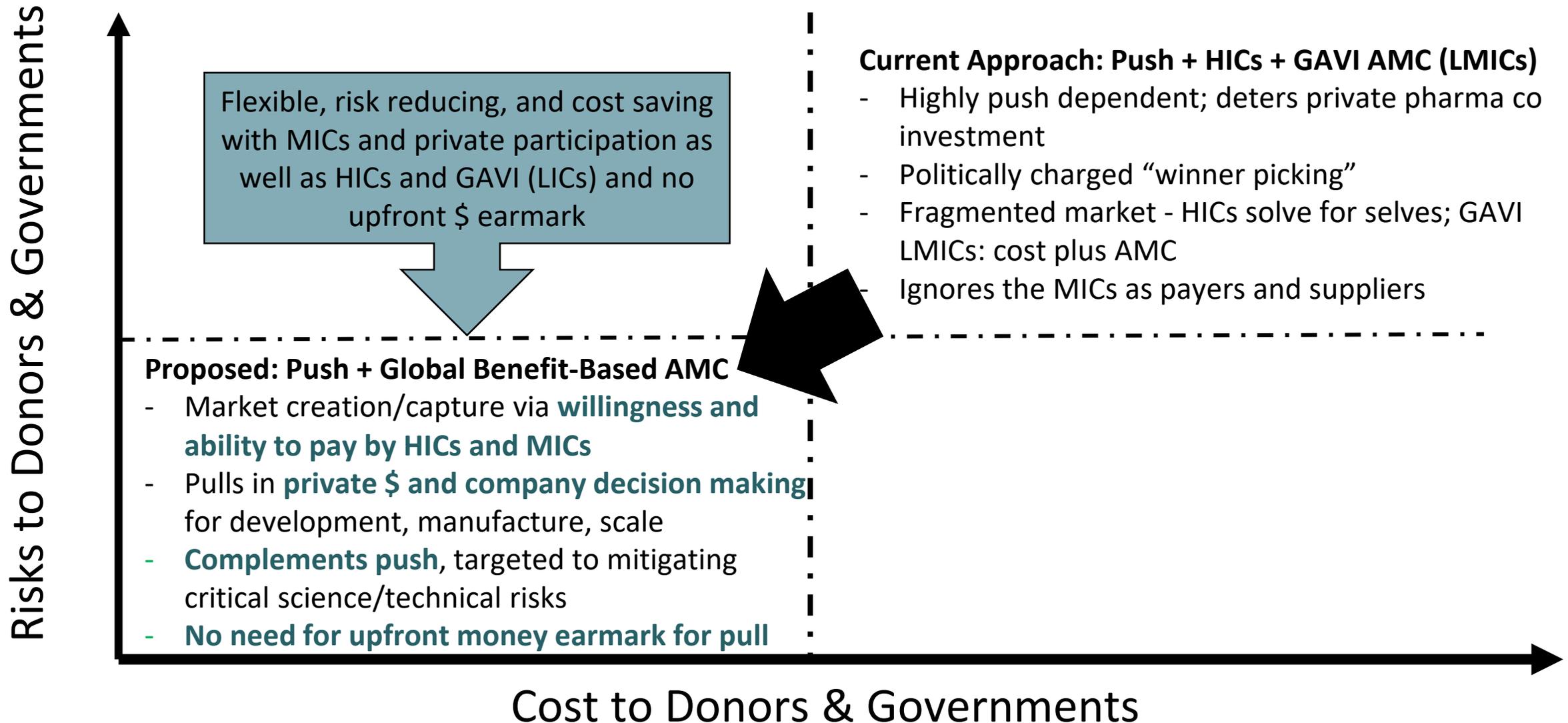


Designing a Benefit-Based AMC for COVID-19

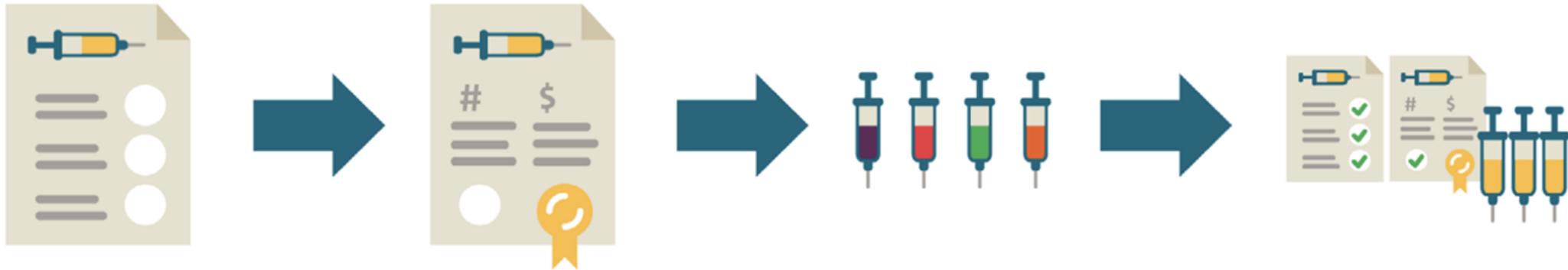
*How to ensure value and get
a vaccine fast for everyone in need*



Shifting to the left - a Lower-Risk, Lower-Cost Approach



Our Solution: A Benefit-Based AMC (BBAMC)



Health Technology Assessment

Country governments identify the innovation they need and, using their own established HTA agencies, assess how much value that innovation would add compared to alternatives, helping them decide how much they are willing to pay given their healthcare budget and competing demands.

Advance Purchase Commitments

Based on HTA results, governments make advance purchase commitments (by price and volume), which are guaranteed by a multilateral development bank.

Private Sector Invests in Innovation

Incentivized by the guaranteed market, private sector innovators develop new health products for use.

Countries Buy and Deploy Innovative Products

If and when an innovative product comes to market that meets the country's needs, the country fulfills their advance purchase commitment and deploys the innovation for its population.

Our Starting Point: Key Assumptions

1. Need a global solution to solve for the pandemic
 - Must engage entire global community --not just aid eligible countries and a few HICs,
 - Despite political challenges, must create incentives for USA and China to join as participants and financial contributors
 - High likelihood that successful vaccine candidate(s) developed in one of those two countries
2. Market is not predictable enough to work on its own (at a fast-enough pace)
 - Market for a vaccine is uncertain, even in high-income countries
 - Anticipate high demand now, but this may diminish if effective therapeutics are discovered or herd immunity gradually develops over mid-term time horizon
 - MICs a big question mark
3. Push funding alone will not result in a successful vaccine
 - History of large-scale push funding leading to [late-stage failures](#) or vaccines with low efficacy
 - A donor “picking winners” approach may crowd out private investment and, inadvertently, pass over what could be “best candidates” – need incentives to crowd in as many ideas as possible
 - Need to match push funding for R&D with other tools to ensure scale and global access

The Missing Middle: why the Benefit-Based AMC (BBAMC) that crowds in MICs and the private sector is the most efficient

1. Offers Inclusive *Global* Solution Pooling Global Markets

- BBAMC explicitly pools commitments from HICs, MICs, and LICs (with support from donors via GAVI)
 - Including largest markets/ability to pay, bulk of global populations, and manufacturing/supply chain capacity needed for scale (facilities, adjuvants, raw materials/APIs, vial glass)
- Does not rely on aid only, or the expected market of just one or two high-income countries, to create the market pull for manufacturers
 - Single-country or aid-only approach will not create predictable pull sufficient to mobilize required manufacturing scale-up and is likely to lead to bidding wars; also risk for that country if successful vaccine is developed elsewhere
 - Need to ensure that LICs are served for equity/solidarity but also to prevent resurgence/reintroduction

2. Crowds-In Private Investment through Effective Pulling Mechanism

- Governments are unlikely to take on full burden and scientific risk with up-front push funds (and should not be expected to do so)
 - Total price tag may be \$100+ billion (Kremer et al.)
 - Don't want to be in a position of countries double-paying—for up front development (de-risking) and for the final product (through price)
- BBAMC offers risk-sharing—and access to an upside reward—needed to create the right incentives for industry to move best vaccine candidates through the pipeline
 - The private sector, with full visibility into candidate vaccines, is best placed to pick likely “winners”, raise private money, acquire promising products or start ups and invest in risky, costly late-stage trials
 - ...but they will only do so if they believe their risk will be compensated via an upside reward if they are successful

3. Rewards Performance—with a Local Lens

- A successful vaccine is not a certainty
 - BBAMC hardwires product performance to ensure only high-value innovation is supported
 - Avoids potential for push funding to bring a low-efficacy product to market, which may not make sense to deploy at scale
 - Paying more for a better vaccine creates incentives to bring the best products to market
 - “Value” here reflects only health gains—not economic gains to a prevented or shortened recession; the latter would transfer all social gains to industry and defeat the point of action
- BBAMC recognizes value is local!
 - Different countries have different abilities to pay for health improvement; should pay different prices for the vaccine
 - Uses value-based tiered pricing (compatible with pooled purchasing arrangements) to ensure that all but the poorest countries kick in for R&D costs but receive access at locally affordable prices

4. Secures Market by Committing Future Health Expenditure—Not Only Aid

- Countries commit to purchase a successful vaccine for their own populations though national health expenditure
 - Donors/ODA pay only for the poorest countries
- BBAMC uses guaranteed commitments—not a ring-fenced pot of money
 - In a tight fiscal environment, governments do not need to tie up scarce resources up-front
 - Governments pay only if and when a vaccine comes to market *that meets the TPP*
 - Financial instruments/government bonds/multilateral development banks underwrite national commitments to increase private sector confidence

How a BBAMC Would Work

BBAMC: A Four-Pronged Approach

Early Health Technology Assessment:

To estimate the **size of the market** including price and volumes for the COVID-19 vaccine, using the WHO max and min target product profile (TPP), and assessed country by country; this is translated into commitments and implementation/success payments.

Underwriting:

To calculate and guarantee an **advance purchase commitment** from payers for a COVID-19 vaccine, addressing country (e.g. payer's credibility) and disease (e.g. herd immunity levels) specific risks.

Global governance:

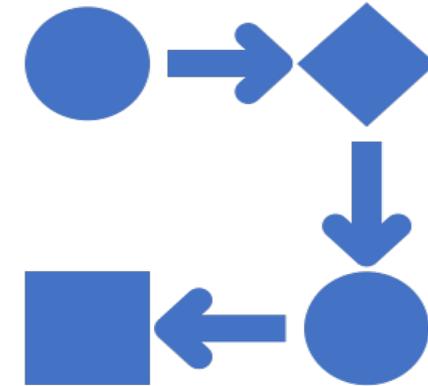
To develop a governance model (preferably using an existing initiative or institution) which coordinates HIC, MICs and donors alongside industry, establishing **credibility and trust**.

Manufacturing and distribution:

To ensure adequate volumes and coordinated supply chains for equitable and efficient access **aligned with industrial policy** objectives of MICs and comprising early stage publicly funded and later stage company (and Gavi) funded elements.

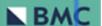
Early HTA Basis for Advanced Commitment

- Early health technology assessment (HTA), building on countries' existing national and regional HTA processes, such as UK's NICE, Australia's PBAC, or Thailand's HITAP, would be used to understand how helpful a vaccine would be in different country contexts and determine the ability of each country to pay.
- The results would then be adjusted downwards for relevant push funding and "locked in" to provide overall market predictability.
- Early HTA norm for industry and carried out by governments incl MICs like Thailand with [HITAP's early HTA of an HIV vaccine](#)



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Is a HIV vaccine a viable option and at what price? An economic evaluation of adding HIV vaccination into existing prevention programs in Thailand

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Value-based Price Protects Against Suboptimal Product

- BBAMC would offer multiple value-based entry market commitments (country-specific tiered prices for guaranteed volumes) to multiple developers that meet the minimum effectiveness threshold (as per the WHO TPP)
- Offers an incentive to keep many different potential innovators in the game post launch.
- Hedges risk against late failure of one or more early candidates and/or safety risks after widespread deployment

Underwriting the Commitment through Multilateral Development Banks (MDBs) and Central Banks

- Uses a financial intermediary like a multilateral development bank for MICs or HICs' national bank reserves or holdings of government bonds, to underwrite countries' own value-based advance market commitments, so countries do not need to put scarce resources aside until an effective product comes to market.
- All countries could participate in the mechanism to guarantee a large total market commitment, but their contributions to the total market would vary based on their respective ability to pay and population sizes.



Governance

- Role of inclusive governance structure to coordinate and enforce country advanced commitments; align behind TPP and value estimation approach
- Consider how to engage current initiatives whilst also prioritizing buy in from major powers incl USA, China?
 - E.g. explore how Access to COVID-19 Tools Accelerator or other global initiative or institution might serve as a politically neutral and widely acceptable governance platform joining HICs, MICs, LICs and global donors, alongside non-profit partners and industry



Facilitating Access for LICs

As a condition of accessing the guaranteed market, the payers/governments would require successful innovator(s) to license their vaccines out to other suppliers at low or zero cost to facilitate widespread scale-up across all LICs.

Gavi plays critical role as major procurer and market maker to secure volumes for and access to LICs.

Manufacturing Scale-Up

Early Stage:

Public money invests in platform-agnostic capacity
Push investments factored into final value-based price

Late Stage:

For HICs/MICs: company pays to manufacture frontrunner products through CMOs/subcontracts
For LICs: voluntary licensing / Medicines Patent Pool access for DCVMs/CMOs so they can respond to Gavi AMC

BBAMC Complements Other Proposals

	Gavi AMC	Accelerating HT Group	BBAMC
Early R&D push	Combination of push (CEPI, BARDA) and company investing in response to HIC markets	Combination of push (CEPI, BARDA) and company investing in response to HIC markets	Combination of push (CEPI, BARDA) and company investing in response to HIC markets
Ph IIb onward development and portfolio management	\$ and risk shared between companies (HIC pull) and push/CEPI Scientific committee of experts through CEPI support portfolio mgmt.	\$ and risk shared between companies (HIC pull) and push/CEPI	Comparatively more \$/Risk to companies responding to both HICs and BBAMC - private sector decisions on product selection based on performance and TPP
Manufacturing	Explicitly focused on supply needs of LMICs starting with priority health care workers; AMC pull in private investment to secure mfting supply at affordable price; complements early at-risk push (and private) investments in mfting capacity	85% push/15% pull funding to secure sufficient manufacturing capacity for 20 vaccine candidates. Focus on speed – utilize proposed AMC to encourage companies to invest in global capacity vs HIC/home markets only	Also combination of tools – innovators supply MICs/HICs motivated by BBAMC; agree to subcontract and license out to accelerate scaling for LMICs; complements any early at-risk push investments
Price	TBC which “ cost plus” pricing in exchange for advanced volume commitments or offering topped up “AMC prices” up to a certain amount; price per dose \$2-4.5 from Gavi and \$5-6 from Gates White Paper	Use top up on cost plus price as incentive to companies (either fixed mark up across total committed volume or tiered to further reward early investors)	Countries’ price/volume commitment as part of AMC negotiated in advance based on performance tiers, value assessment, ability to pay
Procurement	Negotiated via UNICEF (LMICs); MICs TBC – could also be via GAVI for price but not funding	LMICS via GAVI/UNICEF; HICs bilateral negotiations,	Company engages with countries bilaterally or through GAVI/other centralized procurer (PAHO) for actual procurement within BBAMC framework re total market value (see annex)
Source of private monies	Through IFFM mechanism to resource “pool”; and assumes companies share costs/risks of mfting scale up	Expecting companies to share some of the costs of manufacturing per arrangement above	Designed to crowd in private investment for late stage development and manufacturing in response to BBAMC
Country eligibility	LICs; MICs might access price negotiated via pool but not funding	Proposal is focused on global; prioritization for essential/health care workers, elderly etc.	Pool to include HICs, MICs and LICs (via GAVI); prioritization TBC
IP	Companies maintain IP	Companies maintain IP	IP maintained by companies subject to honoring outlicensing agreement re LIC access

A global cooperation solution for a global problem

• **Global Solution**

• **Crowd in private sector**

Aggregates global markets with attention to HICs, MICs and LICs/ODA

Crowds in private sector \$ and shares risk without need for earmarking large public sums

• **No need for ringfencing public \$**

• **Rewards performance**

Secures market with commitments on future health expenditure— not only aid

Rewards quality by paying for performance against TPP

Complements AMC approach with HIC, MIC and private \$ and value assessment

The Market-Driven Value-Based Advance Commitment (MVAC)



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CGD NOTES

Leave No One Behind: Using a Benefit-Based Advance Market Commitment to Incentivise Development and Global Supply of COVID-19 Vaccines

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