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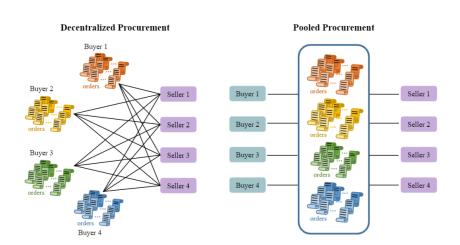
Productivity Seminar, Boston University 2023.3.7

(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



# 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

- Introduction
- 2 Institutions and Data
- Baseline Analyses
- Additional Analyses
- Conclusion

- Price impacts of pooling procurement
  - Theoretically & empirically ambiguous: depends on relative bargaining leverage of buyers & cost structure (Chipty & 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)
- 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

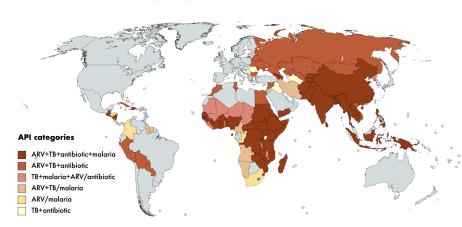


# Data: drugs supplied, suppliers, categories, & others

- 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



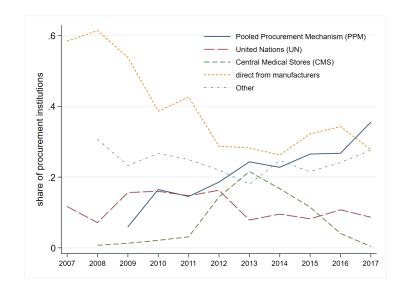
# Sample importance and representativeness

- 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

Data



# Summary Statistics

| Drug prodcountry-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 = drug, c = country, t = year)

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

- $\bullet$   $Y_{jct}$ : outcome variable (price, delay, procurement lead time)
- $S_{jct}^m$ : share of transactions using procurement institution m
- X<sub>jct</sub>: 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: In(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            | Υ        |          |
| Country-product FE | Υ        | Υ        |
| Country-year FE    |          | Υ        |
| N                  | 14681    | 14681    |

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

Results

| Dep var: In(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)   |
| In(Transaction volume)   |          |          | -0.028*** | -0.025*** |
|                          |          |          | (0.0074)  | (0.0076)  |
| Year FE                  | Υ        | Υ        | Υ         | Υ         |
| Country-product FE       | Υ        |          | Υ         |           |
| Country-buyer-product FE |          | Υ        |           | Υ         |
| 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 pa                                 | atent status   |          | approval year |          |
|               |          | ever-patented                              | never-patented | pre-1990 | 1990s         | 1997 +   |
| % PPM         | -0.30*** | -0.25***                                   | -0.31***       | -0.36**  | -0.26***      | -0.15*** |
| (pool intl.)  | (0.058)  | (0.063)                                    | (0.067)        | (0.17)   | (0.074)       | (0.050)  |
| % UN          | -0.23*** | -0.24**                                    | -0.22***       | -0.29*** | -0.20***      | -0.13**  |
| (pool intl.)  | (0.053)  | (0.092)                                    | (0.051)        | (0.10)   | (0.059)       | (0.050)  |
| % CMS         | -0.10    | -0.0029                                    | -0.12*         | -0.23    | 0.040         | -0.096   |
| (pool within) | (0.073)  | (0.082)                                    | (0.069)        | (0.14)   | (0.076)       | (0.064)  |
| % Others      | 0.027    | 0.020                                      | 0.028          | 0.024    | 0.014         | -0.0067  |
|               | (0.039)  | (0.046)                                    | (0.043)        | (0.051)  | (0.034)       | (0.060)  |
| Patented      | 0.023    | -0.018                                     |                | 0.020    | -0.068        | -0.0073  |
|               | (0.051)  | (0.056)                                    |                | (0.064)  | (0.050)       | (0.098)  |
| MPP           | -0.31*** | -0.44***                                   |                | , ,      | 0.0019        | -0.16*   |
|               | (0.10)   | (0.15)                                     |                |          | (0.047)       | (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

Results

|                              | baseline                                   | buyer tota<br>high         | l purchases<br>low          | manufact<br>high          | turer HHI<br>low            |
|------------------------------|--|----------------------------|-----------------------------|---------------------------|-----------------------------|
| % PPM<br>(pool intl.)        | -0.30***<br>(0.058)                        | -0.22***<br>(0.054)        | -0.43***<br>(0.085)         | -0.37***<br>(0.066)       | -0.20***<br>(0.051)         |
| % UN<br>(pool intl.)         | -0.23***<br>(0.053)                        | -0.17***<br>(0.043)        | -0.32***<br>(0.071)         | -0.29***<br>(0.065)       | -0.15***<br>(0.050)         |
| % CMS (pool within) % Others | -0.10<br>(0.073)<br>0.027                  | -0.23**<br>(0.10)<br>0.043 | -0.017<br>(0.081)<br>0.0038 | 0.069<br>(0.13)<br>-0.036 | -0.15**<br>(0.061)<br>0.040 |
| 70 Others                    | (0.039)                                    | (0.039)                    | (0.054)                     | (0.050)                   | (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

Results

|               | (1) (2) delay |                                 | (3)<br>lead | (4)<br>time |  |  |
|---------------|---------------|---------------------------------|-------------|-------------|--|--|
|               | panel         | panel transact.                 |             | 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 ´                         | ì.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, o    | 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)







Results

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

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

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

#### Outline

- 4 Additional Analyses

- 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

- ullet 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* 
  - <u>Relevance</u>: participation in intl. pooling for drug j becomes more feasible as more countries join the pool in the same year t
  - <u>Exclusion restriction</u>: 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)

| In(Price)              | OLS      | 2SLS         | 2SLS         | 2SLS         | 2SLS     |
|------------------------|----------|--------------|--------------|--------------|----------|
| % PPM                  | -0.30*** | -0.25***     | -0.29***     | -0.24***     | -0.33*** |
| (pool intl.)           | (0.060)  | (0.057)      | (0.061)      | (0.060)      | (0.069)  |
| % UN                   | -0.23*** | -0.20***     | -0.21***     | -0.19***     | -0.27*** |
| (pool intl.)           | (0.053)  | (0.055)      | (0.057)      | (0.059)      | (0.070)  |
| % CMS                  | -0.10    | -0.080       | -0.099       | -0.077       | -0.089   |
| (pool within)          | (0.075)  | (0.077)      | (0.073)      | (0.077)      | (0.093)  |
| % Others               | 0.027    | 0.045        | 0.034        | 0.048        | 0.13**   |
|                        | (0.040)  | (0.039)      | (0.041)      | (0.041)      | (0.063)  |
| Instrument for         |          | PPM          | UN           | PPM, UN      | All      |
| Controls               | Year FE  | E, 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



Introduction

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

|        | No co     | ntrols                     | All co            | ntrols            | $R_{mi}^2$  | ЭX        | Boundin             | ıg values         |
|--------|-----------|----------------------------|-------------------|-------------------|-------------|-----------|---------------------|-------------------|
|        | β̈́       | $\mathring{\mathcal{R}}^2$ | $\widetilde{eta}$ | $\widetilde{R}^2$ | $\Pi = 1.3$ | $\Pi = 2$ | $\beta^*_{\Pi=1.3}$ | $\beta^*_{\Pi=2}$ |
| Price  |           |                            |                   |                   |             |           |                     |                   |
| 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            |
| Delay  |           |                            |                   |                   |             |           |                     |                   |
| PPM    | -0.242    | 0.072                      | -0.257            | 0.482             | 0.627       | 0.964     | -0.262              | -0.275            |
| Procur | ement Lea | nd Time                    |                   |                   |             |           |                     |                   |
| 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)

$$log(q_{jct}) = \alpha^{p} log(p_{jct}) + \sum_{m} \alpha^{pm} S_{jct}^{m} log(p_{jct}) + X_{jct} \gamma + \delta_{cj} + \delta_{t} + \varepsilon_{jct}$$
(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

Additional Analyses

|                        | OLS        | 2SLS       | 2SLS        |
|------------------------|------------|------------|-------------|
| In(price)              | -0.41***   | -0.31      | -0.30       |
|                        | (0.078)    | (0.19)     | (0.19)      |
| In(price)*% PPM        |            |            | 0.11**      |
| (pool intl.)           |            |            | (0.047)     |
| In(price)*% UN         |            |            | 0.015       |
| (pool intl.)           |            |            | (0.083)     |
| In(price)*% CMS        |            |            | 0.19        |
| (pool within)          |            |            | (0.23)      |
| In(price)*% Others     |            |            | -0.031      |
|                        |            |            | (0.050)     |
| Controls               | Year FE, o | try-prod I | E, controls |
| N                      | 13312      | 13312      | 13312       |
| Cragg-Donald F-stat    |            | 3053       | 594         |
| Kleibergen-Paan 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

Introduction

- 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

Introduction

- 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

Conclusion

### Outline

- Introduction
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- 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



## 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<br>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. |

◆ Back

## Comparison between procurement institutions (figure)

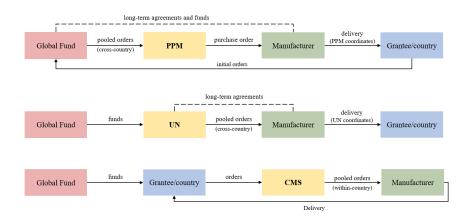


Figure: Procurement institutions comparison

◆ Back: background ◆ Back: delivery results

#### 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.

◆ Back: background

◆ Back: delivery results

## LMIC spending on HIV/AIDS

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

Source: Dieleman et al., 2018 (Back)

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## 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      |

**∢** Back

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

- Intuition:  $\beta \downarrow$  with more observables included (i.e.,  $\tilde{\beta} < \mathring{\beta}$ ), while  $R^2 \uparrow$  (i.e.,  $\tilde{R} > \mathring{R}$ ). Let  $\beta^*$  denote the hypothetical value in the full model with observed and unobserved controls.
- **1** with equal selection:  $\frac{unobserved}{observed} = \frac{\widetilde{\beta} \beta}{\mathring{\beta} \widetilde{\beta}} = \frac{R_{max} \widetilde{R}}{\widetilde{R} \mathring{R}}$
- ② with proportional selection:  $\frac{\widetilde{\beta}-\beta}{\mathring{\beta}-\widetilde{\beta}}=\delta \frac{R_{\max}-\widetilde{R}}{\widetilde{R}-\mathring{R}}$
- **1** Interval (bounds):  $\Delta_s = [\beta^*(\overline{R_{max}}, 1), \widetilde{\beta}]$

Compute: 
$$\beta^* = \widetilde{\beta} - \delta(\mathring{\beta} - \widetilde{\beta}) \frac{R_{\max} - \widetilde{R}}{\widehat{R} - \mathring{R}}$$
 

(Back)

## Delays: patent status and approval year (panel)

|               | (1)             | (2)              | (3)           | (4)      | (5)      |
|---------------|-----------------|------------------|---------------|----------|----------|
|               | country pa      | atent 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-p | rod FE, controls |               |          |          |
| N             | 3389            | 11292            | 4937          | 4169     | 5575     |

◆ Back

## Delays: buyer size and seller concentration (panel)

|               | (1)                             | (2)        | (3)         | (4)      | (5)       |
|---------------|---------------------------------|------------|-------------|----------|-----------|
|               | baseline                        | buyer tota | l purchases | manufact | turer HHI |
|               |                                 | high       | low         | high     | low       |
| % PPM         | -0.26***                        | -0.27***   | -0.26***    | -0.32*** | -0.24***  |
| (pool intl.)  | (0.050)                         | (0.054)    | (0.074)     | (0.069)  | (0.054)   |
| % UN          | 0.084                           | 0.068      | 0.10        | 0.073    | 0.11*     |
| (pool intl.)  | (0.056)                         | (0.059)    | (0.081)     | (0.069)  | (0.059)   |
| % CMS         | -0.080                          | 0.021      | -0.17*      | -0.11    | -0.079    |
| (pool within) | (0.083)                         | (0.098)    | (0.092)     | (0.17)   | (0.094)   |
| % Others      | -0.044                          | -0.0043    | -0.11*      | -0.059   | -0.017    |
|               | (0.040)                         | (0.040)    | (0.054)     | (0.042)  | (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 pa    | atent 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, ct   | try-prod FE, contr | ols (ctry-yr a | and ctry-year | -prod)   |  |
| N             | 3389          | 11292              | 4937           | 4169          | 5575     |  |

◆ Back

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

|               | (1)      | (2)         | (3)                   | (4)           | (5)       |
|---------------|----------|-------------|-----------------------|---------------|-----------|
|               | baseline | buyer total | buyer total purchases |               | turer 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      |          | • •         | ,                     | ry-yr and ctr | ,         |
| 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           | r Controls Year FE, ctry-prod FE |                       |
|                          | controls (ctry                   | /-yr, ctry-year-prod) |
| N                        | 32,855                           | 32,855                |



# PEPFAR and drug prices

|                 | (1)<br>Pane | (2)<br>I-level | (3)<br>Transact | (4)<br>tion-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 ´         | Ò.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***          |
|                 |             | (880.0)        |                 | (0.053)           |
| PEPFAR*% Others |             | 0.0028         |                 | -0.0032           |
|                 |             | (0.071)        |                 | (0.052)           |

## CHAI and drug prices

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



## Robustness: control for prepayment

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



### Prices relative to benchmark prices

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

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## No evidence of PPM startup effects

|                       | (1)<br>Pane         | (2)<br>I-level      | (3)<br>Transac     | (4)<br>tion-level   |
|-----------------------|---------------------|---------------------|--------------------|---------------------|
| % PPM                 | -0.30***            | -0.30***            | -0.16**            | -0.18***            |
| (pool intl.)<br>% UN  | (0.063)<br>-0.23*** | (0.063)<br>-0.23*** | (0.067)<br>-0.11** | (0.059)<br>-0.13*** |
| (pool intl.)<br>% CMS | (0.053)<br>-0.10    | (0.053)<br>-0.099   | (0.043)<br>-0.035  | (0.043)<br>0.016    |
| (pool within)         | (0.076)             | (0.077)             | (0.063)            | (0.070)             |
| % Others              | 0.027<br>(0.040)    | 0.027<br>(0.040)    | 0.077**<br>(0.035) | 0.062**<br>(0.031)  |
| % PPM*(2009-2011)     | 0.0050<br>(0.046)   |                     | -0.061<br>(0.063)  |                     |
| % PPM*2009            | (====)              | 0.027               | (0.000)            | -0.026<br>(0.076)   |
| % PPM*2010            |                     | (0.070)<br>-0.015   |                    | (0.076)<br>-0.027   |
| % PPM*2011            |                     | (0.059)<br>0.017    |                    | (0.059)<br>-0.070   |
|                       |                     | (0.048)             |                    | (0.097)             |
| Ctry-buyer-prod FE    |                     | Υ                   |                    | Υ                   |

# Other groups

|                    | (1)<br>Pane | (2)<br>I-level | (3)<br>Transact | (4)<br>tion-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 |             | Υ              |                 | Υ                 |

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

> "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

"HIV Drug IP Waiver Success Should Guide COVID Vax Rollout" (Law 360, 2021, 5,21)

Doha Declaration of 2001



Reto Hilty (director of MPI for innovation & competition)



complement to other policies."

Lisa Ouellette (professor at Stanford Law School)



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

### 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 lowand middle-income countries

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

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

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

CSIC offers serological test to C-TAP

World Health Organization 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/23-11-2021who-and-mpp-announce-the-first-transparent-global-non-exclusive-licence-for-a-covid-19-technology)