agreements between health economists on HOC vs. WTP cost-effectiveness thresholds³.

Go hybrid: a global differential pricing mechanism likely need to be “hybrid”, e.g.,

- For potential in-country segmentation in LMIC: HOC could guide public formulary decisions, and WTP could inform private-pay segments or donor-funded program^{1,5}.
- For potentially combining HTA and HBP elements in LMIC⁸.
- Potentially to adapt different global differential pricing solutions over the product lifecycle.
- For potential incorporation of new measures of HIC vs. LMIC considerations, e.g., countries varied contribution to the joint cost of innovation⁹
- Better understanding of impact on static and dynamic efficiency, equity and health displaced in LMIC through pilots / modeling/ simulations required, e.g., exploring price x volume x reach x time^{10,11}.

Stay tuned! Work in progress by the ISPOR GAMI SIG Working Group on Global Differential Pricing

- Please speak up to strengthen efforts. Share your experience, perspective, questions

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⁵Edited by: Norheim et al. *Global health priority-setting. Beyond cost-effectiveness*. Oxford University Press. 2020

⁶Danzon P et al.. *Value-based differential pricing: efficient prices for drugs in a global context*. Health Econ. 2015. PMID: 24327269.

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HOC: health opportunity cost; LMIC: low- and middle-income countries; WTP: willingness-to-pay threshold

HBP: health benefit package; HIC: high-income country; HOC: health opportunity cost; LMIC: low- and middle-income countries. UHC: universal health coverage.; WTP: willingness-to-pay