Appropriate Access to Existing and Novel Antibiotics

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National Academies of Science, Engineering and Medicine

March 2024

GARDP

Global Antibiotic Research & Development Partnership

GARD P
Global Antibiotic Research & Development Partnership

Our Vision

All infections are treatable for everyone, everywhere

Our Mission

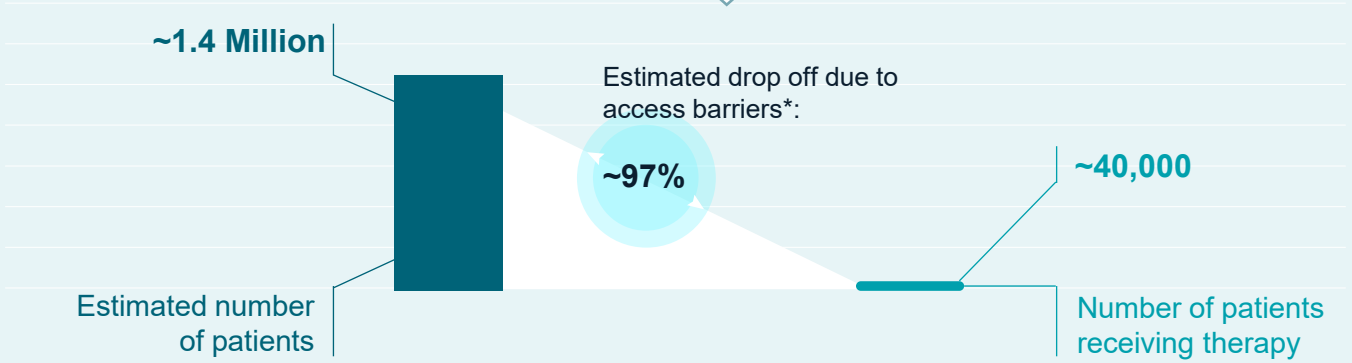
We work with partners to **accelerate the development and access to treatments** for drug-resistant infections

Challenges prevent sustainable access to life-saving antibiotics

KEY ACCESS HURDLES

- Lack of appropriate evidence to inform optimal use of antibiotic treatments
- Lack of interest from suppliers to commercialize antibiotics
- Lack of registration in LMICs**
- New antibiotics are priced out of reach
- Poor uptake systems, weak stewardship and lack of adequate & timely diagnosis

Above country | In-country

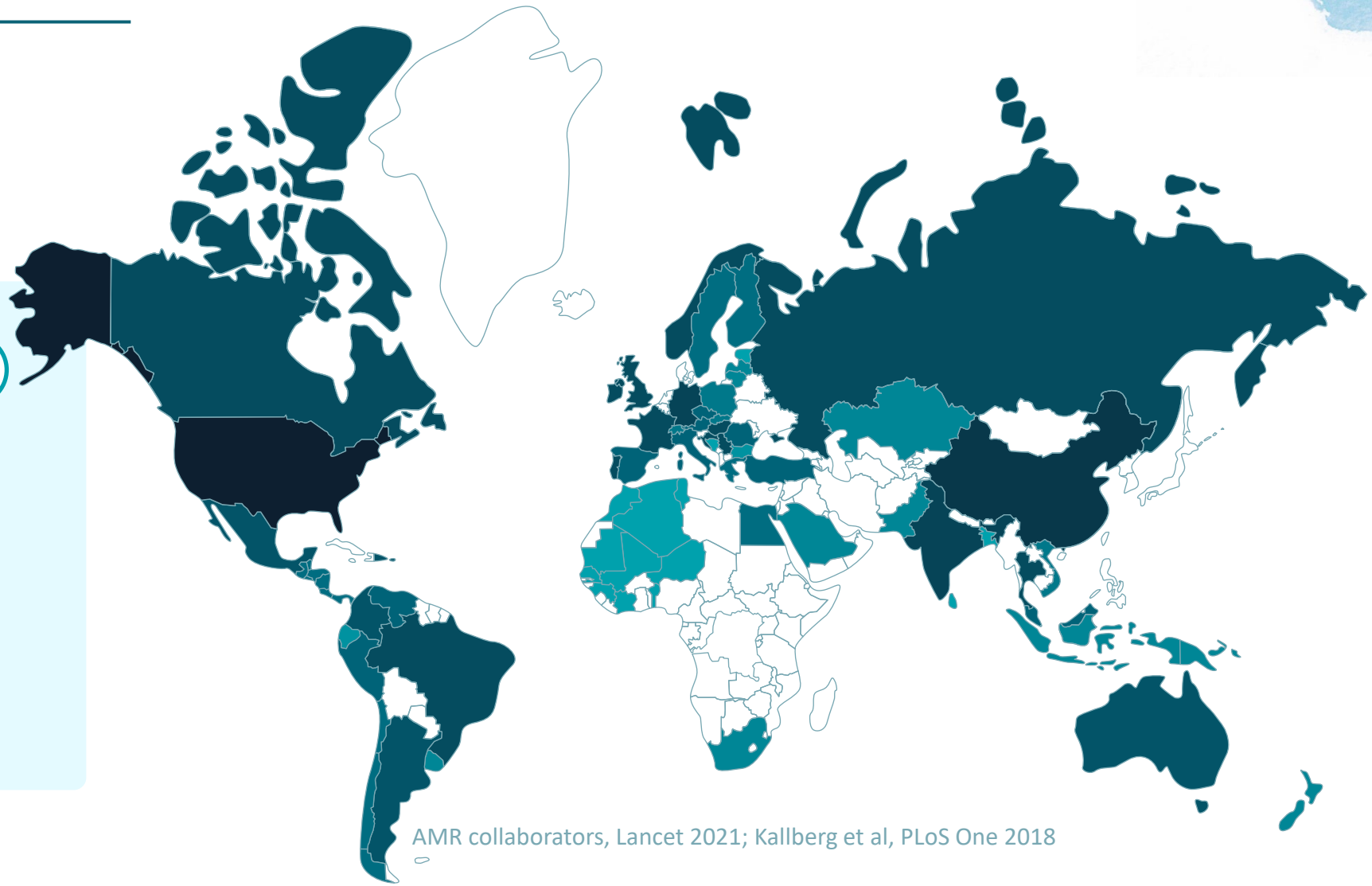


*Using estimates from 2019 GRAM study (published in Lancet), we have calculated the access levels for Carbapenem resistant bacterial infections in South Asia

Registration: Availability does not match burden

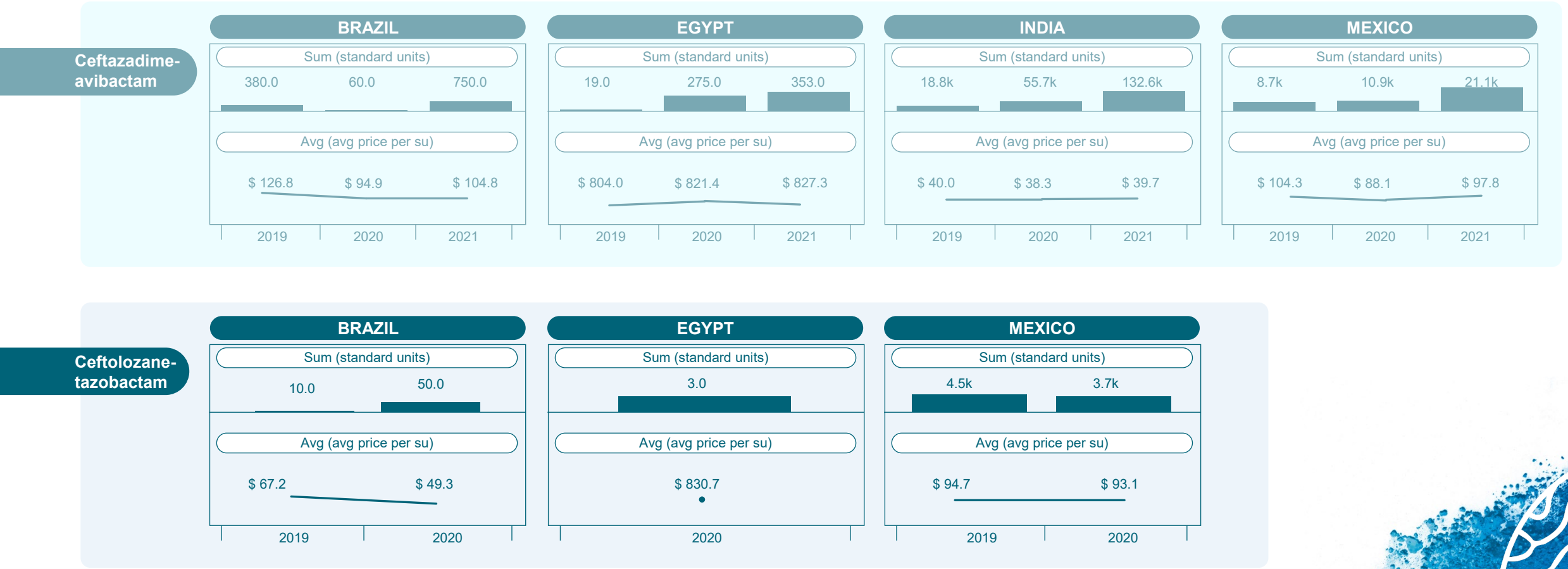
Not widely registered

Number of antibiotics registered 1999-2014

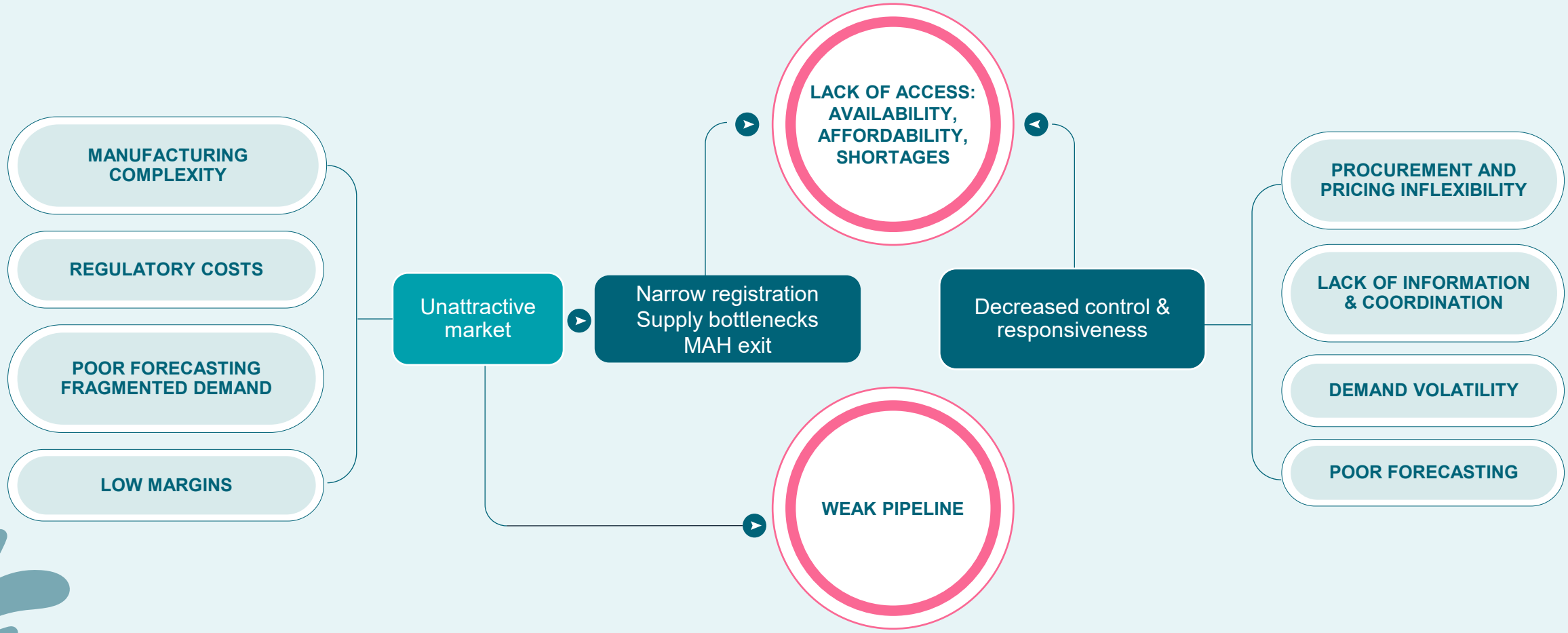


AMR collaborators, Lancet 2021; Kallberg et al, PLoS One 2018

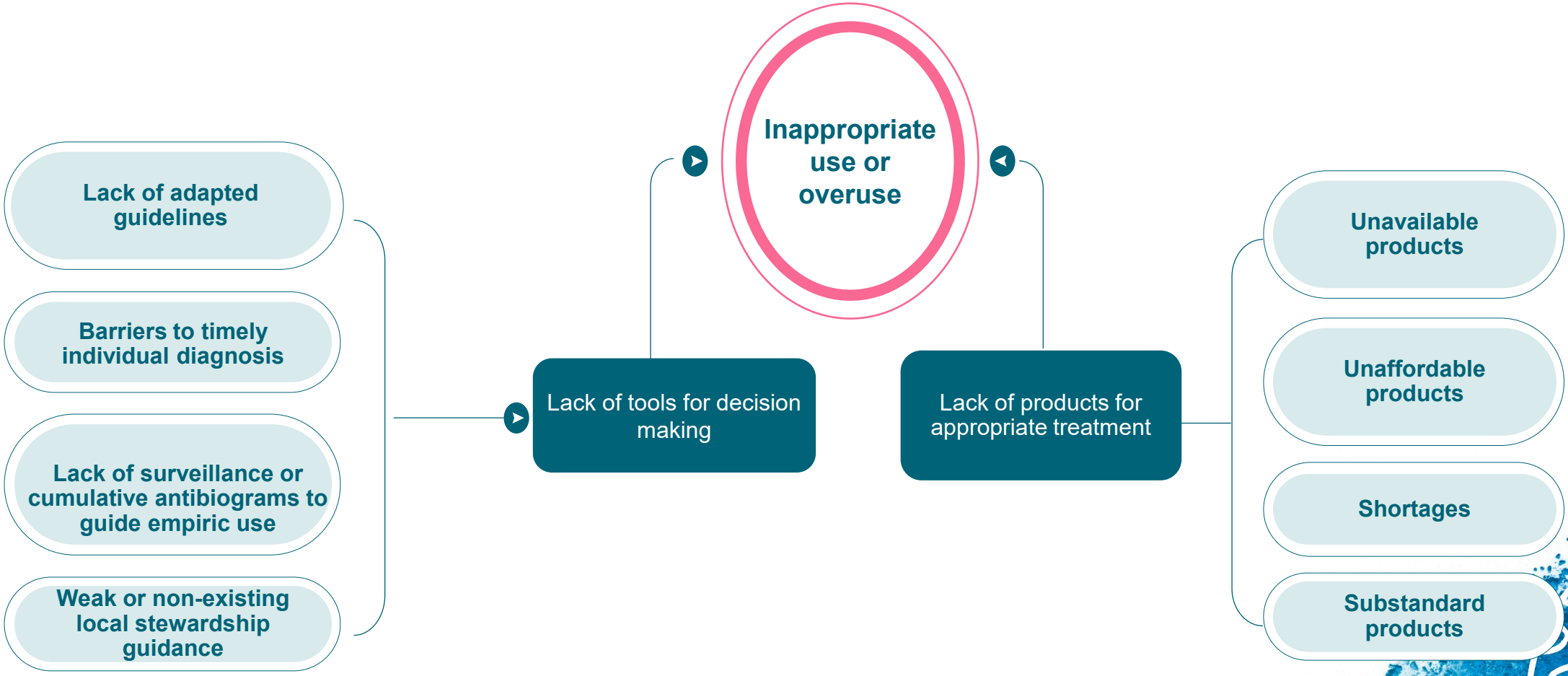
Prices: High and variable for on-patent newer Reserve antibiotics (price in USD per vial)



Supply and demand-side barriers: A multi-faceted problem

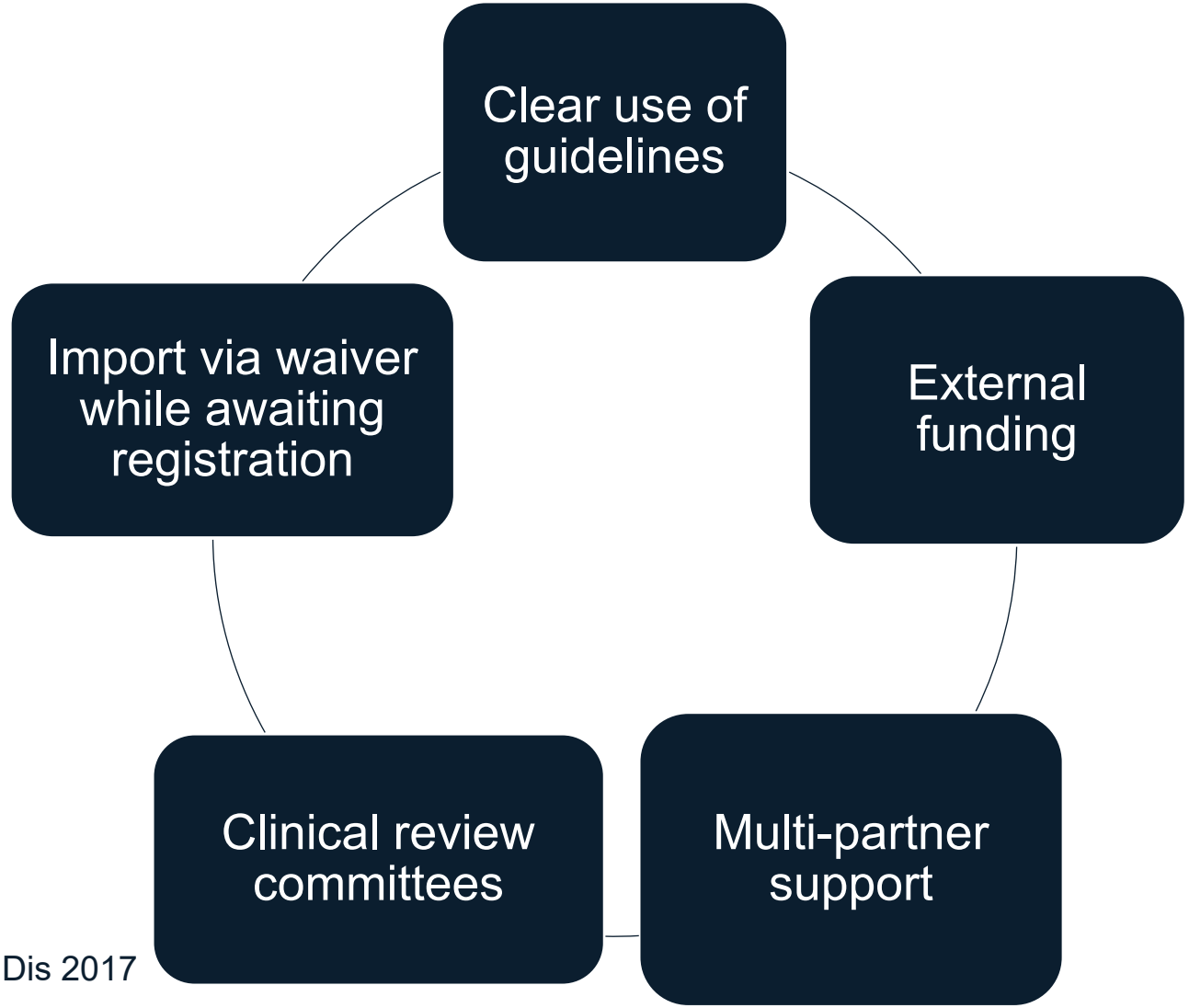


Access and stewardship are linked



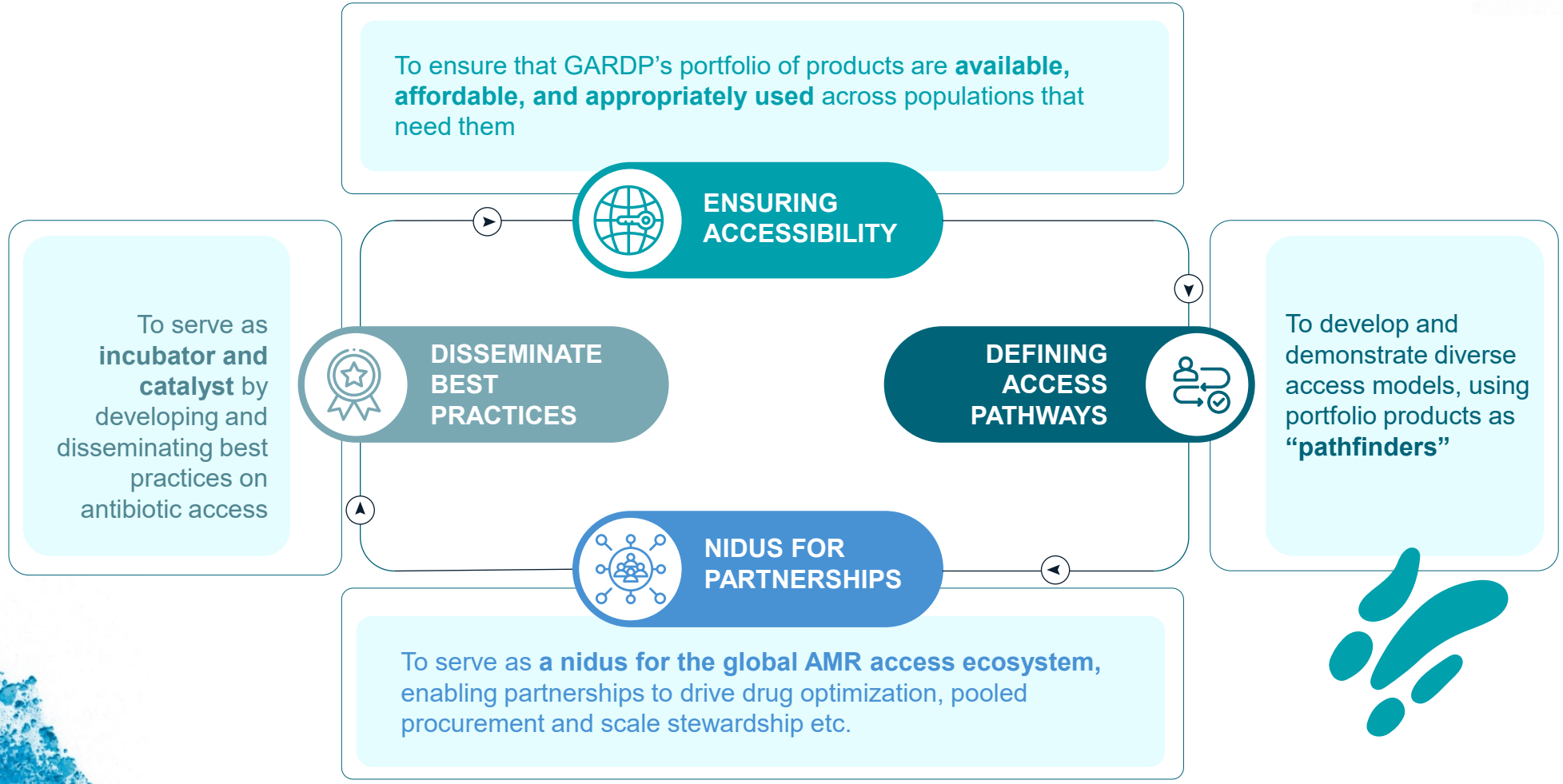
Improving appropriate access

What can we learn from MDR tuberculosis: Bedaquiline introduction and appropriate use



Guglielmetti et al. Int J Tuberc Lung Dis 2017

GARDP's vision for access



Case Study 1

Cefiderocol:
A pathfinder project addressing serious bacterial infections

A breakthrough licensing agreement and comprehensive access program

A "first-of-its kind" licensing agreement signed between Shionogi & GARDP* in June 2022 to improve access to cefiderocol in 135 countries, mostly low- and middle-income, can pave the way for sustained, stewardship driven access to this and establish a pathway for other novel antibiotics.

Manufacturing
Affordable and quality-assured products from a licensed manufacturer

Registration
Support for commercialization in high-burden countries

Implementation
Partnerships to co-develop and introduce robust implementation plans

Guidelines
Evidence-based guidance to steward appropriate use

*In addition to the licensing agreement signed between Shionogi & GARDP, we also signed a 3-way collaboration agreement with Clinton Health Access Initiative (CHAI) to drive the execution against the above-mentioned objectives

Cefiderocol as an access pathfinder

BARRIERS ADDRESSED

- New antibiotics are priced out of reach
- Lack of interest from suppliers to commercialize antibiotics
- Lack of registration in LMICs

June 2022: **"First of its kind" licensing agreement** signed between Shionogi & GARDP for Cefiderocol access in LMICs

June 2022: **Collaboration agreement signed between GARDP, CHAI and Shionogi** to enable access for Cefiderocol in LMICs

April 2023: **WHO issues "expression of interest" inviting applications for filing PQ for Cefiderocol**

May 2023: **Finalize collaboration agreement with Global Drug Facility** (GDF) for pooled procurement for GARDP portfolio including Cefiderocol

September 2023: **Sign manufacturing sub-license with sub-licensee including stewardship, EHS, commitment for rapid registration, COGs-plus pricing**

The cefiderocol access project has provisions for appropriate use

Every step is a potential "stewardship lever"

LICENSE AND MANUFACTURE

- Adhere to marketing guidelines / no marketing
- Quality assurance
- No incentives for volume sales
- Waste management
- Report on forecasts versus volume sales

GUIDELINES

- Provide data for guidance development
- Identification of local evidence needs
- Align EML and regulatory prioritization to guidelines

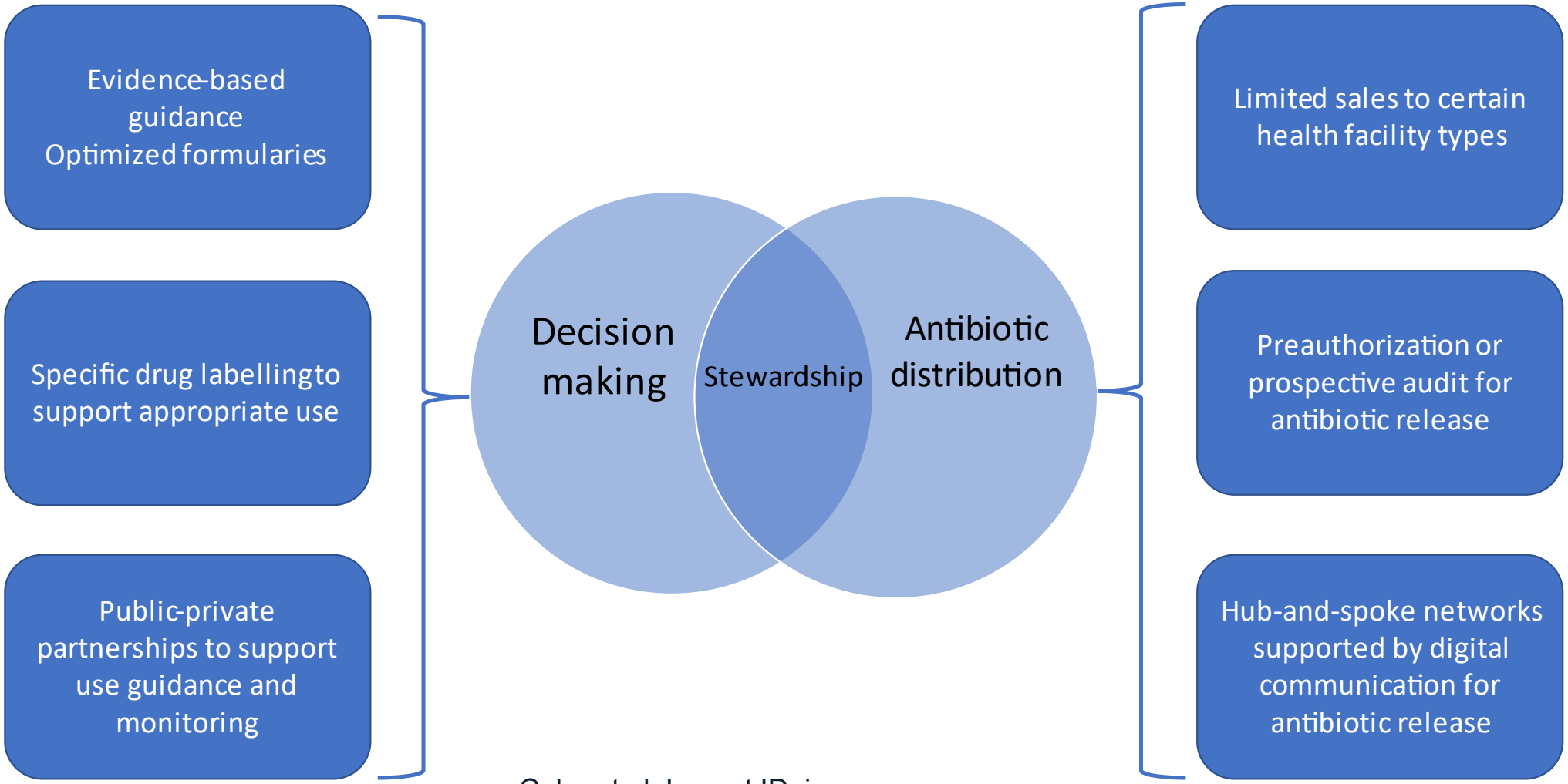
IMPLEMENTATION

- Cumulative antibiograms
- Strengthen local antibiograms
- Diagnostic network map and strengthening
- Training, site monitoring and mentorship
- Incentives for appropriate use?

POST-APPROVAL RESEARCH

- Real world data on optimal use
- Operational research on stewardship models

Stewardship is Access



Cohn et al. Lancet ID, in press

Product prioritization and guidance

Process: Consolidate information on local epidemiology, burden, current formularies, unmet needs to support prioritization and guideline development	Stakeholders: MOH, infectious disease experts, patient groups, NRAs

Registration

Process: Joint decision making between MOH and NRAs to link prioritized products to accelerated registration pathways, MOH supports NRA to create limited use labeling	Stakeholders: MOH, NRAs

Targeting availability to appropriate facilities

Process: Criteria for access or level of facility for access to Reserve antibiotics agreed, facilities assessed on criteria, facility level or approval based on criteria included in guidance and reimbursement	Stakeholders: MOH, representatives of private healthcare systems, insurance and national health benefits programs, patient groups

Facility-level stewardship

Process: Assessment of current stewardship practices, resources of facilities targeted for Reserve antibiotic access. Plan for stewardship strengthening including either prospective audit or pre-authorization, with consideration for inclusion of task shifting	Stakeholders: Facility leaders, infectious disease specialists, pharmacists and units that frequently use Reserve antibiotics, professional bodies, stakeholders in charge of relevant policies for task shifting

A network approach

Process: Identification of hubs and associated spokes (may use criteria for assessment of facilities to target for antibiotic access above), design of information flow and product transfer processes, costing of such processes	Stakeholders: Facility and health system leadership, information technology staff, logistics and procurement

Cohn et al. Lancet ID, in press

Case Study 2

SECURE: A joint WHO-GARDP initiative to improve access to essential antibiotics

How SECURE aims to address the key access challenges:
Outcomes and Impact

- Optimise country level antibiotic portfolios for treating drug-resistant infections
- Improve transparency of information for antibiotic purchase decisions
- Increase product availability and lower prices through better market predictability and efficiencies
- Steward new product introduction pathways to safeguard effectiveness of antibiotics

1. **Increased patient availability, affordability, and appropriate use of prioritized antibiotics**
2. **Reduced number and/or duration of shortages**

Reduction in AMR-related mortality in LMICs including neonates and children

Access ⟷ Stewardship

- Designing and testing creative solutions
- Building an access ecosystem
- Documenting and scaling success


Thank you