Context-Appropriate Medical Device Innovation

Cultural & Contextual Considerations for MedTech Innovation

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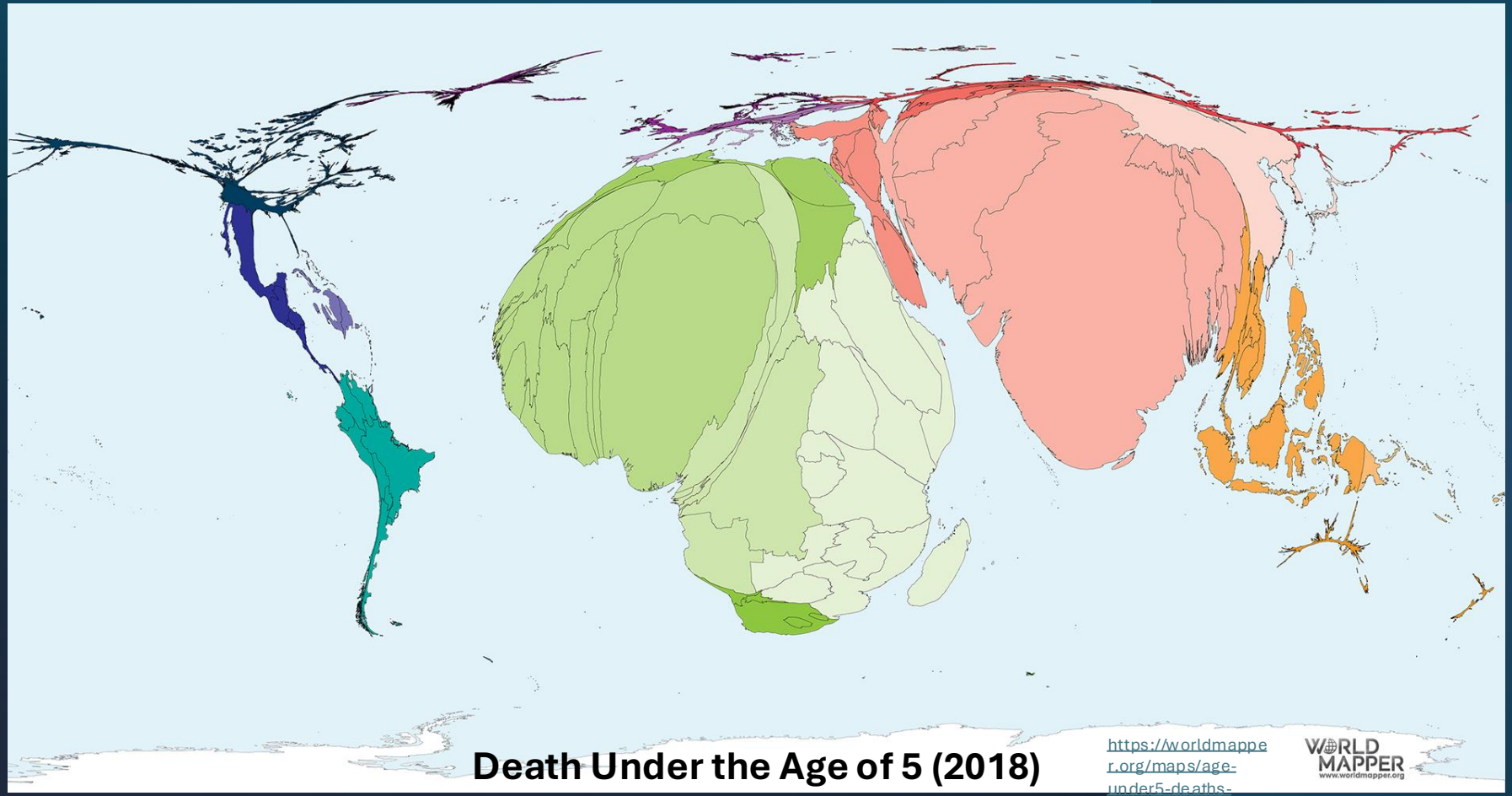
Lack of appropriate technologies affects delivery of healthcare

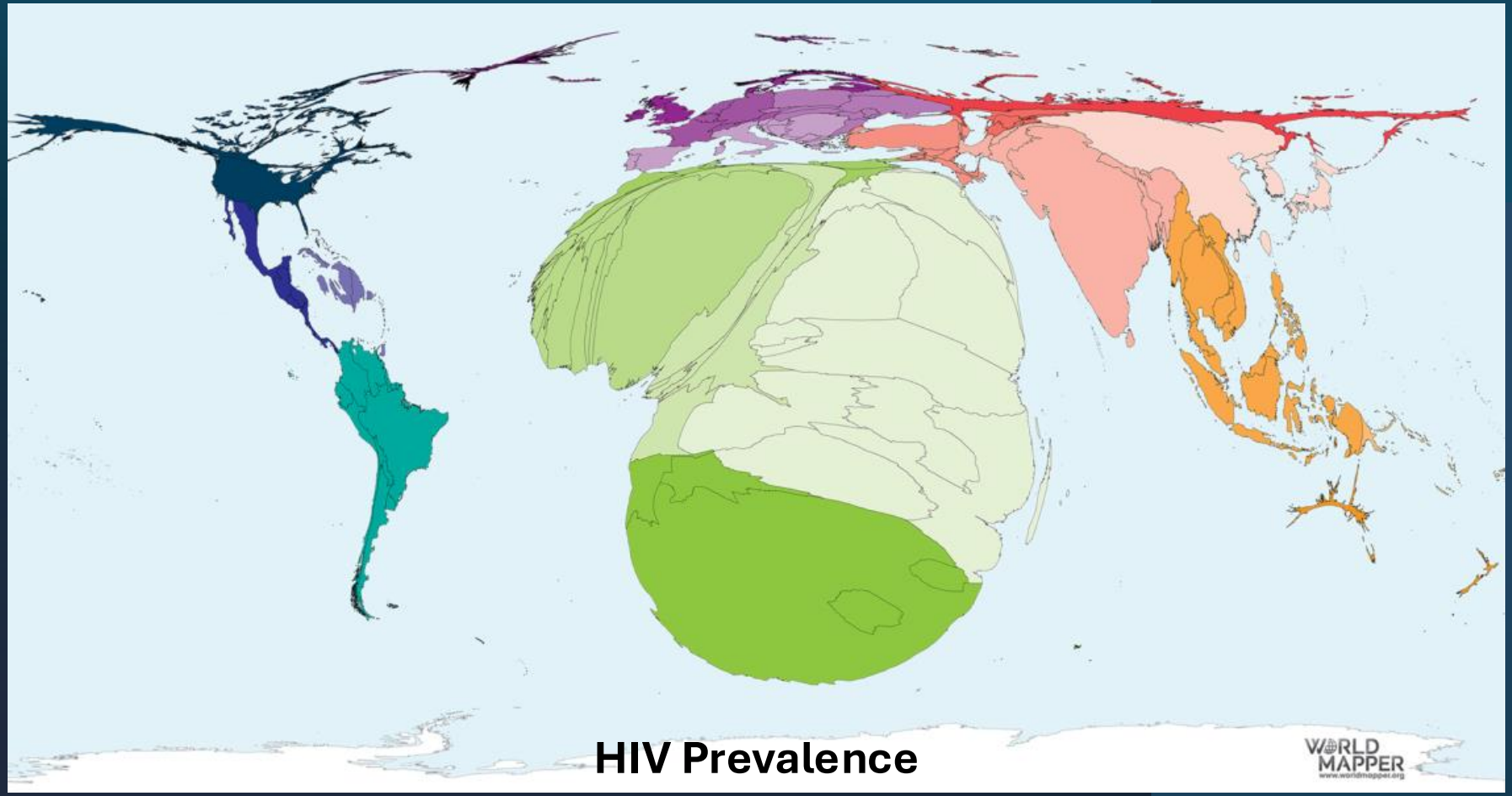
2 out of 3 people globally lack access to essential medical technologies

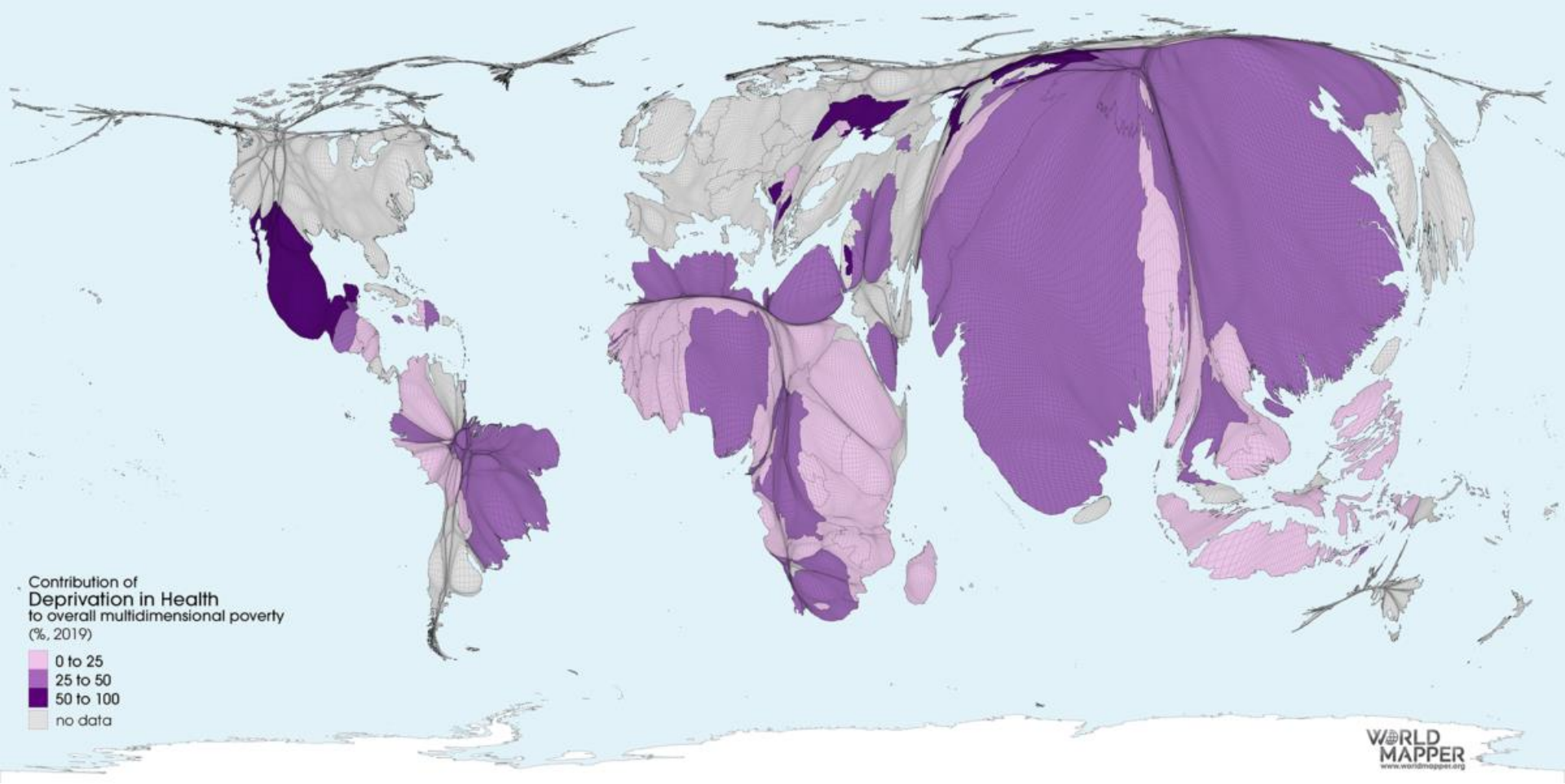


Death Under the Age of 5 (2018)

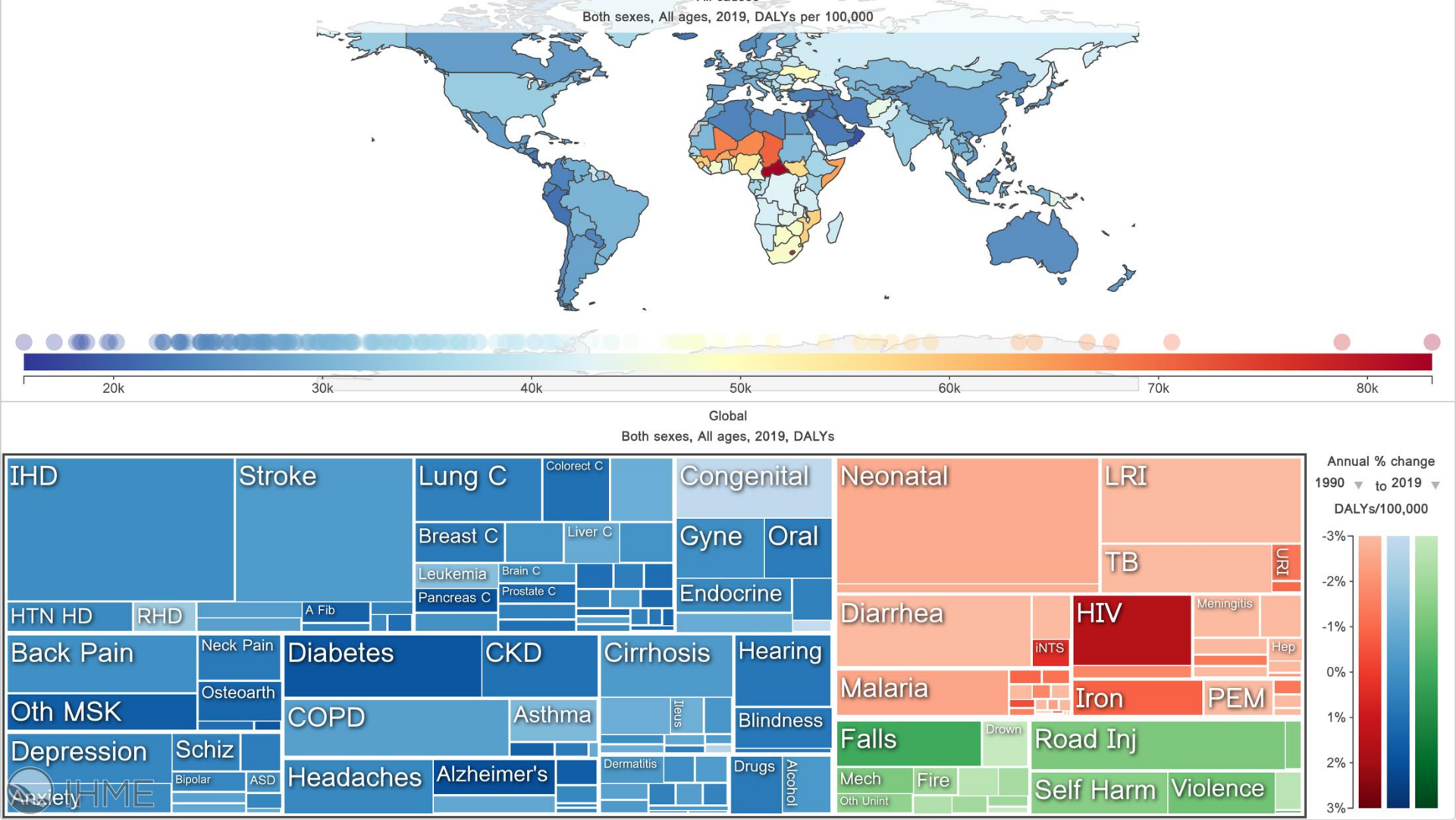
https://worldmapper.org/maps/age-under5-deaths-2015/

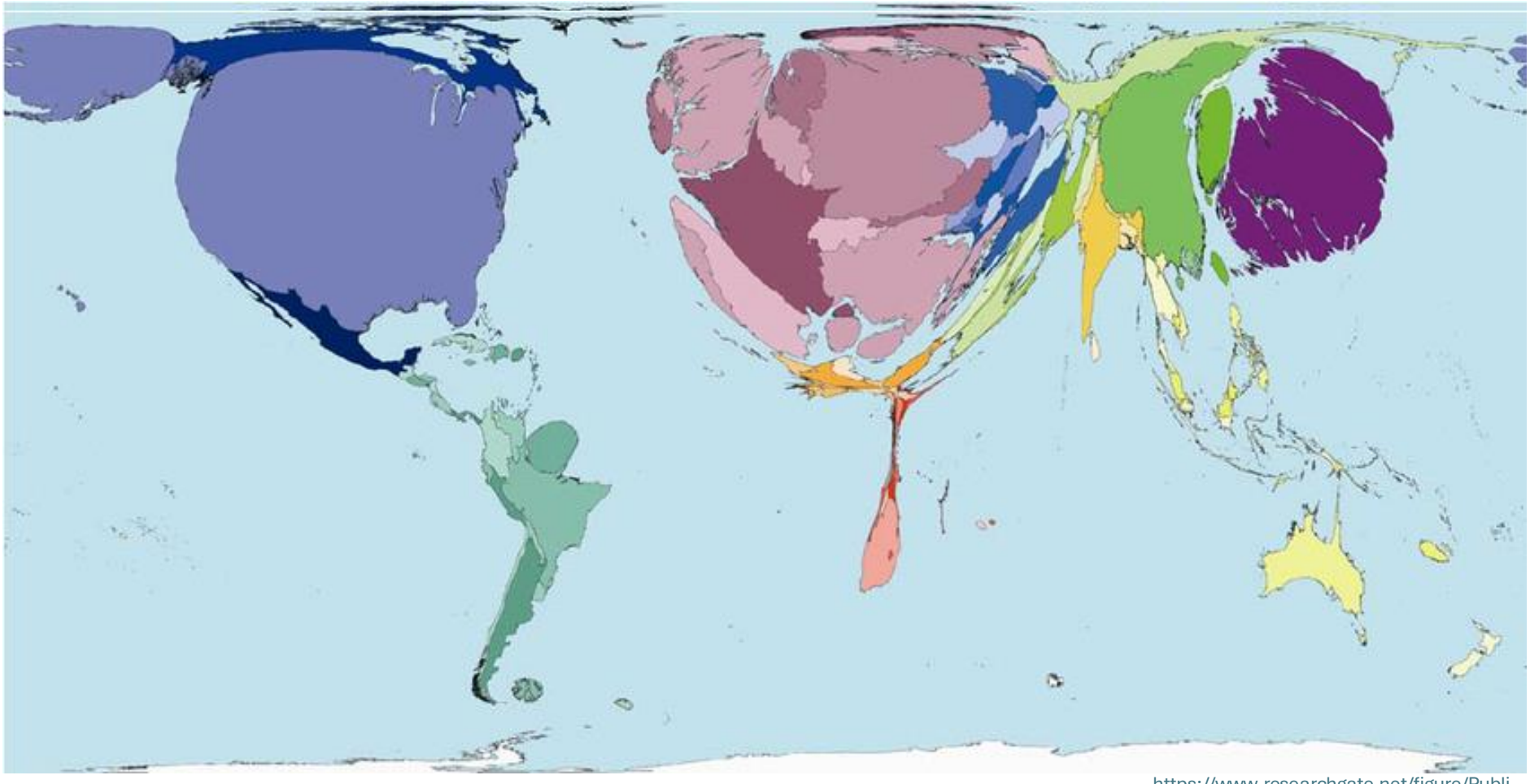
WORLD MAPPER
www.worldmapper.org


HIV Prevalence
WORLD MAPPER
www.worldmapper.org



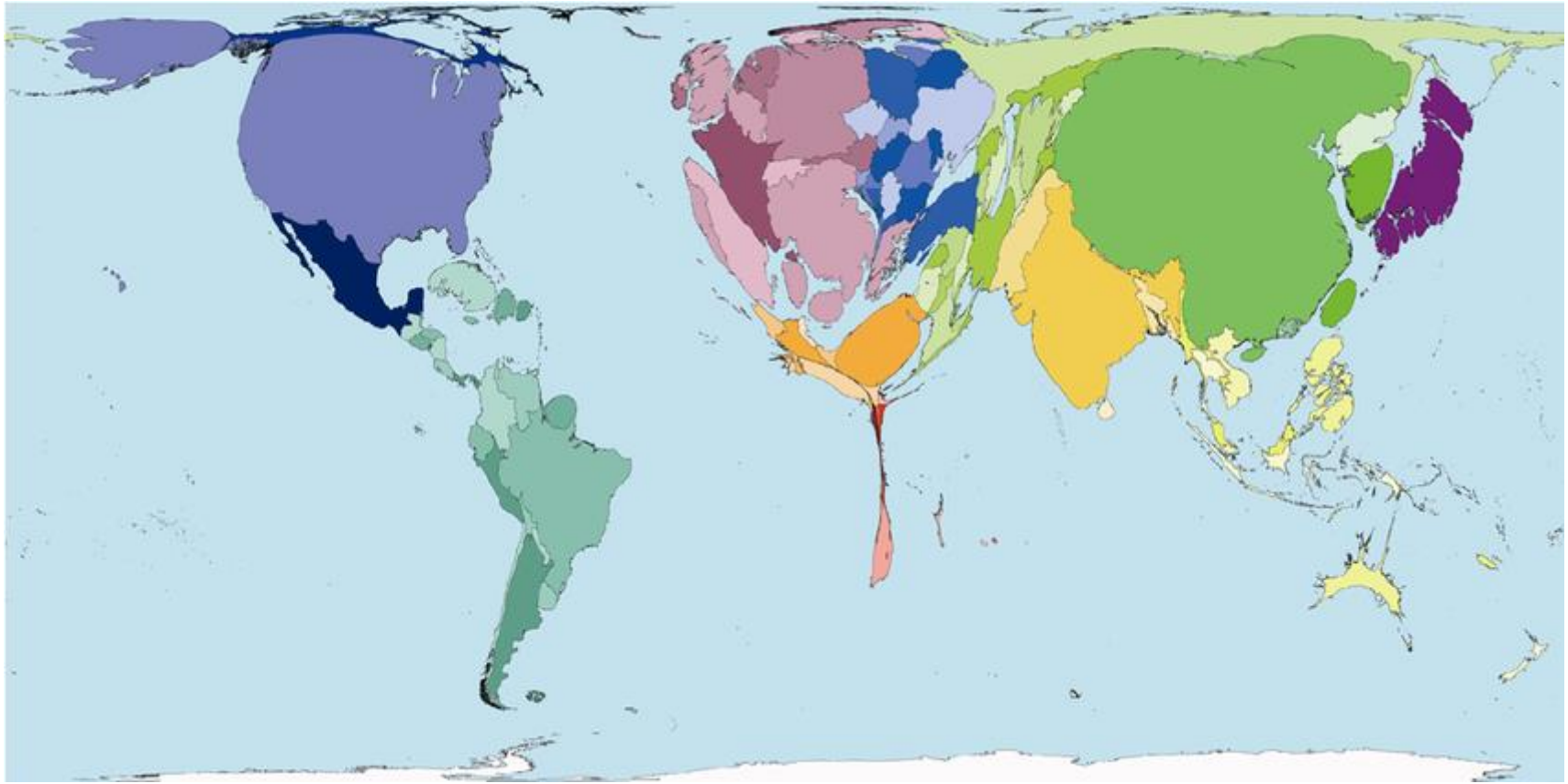
Contribution of Deprivation in Health to overall Multidimensional Poverty


Both sexes, All ages, 2019, DALYs per 100,000
20k
30k
40k
50k
60k
70k
80k
Global
Both sexes, All ages, 2019, DALYs
IHD
Stroke
Lung C
Colorect C
Congenital
Neonatal
LRI
Breast C
Liver C
Gyne
Oral
TB
URI
Leukemia
Brain C
Pancreas C
Prostate C
Endocrine
HTN HD
RHD
A Fib
Diarrhea
iNTS
HIV
Meningitis
Hep
Back Pain
Neck Pain
Diabetes
CKD
Cirrhosis
Hearing
Malaria
Iron
PEM
Osteoarth
Oth MSK
COPD
Asthma
Ileus
Blindness
Falls
Drown
Road Inj
Depression
Schiz
Bipolar
ASD
Headaches
Alzheimer's
Dermatitis
Drugs
Alcohol
Mech
Fire
Self Harm
Violence
Anxiety
Oth Unint
Annual % change
1990
to 2019
DALYs/100,000
-3%
-2%
-1%
0%
1%
2%
3%



Global Health Care Spend

https://www.researchgate.net/figure/Public-Health-Spending-Worldmapper-Poster-213_fig1_6411307



Physicians Working

https://www.researchgate.net/figure/Public-Health-Spending-Worldmapper-Poster-213_fig1_6411307

Innovation fails

The reasons your innovations fail and how to overcome the issue

Product Innovation fails

[Product Innovation: 95% of new products miss the mark | MIT Professional Education]


When there is no eco-system….

The Global MedTech Challenge

90%

of medical devices are designed
for high-income settings

80%

of the global population lives
in low- and middle-income countries

This mismatch creates a critical innovation gap — devices that work in well-resourced hospitals often fail in the environments where they are needed most.

What Is Context-Appropriate Innovation?

Context-appropriate innovation goes beyond making devices “cheaper.” It means designing health technologies that are fundamentally aligned with the clinical realities, cultural norms, infrastructure constraints, and health system architectures of the communities they serve.

Clinical Reality

Disease burden, PHC workflows

Cultural Fit

Beliefs, practices, language

System Alignment

Supply chains, training, maintenance

Key Principle

Design WITH communities, not FOR them.

Co-creation ensures relevance, adoption, and sustainability.

Part 1: Cultural Considerations

Understanding the human dimensions of MedTech adoption

Cultural Determinants of Device Acceptance

Health Beliefs & Traditional Medicine

Many communities integrate traditional healing with biomedical care. Device design must respect and complement existing health-seeking behaviours rather than replace them.

Gender & Power Dynamics

Who in the household decides about healthcare? Women's autonomy in health decisions varies widely, influencing device acceptance for maternal and reproductive health.

Language & Health Literacy

Interfaces, instructions, and training materials must be accessible in local languages and appropriate literacy levels — pictographic instructions often outperform text.

Stigma & Social Perception

Conditions like epilepsy, HIV, and mental health carry stigma in many contexts. Discreet, non-stigmatising device design significantly improves compliance.

Infrastructure Constraints in LMICs

Unreliable Power Supply

Load shedding, diesel generators, solar variability. Devices must operate on battery, tolerate power fluctuations, or function without electricity entirely.

Limited Cold Chain

Temperature-sensitive diagnostics and reagents require cold storage that may not exist beyond district hospitals. Design for ambient conditions.

Harsh Environments

Dust, humidity, extreme heat, limited climate control. IP ratings and robust materials are not luxuries — they are necessities.

Connectivity Gaps

Many PHC facilities lack reliable internet. Cloud-dependent devices fail. Prioritise offline-first with opportunistic sync capabilities.

Designing for Primary Healthcare (PHC)

PHC is the first point of contact for the majority of patients in Africa and other LMIC settings. Devices designed for tertiary hospitals rarely survive the realities of district clinics and community health posts.

1

Task-Shifting Readiness

Devices must be operable by community health workers and nurses, not only by specialist physicians. Simplified workflows and built-in decision support are essential.

2

Maintenance & Repair

The WHO estimates 40–70% of medical equipment in developing countries is non-functional. Design for local repair with available components and minimal specialised tools.

3

Supply Chain Integration

Consumables and spare parts must be sourced through existing procurement systems. Proprietary lock-in creates dependency and ultimately device abandonment.

Navigating the Regulatory Landscape

Regulatory pathways in LMICs are evolving rapidly. Context-appropriate innovation requires navigating fragmented systems while maintaining quality and safety standards.

Challenges

- Fragmented regulatory frameworks across African nations
- Limited local testing and certification facilities
- Reliance on CE/FDA markers not designed for LMIC contexts
- Long approval timelines discouraging local innovators

Emerging Solutions

- African Medical Devices Forum (AMDF) harmonisation
- AMTZ collaboration for testing & certification in India
- WHO prequalification pathways for priority devices
- Target Product Profiles (TPPs) guiding market entry

Target Product Profiles for LMIC Markets

TPPs define minimum and optimal specifications that a device must meet for a specific use case in a specific context. They bridge the gap between clinical need and engineering requirements.

TPP Dimension	HIC Default	Context-Appropriate Target
Power source	Mains electricity (stable)	Battery / solar / hand-powered
Operator skill	Specialist physician	CHW / nurse with brief training
Maintenance	Biomedical engineer on-site	Self-diagnostic; local repair
Consumables	Proprietary, cold-chain	Locally sourced, ambient stable
Connectivity	Always-on internet	Offline-first, SMS/USSD fallback
Cost target	$5,000–$50,000+	<$500 (device) + <$1/test

AI & Digital Health: Bridging the Adoption Gap

The AI Adoption Gap

AI-powered medical devices promise transformative diagnostics — but algorithmic bias, data scarcity, and digital infrastructure gaps create a widening adoption divide between HICs and LMICs.

Without deliberate contextualisation, AI risks amplifying existing health inequities rather than reducing them.

Data Representation

Training datasets overwhelmingly from HIC populations. Skin lesion classifiers fail on darker skin tones; chest X-ray AI trained on Western demographics.

Edge Computing

AI models must run locally on low-spec hardware. Cloud-dependent solutions fail where connectivity is unreliable.

Explainability

Clinicians in LMICs need to understand and trust AI recommendations. Black-box models face resistance from healthcare workers.

10 Principles for Context-Appropriate MedTech

1. Design with, not for — co-create with end users and communities
2. Understand the full patient journey, not just the clinical encounter
3. Prioritise robustness over sophistication — it must survive the environment
4. Plan for maintenance from Day 1 — design for local repair
5. Respect cultural health beliefs and integrate with existing practices
6. Build for task-shifting — empower CHWs and nurses as primary operators
7. Ensure offline functionality — connectivity is a bonus, not a requirement
8. Use Target Product Profiles to define context-specific specifications
9. Pursue regulatory harmonisation while advocating for LMIC-relevant pathways
10. Measure real-world patient impact, not just technical performance

Thank You

"The best medical device for Africa is one that Africa helps design."

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