

# Procurement Institutions and Essential Drug Supply in Low and Middle-Income Countries

Lucy Xiaolu Wang<sup>1,2,3</sup>    Nahim Bin Zahur<sup>4</sup>

<sup>1</sup>University of Massachusetts Amherst, United States

<sup>2</sup>Max Planck Institute for Innovation and Competition, Germany

<sup>3</sup>Canadian Centre for Health Economics, Canada

<sup>4</sup>Queen's University, Canada

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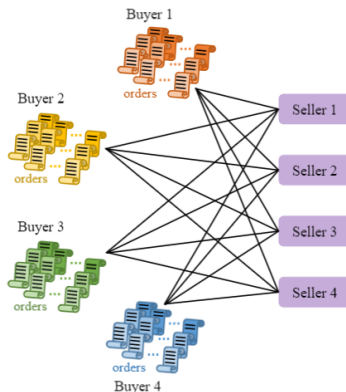
2023.5.9 (<https://ssrn.com/abstract=3926761>)

# Institutional Failures in Access to Medicines

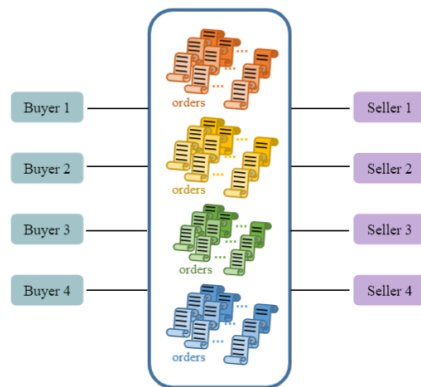
- Slow diffusion of drugs to low and middle income countries (LMIC)
- Multiple barriers to drug diffusion
  - Weak commercial incentives to invest and sell in LMIC
  - Supply chains bottlenecks & local production capacity limits
  - Intellectual property (IP): patents, exclusivity, trade secrets
- Procurement institutions play a big role in LMIC drug supply
  - but we know little on the efficiency & tradeoffs
  - crucial to understand how procurement institutions contribute to efficiency of health systems in LMIC
- A need for novel procurement and delivery institutions
  - E.g., COVAX vs bilateral vaccine deals for LMIC

# Decentralized vs. pooled procurement institution

## Decentralized Procurement



## Pooled Procurement



# Research Questions

What are the efficiencies and tradeoffs across procurement institutions (intl. & domestic) for LMIC drug supply?

- Analyze effects on multiple key outcomes: price, delays and procurement lead time, and drug choices
- Examine heterogeneity of procurement institutions wrt the age of drugs, market concentration, buyer size and patent status
- Understand the relative merits of procurement and IP licensing institutions across drug types

# Preview of Main Findings

- Pooled procurement institutions lower drug prices, esp. for
  - Older drugs
  - More concentrated markets
  - Smaller buyers
- One major pooled procurement institution reduces delays, but at the cost of longer procurement lead times
- Pooled procurement institutions supplement IP licensing institution for LMIC drug supply

# Literature & Contribution

- **Centralized procurement and drug prices** Waning et al. 2009; Danzon et al. 2015; Gallien et al. 2017; Kim & Skordis-Worrall 2017; Seidmun & Atun, 2017; Dubois et al. 2021; Clark et al. 2021
  - Our paper provides a systematic empirical analysis of different types of procurement institutions & on outcomes beyond prices
- **Global drug diffusion** Acemoglu & Linn 2004; Williams 2013; Cockburn et al. 2016; Kyle & Qian 2017; Gaessler & Wagner 2019; Williams & Sampat 2019; Wang 2022; Galasso & Schankerman 2022; Fitzpatrick 2022
  - We focus on procurement institutions that tackle non-IP barriers and supplement IP licensing institutions

# Outline

- 1 Introduction
- 2 Institutions and Data**
- 3 Baseline Analyses
- 4 Additional Analyses
- 5 Conclusion

# Conceptual Considerations

- Price impacts of pooling procurement
  - Theoretically & empirically ambiguous: depends on relative bargaining leverage of buyers & cost structure (Chitty & Snyder 1999, Inderst & Wey 2007, Waning et al. 2009, Dubois et al. 2021)
  - Impact on price may vary by extent of supply-side concentration, buyer size and characteristics of procured goods
- Non-price impacts on transaction costs, quality, administrative efficiency and delivery conditions
  - No theoretical guidance & empirically unclear (Clark et al. 2021)
  - Pooled procurement often uses long-term contracts: trade-off between more certainty & reduced flexibility (OECD 2011; Moszoro & Spiller 2019)
- It remains an empirical question how pooled procurement institutions affect prices and delivery outcomes



# Background: what are the procurement institutions?

- Direct from Manufacturers: decentralized
- Central Medical Stores (**CMS**): pooling orders within-country:  
South Africa, Senegal, Cameroon, Tunisia, Namibia, Mauritania, +5...
- Global Fund's Pooled Procurement Mechanism (**PPM**): pooling  
orders across countries (take pooling to the limit; integrated payment)
- United Nations (**UN**): pooling orders across countries (inter-gov.)
- Others: non-profit procurement/dev. organizations, private  
wholesalers, intl. health NGOs

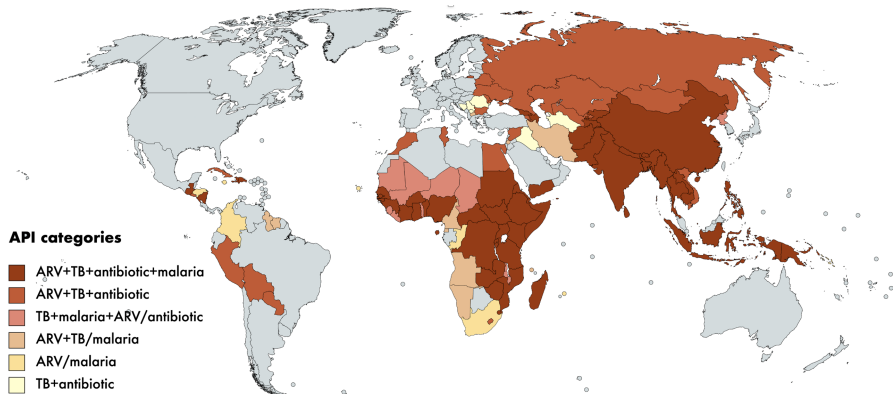
[▶ List of institutions](#)[▶ Graphic comparison](#)[▶ PPM details](#)

# Data: drugs supplied, suppliers, categories, & others

- LMIC drug procurement from Global Fund, 2007-2017
  - Price, quantity, scheduled and actual delivery dates, order date
  - Procurement agencies, manufacturer, destination countries
  - All purchases are Global Fund-funded: comparable in funding source
- Drug-level: disease categories, approval year, and drug classes
  - WHO, US FDA, and extensive medical literature search
- Drug-country-year: patent status & IP licensing institution
  - MedsPaL, Pat-Informed, DrugPatentWatch; Medicines Patent Pool
- Country-year level characteristics: demographics, income, disease portfolios, within-country institutional features, etc.
  - World Bank, UN, Institute for Health Metrics & Evaluations

# Descriptives: coverage on drug categories

- 83 drug products (APIs) supplied to 106 LMIC in 2007-2017



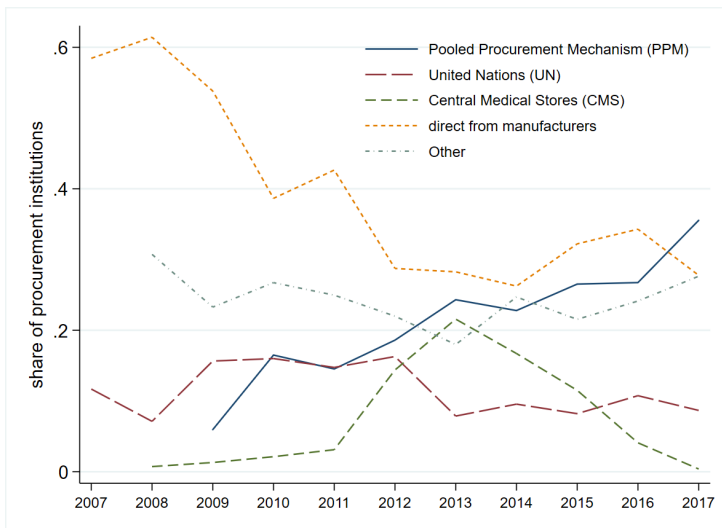
# Sample importance and representativeness

- LMIC have not fully recovered from the HIV/AIDS pandemic
- “The big three” (HIV/AIDS, tuberculosis, malaria) remain the top infectious diseases that kill almost 3 million people/year
- They are estimated to generate larger disease burdens than Covid-19 in many developing countries (Bell & Hansen, 2021)
- The infrastructure/investments for the AIDS pandemic are critical first responders to Covid-19 in many LMIC

Sample Coverage: during sample period 2007-2017

- % compound: 23/27 HIV, 13/15 malaria & 18/18 TB in EML
- Data cover 40% of HIV/AIDS drug purchases by LMIC
- We observe 60+% of WHO pre-qualified manufacturers + all major manufacturers qualifying via other channels

# Trends in procurement institution representation (%)



# Summary Statistics

Drug prod.-country-year panel summary statistics

	# obs.	mean	s.d.	min	max
Price (US\$/product)	14681	0.49	1.49	0.001	61.13
Spending (\$1000)	14681	384	2450	0.002	86300
Procurement lead time (days)	14681	171.58	121.13	0	1197
% delayed	14681	0.52	0.45	0	1
% PPM	14681	0.28	0.44	0	1
% UN	14681	0.15	0.34	0	1
% CMS	14681	0.02	0.14	0	1
% Direct from manufacturers	14681	0.24	0.42	0	1
% Others	14681	0.32	0.46	0	1
Patented	14681	0.2	0.4	0	1
Medicines Patent Pool (MPP)	14681	0.09	0.28	0	1

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# Empirical Framework

- We estimate the relationship between procurement institutions utilized and various outcomes ( $j = \text{drug}$ ,  $c = \text{country}$ ,  $t = \text{year}$ )

$$Y_{jct} = \sum_m S_{jct}^m \beta^m + X_{jct} \gamma + \delta_{cj} + \delta_t + \varepsilon_{jct} \quad (1)$$

- $Y_{jct}$ : outcome variable (price, delay, procurement lead time)
- $S_{jct}^m$ : share of transactions using procurement institution  $m$
- $X_{jct}$ : income, disease prevalence & incidence (HIV, TB, malaria), demographics, governance, patent, IP licensing status (MPP)
- $\delta_{cj}$ ,  $\delta_t$ : drug-country & year fixed effects; two-way clustering of s.e. by country and by drug (Cameron & Miller, 2015)
- We also conduct the analysis at the transaction level (+buyer FE)
- Additional analyses: (i) IV strategy, (ii) the AET-O method, ...



# Procurement institution and price

Dep var: $\ln(\text{price})$	(1)	(2)
% PPM	-0.30***	-0.38***
(pool intl.)	(0.058)	(0.073)
% UN	-0.23***	-0.23***
(pool intl.)	(0.053)	(0.061)
% CMS	-0.10	-0.041
(pool within)	(0.073)	(0.14)
% Others	0.027	-0.040
	(0.039)	(0.054)
Patented	0.023	-0.0023
	(0.051)	(0.051)
MPP	-0.31***	-0.27***
	(0.10)	(0.089)
Year FE	Y	
Country-product FE	Y	Y
Country-year FE		Y
N	14681	14681

- Prices lower with cross-country pooling (30-38% for PPM, 23% for UN)

# Transaction-level analysis, and with country-buyer FE

Dep var: $\ln(\text{price})$	(1)	(2)	(3)	(4)
PPM	-0.20***	-0.18***	-0.19***	-0.17***
(pool intl.)	(0.052)	(0.058)	(0.053)	(0.059)
UN	-0.13***	-0.10**	-0.13***	-0.10**
(pool intl.)	(0.044)	(0.043)	(0.045)	(0.044)
CMS	0.014	-0.041	-0.062	-0.083
(pool within)	(0.067)	(0.061)	(0.056)	(0.056)
Others	0.063*	0.079**	0.055*	0.073**
	(0.032)	(0.035)	(0.032)	(0.036)
$\ln(\text{Transaction volume})$			-0.028***	-0.025***
			(0.0074)	(0.0076)
Year FE	Y	Y	Y	Y
Country-product FE	Y		Y	
Country-buyer-product FE		Y		Y
N	39,289	39,289	39,289	39,289

- Transaction-level prices lower with cross-country pooling (17-20% for PPM, 10-13% for UN); significant but very small effect of buying in bulk

# Heterogeneity by patent status and approval year

	(1)	(2)	(3)	(4)	(5)	(6)
	baseline	country patent status ever-patented	never-patented	pre-1990	approval year 1990s	1997+
% PPM (pool intl.)	-0.30*** (0.058)	-0.25*** (0.063)	-0.31*** (0.067)	-0.36** (0.17)	-0.26*** (0.074)	-0.15*** (0.050)
% UN (pool intl.)	-0.23*** (0.053)	-0.24** (0.092)	-0.22*** (0.051)	-0.29*** (0.10)	-0.20*** (0.059)	-0.13** (0.050)
% CMS (pool within)	-0.10 (0.073)	-0.0029 (0.082)	-0.12* (0.069)	-0.23 (0.14)	0.040 (0.076)	-0.096 (0.064)
% Others	0.027 (0.039)	0.020 (0.046)	0.028 (0.043)	0.024 (0.051)	0.014 (0.034)	-0.0067 (0.060)
Patented	0.023 (0.051)	-0.018 (0.056)		0.020 (0.064)	-0.068 (0.050)	-0.0073 (0.098)
MPP	-0.31*** (0.10)	-0.44*** (0.15)			0.0019 (0.047)	-0.16* (0.082)
Controls	Year FE, ctry-prod FE, observable controls					
N	14681	3389	11292	4937	4169	5575

- Cross-country pooling reduces prices more for older drugs
- Similar prices by patent status

# Heterogeneity by buyer size and seller concentration

	baseline	buyer total high	purchases low	manufacturer HHI high	HHI low
% PPM (pool intl.)	-0.30*** (0.058)	-0.22*** (0.054)	-0.43*** (0.085)	-0.37*** (0.066)	-0.20*** (0.051)
% UN (pool intl.)	-0.23*** (0.053)	-0.17*** (0.043)	-0.32*** (0.071)	-0.29*** (0.065)	-0.15*** (0.050)
% CMS (pool within)	-0.10 (0.073)	-0.23** (0.10)	-0.017 (0.081)	0.069 (0.13)	-0.15** (0.061)
% Others	0.027 (0.039)	0.043 (0.039)	0.0038 (0.054)	-0.036 (0.050)	0.040 (0.032)
Controls	Year FE, ctry-prod FE, observable controls				
N	14681	7483	7198	7236	7445

- Pool **within** most effective when: (i) market *less* concentrated (ii) buyers *large*
- Pool **intl.** most effective when: (i) market *more* concentrated (ii) buyers *small*

# Procurement lead time and delays

- Stockout of essential drugs is a major problem in LMICs (e.g., Gallien et al., 2017; Fitzpatrick, 2022)
- Stockout risk can be increased by either lengthy *procurement lead time* or unexpected *delays* (or both)
  - Procurement lead time: number of days between date of order and date of delivery
  - Delay: indicator for whether the *actual* delivery date was after the *scheduled* delivery date
- We test how these delivery outcomes vary by procurement institutions

# Procurement lead time and delays

	(1)	(2)	(3)	(4)
	delay		lead time	
	panel	transact.	panel	transact.
% PPM	-0.26***	-0.28***	105.4***	113.8***
(pool intl.)	(0.050)	(0.049)	(10.5)	(13.3)
% UN	0.084	0.059	1.45	3.86
(pool intl.)	(0.056)	(0.048)	(11.8)	(11.1)
% CMS	-0.080	-0.35***	-23.6	-38.7***
(pool within)	(0.083)	(0.063)	(23.5)	(12.3)
% Others	-0.044	-0.072*	12.8	24.8**
	(0.040)	(0.041)	(7.77)	(9.60)
Controls	Year FE, ctry-prod FE, controls			
N	14,681	39,289	14681	39289

- Although shipments are 26-28% less likely to be delayed, procurement lead time is substantially longer for PPM (by 105 - 114 days)

► heterogeneity (delays)

► hetero. (lead time)

► drop pre-planned orders

► graphic comparison

# Drug choices: patent, generation

- Test if proc. institutions restrict drug choices (country-year-drug category level)

Dependent variable:	(1) % patented	(2) % pre-1990s
% PPM (pool intl.)	0.0040 (0.021)	0.053 (0.041)
% UN (pool intl.)	0.031 (0.026)	0.021 (0.030)
% CMS (pool within)	0.0042 (0.023)	0.10 (0.11)
% Others	0.000098 (0.0093)	0.047 (0.032)
Controls	Year FE, ctry-cat FE, controls	
N	2050	2050

- No significant difference in % of patented or older generation drugs purchased

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# 1. Instrumental variable approach: motivation

- Concerns: Procurement institutions are not chosen at random
- Learning-by-doing can lead to selection even after controlling for drug-country & year FEs & country-year observables:
  - Countries with more experience purchasing a drug may be able to negotiate lower prices
  - Countries with more experience are better able to meet requirements for participating in international pooled procurement institutions (PPM, UN)
- This can lead to a negative correlation between prices and share of purchases from intl. pooled procurement institutions

# 1. Instrumental variable approach: justification

- Two sets of IVs for procurement share of institution  $m$ ,  $S_{jct}^m$
- 1. Procurement share of institution  $m$  for the same drug  $j$  in other countries in period  $t$ 
  - Relevance: participation in intl. pooling for drug  $j$  becomes more feasible as more countries join the pool in the same year  $t$
  - Exclusion restriction: drug  $j$  purchases by other countries in year  $t$  uncorrelated w/ learning by country  $c$  in buying drug  $j$
- 2. Procurement share of institution  $m$  for other drugs by same country  $c$  in period  $t$ 
  - Relevance: participation in intl. pooling for other drugs makes it easier to use same institution for buying drug  $j$
  - Exclusion restriction: learning effects are uncorrelated across different drugs purchased by the same country, conditional on drug-country fixed effects

# 1. Instrumental variable estimation results (panel)

ln(Price)	OLS	2SLS	2SLS	2SLS	2SLS
% PPM (pool intl.)	-0.30*** (0.060)	-0.25*** (0.057)	-0.29*** (0.061)	-0.24*** (0.060)	-0.33*** (0.069)
% UN (pool intl.)	-0.23*** (0.053)	-0.20*** (0.055)	-0.21*** (0.057)	-0.19*** (0.059)	-0.27*** (0.070)
% CMS (pool within)	-0.10 (0.075)	-0.080 (0.077)	-0.099 (0.073)	-0.077 (0.077)	-0.089 (0.093)
% Others	0.027 (0.040)	0.045 (0.039)	0.034 (0.041)	0.048 (0.041)	0.13** (0.063)
Instrument for Controls	PPM      UN      PPM, UN      All Year FE, ctry-prod FE, controls (ctry-yr and patent)				
N	14,681	13,645	13,645	13,645	13,645
Cragg-Donald F-stat		4534	2108	1069	439
Kleibergen-Paap F-stat		168	62	48	16
Olea-Pflueger F-stat		213	130		

- Similar results to before: significant reductions in price from PPM and UN
- IV results are similar to benchmark at transaction level, & for delay/lead time

## 2. Altonji-Elder-Taber-Oster (AET-O) method

- Q: Are the key patterns driven by unobserved heterogeneity? (i.e., to what extent the omitted variables matter)
- AET-O: Altonji et al. (2005), generalized in Oster (2016)
  - AET: relationship btw treatment & observed ctrls can provide info on the relationship btw treatment and unobserved ctrls.
  - O: use  $\Delta R^2$  to measure predictive power of ctrls; calc. bounds
- Compute bounds of “treatment” estimates  $\beta^*$ 
  - Tight bounds for each of the main coefficient estimates

► Details

# Altonji-Elder-Taber-Oster (AET-O): Results

	No controls		All controls		$R^2_{max}$		Bounding values	
	$\hat{\beta}$	$\hat{R}^2$	$\tilde{\beta}$	$\tilde{R}^2$	$\Pi = 1.3$	$\Pi = 2$	$\beta^*_{\Pi=1.3}$	$\beta^*_{\Pi=2}$
<b>Price</b>								
PPM	-0.190	0.014	-0.299	0.967	1	1	-0.303	-0.303
UN	-0.188	0.014	-0.226	0.967	1	1	-0.227	-0.227
CMS	0.019	0.014	-0.101	0.967	1	1	-0.105	-0.105
<b>Delay</b>								
PPM	-0.242	0.072	-0.257	0.482	0.627	0.964	-0.262	-0.275
<b>Procurement Lead Time</b>								
PPM	106.30	0.142	105.40	0.600	0.780	1	105.05	104.61

### 3. Reduced-form demand: estimation

- One concern: demand elasticities differ for buyers that purchase using different procurement institutions. (i.e., Price-discriminating sellers may charge lower prices to buyers with more elastic demand)

$$\log(q_{jct}) = \alpha^P \log(p_{jct}) + \sum_m \alpha^{pm} S_{jct}^m \log(p_{jct}) + X_{jct} \gamma + \delta_{cj} + \delta_t + \varepsilon_{jct} \quad (2)$$

- $\alpha^P$ : demand elasticity when all of the drugs are purchased directly from manufacturers.  $\alpha^{pm}$ : how the demand elasticity changes as the share of transactions by procurement mechanism  $m$  increases
- Hausman (1996) IV: prices in other markets reflect unobserved cost shocks & hence serve as supply shifters

### 3. Reduced-form demand: results

	OLS	2SLS	2SLS
ln(price)	-0.41*** (0.078)	-0.31 (0.19)	-0.30 (0.19)
ln(price)*% PPM (pool intl.)			0.11** (0.047)
ln(price)*% UN (pool intl.)			0.015 (0.083)
ln(price)*% CMS (pool within)			0.19 (0.23)
ln(price)*% Others			-0.031 (0.050)
Controls	Year FE, ctry-prod FE, controls		
N	13312	13312	13312
Cragg-Donald F-stat		3053	594
Kleibergen-Paap F-stat		57	12

- Demand not more elastic for cross-country pooled purchases
- Addresses concern that lower prices are due to more elastic demand by buyers using cross-country pooling

## 4. Other institutional factors & management practices

- The estimates on procurement institutions remain similar when we further account for other institutional aspects:
  - the role of other large buyers (i.e., PEPFAR) ▶ PEPFAR
  - ceiling or reference prices provided by CHAI ▶ CHAI
- Procurement institutions are associated with lower variability in manufacturer orders ▶ Variability
- Other market-level analyses: comparison of in-sample prices to median prices in intl. guidelines and supplier pool coverage.  
▶ Comparison to MSH prices
- Examine a set of management variables: tiered pricing, advanced payment practices, drug subsamples, start-up effect of PPM,...  
▶ Prepayment ▶ Startup
- Results are robust to other definitions of the “other” group ▶ Results



## 5. Other results

- Heterogeneity by drug category
  - Largest price reductions from cross-country pooling for antiretroviral and tuberculosis drugs (but limited power)
- Testing the complementarity of pooled procurement institutions and the pooled IP licensing institution by adding an interaction term
  - No statistically significant evidence of substitution/complement
- Capturing heterogeneity in grantee access to procurement institutions by controlling for the shares of grants awarded to government, multilateral, and other sectors, respectively
  - Results are robust to the inclusion of these controls

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## Conclusion & Discussion

- Pooled institutions lower drug prices, and potentially reduce delays at the cost of longer procurement lead times
- Pooled procurement institutions are overall effective in facilitating drug supply, esp. older generation drugs
- No one-size-fits-all institution; countries may consider using a mix of institutions for various scenarios (regular vs emergency)

Related: Wang, L.X. (2022). Global Drug Diffusion and Innovation with the Medicines Patent Pool. *Journal of Health Economics*, 85. <https://doi.org/10.1016/j.jhealeco.2022.102671>

# Outline

## 6 Appendices

## List of procurement institutions

Category	Description
PPM	Global Fund's Pooled Procurement Mechanism, implemented mostly by the Partnership for Supply Chain Management Inc (PFSCM)
UN	United Nations Children's Fund (UNICEF), United Nations Population Fund (UNFPA), World Health Organization (WHO)
CMS	Central Medical Stores
Others	(1) non-profit development agencies, such as Crown Agents, and Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ); (2) non-profit procurement organizations, such as Global Drug Facility (GDF), IDA Foundation (IDA), Population Services International (PSI), and i+ Solutions; (3) foundations, international NGOs (Medicins Sans Frontieres, Population Services International), private wholesalers.

# Comparison between procurement institutions (figure)

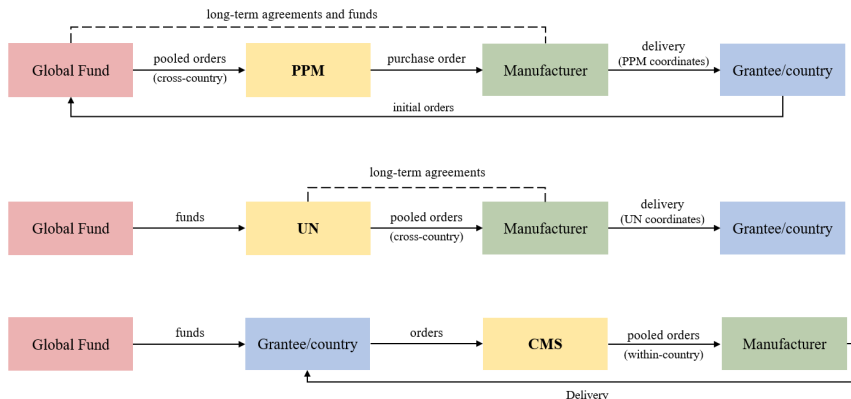


Figure: Procurement institutions comparison

# Procurement Process for PPM

1. Country places procurement request with the PPM.
2. PPM places a purchase order and agrees with a manufacturer on a scheduled delivery date
3. PPM waits for other orders to reach the volume thresholds pre-specified in the long-term agreements with manufacturers.
  - Depending on which volume threshold is reached, the actual price is finalized accordingly.
4. Manufacturer delivers. Actual delivery date is realized, which can be either earlier or later than the scheduled delivery date.

# LMIC spending on HIV/AIDS

	<b>Health spending, 2015 (US\$ bn)</b>		
	<i>Low-income countries</i>	<i>Lower-middle income countries</i>	<i>Upper-middle income countries</i>
Overall	71.53	759.23	1,745.04
HIV/AIDS	8.03	9.40	9.52

Source: Dieleman et al., 2018 [◀ Back](#)



# No. of APIs purchased using procurement institution

	Direct from manufacturer	PPM	UN	CMS	Others
All	80	57	58	33	73
HIV/AIDS	36	33	31	22	34
Tuberculosis	22	10	12	5	23
Malaria	16	13	13	5	9
Antibiotics	6	1	2	1	7

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# Altonji-Elder-Taber-Oster (AET-O): details explained

- Intuition:  $\beta \downarrow$  with more observables included (i.e.,  $\tilde{\beta} < \check{\beta}$ ), while  $R^2 \uparrow$  (i.e.,  $\tilde{R} > \check{R}$ ). Let  $\beta^*$  denote the hypothetical value in the full model with observed and unobserved controls.

① with equal selection:  $\frac{\text{unobserved}}{\text{observed}} = \frac{\tilde{\beta} - \beta}{\check{\beta} - \beta} = \frac{R_{\max} - \tilde{R}}{\tilde{R} - \check{R}}$

② with proportional selection:  $\frac{\tilde{\beta} - \beta}{\check{\beta} - \beta} = \delta \frac{R_{\max} - \tilde{R}}{\tilde{R} - \check{R}}$

③ Interval (bounds):  $\Delta_s = [\beta^*(\overline{R_{\max}}, 1), \tilde{\beta}]$

Compute:  $\beta^* = \tilde{\beta} - \delta(\check{\beta} - \tilde{\beta}) \frac{R_{\max} - \tilde{R}}{\tilde{R} - \check{R}}$

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# Delays: patent status and approval year (panel)

	(1)	(2)	(3)	(4)	(5)
	country patent status		approval year		
	ever-patented	never-patented	pre-1990	1990s	1997+
% PPM	-0.20**	-0.27***	-0.27***	-0.30***	-0.23***
(pool intl.)	(0.082)	(0.049)	(0.066)	(0.048)	(0.061)
% UN	0.12	0.072	0.031	0.043	0.14**
(pool intl.)	(0.083)	(0.055)	(0.070)	(0.063)	(0.061)
% CMS	-0.16*	0.016	0.19*	-0.22***	-0.034
(pool within)	(0.084)	(0.091)	(0.11)	(0.054)	(0.12)
% Others	-0.041	-0.045	-0.036	-0.079	0.021
	(0.070)	(0.036)	(0.040)	(0.048)	(0.054)
Controls	Year FE, ctry-prod FE, controls				
N	3389	11292	4937	4169	5575

# Delays: buyer size and seller concentration (panel)

	(1)	(2)	(3)	(4)	(5)
	baseline	buyer total purchases		manufacturer HHI	
		high	low	high	low
% PPM (pool intl.)	-0.26*** (0.050)	-0.27*** (0.054)	-0.26*** (0.074)	-0.32*** (0.069)	-0.24*** (0.054)
% UN (pool intl.)	0.084 (0.056)	0.068 (0.059)	0.10 (0.081)	0.073 (0.069)	0.11* (0.059)
% CMS (pool within)	-0.080 (0.083)	0.021 (0.098)	-0.17* (0.092)	-0.11 (0.17)	-0.079 (0.094)
% Others	-0.044 (0.040)	-0.0043 (0.040)	-0.11* (0.054)	-0.059 (0.042)	-0.017 (0.047)
Controls	Year FE, ctry-prod FE, controls				
N	14681	7483	7198	7236	7445

# Lead time: patent status and approval year (panel)

	(1)	(2)	(3)	(4)	(5)
	country patent status		approval year		
	ever-patented	never-patented	pre-1990	1990s	1997+
% PPM	107.1***	103.0***	83.3***	110.4***	108.5***
(pool intl.)	(13.4)	(11.8)	(14.3)	(14.8)	(12.0)
% UN	-37.9***	10.4	12.2	0.47	-4.90
(pool intl.)	(13.7)	(11.7)	(14.7)	(15.4)	(11.2)
% CMS	-35.4	-3.49	4.98	-29.7	-23.4
(pool within)	(27.7)	(22.4)	(35.1)	(25.8)	(29.5)
% Others	-3.54	14.3	14.1	18.1	6.27
	(13.0)	(8.91)	(12.1)	(11.3)	(10.3)
Controls	Year FE, ctry-prod FE, controls (ctry-yr and ctry-year-prod)				
N	3389	11292	4937	4169	5575

# Lead time: buyer size and seller concentration (panel)

	(1)	(2)	(3)	(4)	(5)
	baseline	buyer total purchases		manufacturer HHI	
		high	low	high	low
% PPM	105.4***	114.8***	92.7***	116.9***	102.4***
(pool intl.)	(11.0)	(12.2)	(11.9)	(14.1)	(10.9)
% UN	1.45	-1.26	-0.62	12.0	-11.1
(pool intl.)	(11.8)	(14.3)	(11.9)	(14.7)	(12.8)
% CMS	-23.6	-27.6	-14.5	-16.1	-26.5
(pool within)	(23.7)	(22.7)	(24.0)	(40.3)	(18.1)
% Others	12.8	19.6*	5.11	16.2	15.6
	(7.84)	(10.1)	(9.36)	(10.4)	(9.91)
Controls	Year FE, ctry-prod FE, controls (ctry-yr and ctry-year-prod)				
N	3389	11292	4937	4169	5575

# Lead time: drop pre-planned orders

	(1)	(2)
% PPM	94.7***	94.8***
(pool intl.)	(6.53)	(7.98)
% UN	-1.43	1.44
(pool intl.)	(7.98)	(7.66)
% CMS	-43.2***	-39.4***
(pool within)	(10.3)	(10.2)
% Others	14.0**	14.2**
	(6.41)	(6.81)
Country-buyer-product FE		Y
Other Controls	Year FE, ctry-prod FE	
	controls (ctry-yr, ctry-year-prod)	
N	32,855	32,855

# PEPFAR and drug prices

	(1)	(2)	(3)	(4)
	Panel-level		Transaction-level	
% PPM	-0.30***	-0.30***	-0.20***	-0.16*
(pool intl.)	(0.060)	(0.078)	(0.052)	(0.081)
% UN	-0.23***	-0.22***	-0.13***	-0.16***
(pool intl.)	(0.053)	(0.057)	(0.044)	(0.054)
% CMS	-0.10	0.027	0.014	0.15**
(pool within)	(0.075)	(0.093)	(0.067)	(0.066)
% Others	0.027	0.027	0.063*	0.063
	(0.040)	(0.046)	(0.032)	(0.046)
PEPFAR		-0.15		0.036
		(0.12)		(0.19)
PEPFAR*% PPM		0.0034		-0.072
		(0.085)		(0.098)
PEPFAR*% UN		-0.0020		0.041
		(0.085)		(0.072)
PEPFAR*% CMS		-0.21**		-0.17***
		(0.088)		(0.053)
PEPFAR*% Others		0.0028		-0.0032
		(0.071)		(0.052)



# CHAI and drug prices

	(1)	(2)	(3)	(4)
	Panel-level		Transaction-level	
% PPM (pool intl.)	-0.30*** (0.060)	-0.30*** (0.060)	-0.20*** (0.052)	-0.20*** (0.052)
% UN (pool intl.)	-0.23*** (0.053)	-0.23*** (0.053)	-0.13*** (0.044)	-0.13*** (0.044)
% CMS (pool within)	-0.10 (0.075)	-0.11 (0.076)	0.014 (0.067)	0.010 (0.065)
% Others	0.027 (0.040)	0.025 (0.040)	0.063* (0.032)	0.063** (0.031)
CHAI ceiling-eligible		0.0040 (0.035)		-0.0026 (0.031)
CHAI reference-eligible		-0.096** (0.043)		-0.081*** (0.028)
N	14681	14681	39289	39289

# Robustness: control for prepayment

	Panel-level	Transaction-level	
	(1)	(2)	(3)
% PPM (pool intl.)	-0.30*** (0.061)	-0.20*** (0.053)	-0.19*** (0.058)
% UN (pool intl.)	-0.22*** (0.053)	-0.12*** (0.043)	-0.083* (0.043)
% CMS (pool within)	-0.10 (0.075)	0.014 (0.067)	-0.041 (0.062)
% Others	0.029 (0.039)	0.066** (0.031)	0.080** (0.035)
Prepaid	-0.018 (0.027)	-0.035 (0.025)	-0.041 (0.025)
Ctry-buyer-prod FE			Y
N	14,681	39,289	39,289

# Prices relative to benchmark prices

Dep var: ln price diff. MSH	Panel-level	Transaction-level	
	(1)	(2)	(3)
% PPM (pool intl.)	-0.22*** (0.059)	-0.16*** (0.052)	-0.12** (0.054)
% UN (pool intl.)	-0.17*** (0.055)	-0.14*** (0.045)	-0.11* (0.056)
% CMS (pool within)	-0.056 (0.096)	0.057 (0.086)	-0.033 (0.088)
% Others	-0.011 (0.034)	0.029 (0.034)	0.042 (0.028)
Ctry-buyer-prod FE			Y
N	9,745	27,415	27,415

# Variation in manufacturer orders

	(1)	(2)
Dependent variable	Order Frequency	Coefficient of variation
% PPM	-5.27**	-0.24***
(pool intl.)	(2.43)	(0.047)
% UN	-3.02	-0.27**
(pool intl.)	(3.31)	(0.12)
% CMS	1.99	-0.60***
(pool within)	(3.12)	(0.091)
% Others	-2.95**	-0.23***
	(1.40)	(0.078)
Controls: manu-year & manu-prod FE, controls (manu-yr-prod)		
N	2296	2296

# No evidence of PPM startup effects

	(1)	(2)	(3)	(4)
	Panel-level		Transaction-level	
% PPM	-0.30***	-0.30***	-0.16**	-0.18***
(pool intl.)	(0.063)	(0.063)	(0.067)	(0.059)
% UN	-0.23***	-0.23***	-0.11**	-0.13***
(pool intl.)	(0.053)	(0.053)	(0.043)	(0.043)
% CMS	-0.10	-0.099	-0.035	0.016
(pool within)	(0.076)	(0.077)	(0.063)	(0.070)
% Others	0.027	0.027	0.077**	0.062**
	(0.040)	(0.040)	(0.035)	(0.031)
% PPM*(2009-2011)	0.0050		-0.061	
	(0.046)		(0.063)	
% PPM*2009		0.027		-0.026
		(0.070)		(0.076)
% PPM*2010		-0.015		-0.027
		(0.059)		(0.059)
% PPM*2011		0.017		-0.070
		(0.048)		(0.097)
Ctry-buyer-prod FE		Y		Y

# Other groups

	(1)	(2)	(3)	(4)
	Panel-level		Transaction-level	
% PPM	-0.30***	-0.30***	-0.18***	-0.19***
(pool intl.)	(0.060)	(0.060)	(0.058)	(0.052)
% UN	-0.23***	-0.23***	-0.11**	-0.13***
(pool intl.)	(0.053)	(0.053)	(0.044)	(0.044)
% CMS	-0.10	-0.100	-0.041	0.013
(pool within)	(0.075)	(0.075)	(0.061)	(0.066)
% Others (not NPO)	-0.018	-0.013	0.084***	0.086**
	(0.058)	(0.058)	(0.029)	(0.036)
% NPO	0.039		0.076*	
	(0.045)		(0.046)	
% IDA		0.064		0.069
		(0.051)		(0.044)
% GDF		0.11*		0.12**
		(0.059)		(0.050)
% Other NPO		-0.099		-0.072
		(0.061)		(0.050)
Ctry-buyer-prod FE		Y		Y

# Debates on barriers in LMIC drug supply

Legal scholars hold very different views on the key issues; but competition can be low even for old, generic drugs (Conti & Berndt 2020)

"Interfering with patent protection means playing with fire" (MPG, 2021.3.15)



Reto Hilty (director of MPI for innovation & competition)

"Stanford's Lisa Ouellette on Waiving COVID-19 Vaccine Patents" (Stanford, 2021.5.4)



Lisa Ouellette (professor at Stanford Law School)

"HIV Drug IP Waiver Success Should Guide COVID Vax Rollout" (Law 360, 2021.5.21)

Doha Declaration of 2001



Francis Ssekandi (lecturer at Columbia Law School; a judge of the World Bank Administrative Tribunal)

"it is **neither necessary nor sufficient** for scaling up global vaccine access."

"it is unclear what role patents play in existing shortages relative to **other barriers like supply chain disruptions and constraints**. Again, waiving patents should be viewed as a complement to other policies."

# Recent news: MPP's achievement during COVID-19

• **2021.11, Pfizer** and the MPP signed a licence agreement to facilitate affordable access of Pfizer's *oral* COVID-19 **antiviral treatment candidate PF-07321332** in combination with low dose **ritonavir** (note: a HIV drug) in 95 countries.

• **2021.10**, MPP and **MSD** signed a voluntary licensing agreement to facilitate affordable access to **molnupiravir** in 105 low- and middle-income countries.

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Source: <https://medicinespatentpool.org/covid-19>

• **2021.7.30**, MPP, WHO, AFRIGEN, BIOVAC, SAMRC, & Africa CDC signed a Letter of Intent to establish the 1<sup>st</sup> COVID-19 mRNA vaccine technology transfer hub in South Africa.

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• **2020.9**, MPP joined the Access to Covid-19 Tool (ACT) Accelerator Therapeutics Pillar led by Unitaid & WHO.

• **2020.5**, WHO called MPP to join the C-TAP to accelerate dev., prod. & access to COVID-19 tests, treatments, & vaccines.

• **2020.3.31**, MPP temporarily expanded mandate to cover Covid-19 related health technology

Note: use of use of a compulsory license does not terminate the MPP license. E.g., see sec 2.4 in the Pfizer licensing contract: <https://medicinespatentpool.org/licence-post/pf-07321332> (Pfizer will retain some consent on sublicensing, and consent can't be "unreasonably withheld")

## WHO and MPP announce the first transparent, global, non-exclusive licence for a COVID-19 technology

### CSIC offers serological test to C-TAP

23 November 2021 | Joint News Release | Geneva | Reading time: 4 min (1026 words)



WHO's **COVID-19 Technology Access Pool (C-TAP)** and the **Medicines Patent Pool (MPP)** today finalized a licensing agreement with the **Spanish National Research Council (CSIC)** for a **COVID-19 serological antibody technology** ... The agreement covers **all related patents and the biological material** necessary for manufacture of the test. **CSIC will provide all know-how to MPP and/or to prospective licensees as well as training.** (Source: <https://www.who.int/news/item/23-11-2021-who-and-mpp-announce-the-first-transparent-global-non-exclusive-licence-for-a-covid-19-technology>)