Solving procurement & access challenges in TB diagnostics:
the role of Stop TB Partnership’s GDF

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Outline

• GDF background and diagnostics catalog
• GDF value-add
• Key procurement and access challenges
GDF Overview

• Unit within the Stop TB Partnership, which is hosted by United Nations Office for Project Services (UNOPS)

• Established in 2001

• Original mandate: pooled procurement mechanism to facilitate access to quality-assured first-line drugs

• Subsequent expansion of products & services

• Any country can order from GDF!
  • Clients: Global Fund principal recipients, national TB programmes with other donor funding, non-governmental organizations, governments with domestic funds

• Funded largely by USAID
GDF Organigram: 39 Staff
29 staff in Geneva; 10 staff in regions

- Project Management Team
  - Knowledge, Project Mgt Officer
  - 3 Assistants

- Market Strategies Team
  - Technical Officer Medicines
  - Technical Officer Diagnostics

- Country Supply Team
  - Manager

  - Country Supply Officers (CSOs)
    - CSO EURO
    - CSO WPRO East - AMRO - AFRO Fr/Lu
    - CSO AFRO Fr - WPRO West
    - CSO AFRO Eng
    - CSO SEARO
    - CSO EMRO
    - India Officer (based in India)

- Demand, Technical Assistance & Capacity building Team
  - Manager

  - Demand & Capacity building
    - Team Leader
    - Technical Officer
    - Regional Technical Advisors (RTAs)
      - RTA Europe
      - RTA Asia/Pacific
      - RTA Africa Eng
      - RTA Africa Fra
      - RTA SE Asia
      - 4 RTAs under recruitment

- Strategic Procurement and Business Intelligence Unit
  - Manager

  - Strategic Procurement Team
    - Global Supply Officer
    - Quality Lead
    - Quality Officer
    - SRS Officer
    - Diagnostics Procurement Officer
    - Diagnostic supply administration
      - 3 Procurement Assistants

- Business and Information and Intelligence Team
  - IT tools Developer
  - Data Officer
Milestones in TB diagnostics procurement at GDF

- Design and evaluation of “TB Diagnostic Kits” (for microscopy): 2004-2006 (GDF/MSH)
- Microscopy equipment and consumables were added to the GDF catalog: 2007-2008
- TB REACH-funded projects including GeneXpert – starting in 2011
- TBXpert Project: 2013-2016 – UNITAID-funded procurement of GeneXperts
- Increasing procurement using Global Fund support, including transitioned projects
- Today, GDF is the largest procurer of TB diagnostics globally (value of 2018 deliveries: US$ 57 million)

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<th>Second-Line Drugs</th>
<th>Microscopy</th>
<th>LPA, MGIT</th>
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<th>Bedaquiline</th>
<th>Delamanid</th>
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GDF Diagnostics Catalog Today

- > 500 items
- Includes a full-range of diagnostic equipment and reagents, laboratory supplies, and ancillary devices to equip and supply a wide range of laboratories

Decentralized facilities that perform smear microscopy, automated molecular testing, and rapid antigen detection tests

Reference laboratories that perform line probe assays, mycobacterial culture, drug susceptibility testing, and species identification
GDF Diagnostics Catalog contents

**Molecular tests and equipment**
- Hain 1st and 2nd line probe assays (LPA)
- Cepheid Xpert MTB/RIF and Ultra cartridges
- Eiken/Human LAMP tests

**Rapid antigen detection tests**
- Alere (Abbott) urine LAM tests

**Culture and DST supplies and equipment**
- BD Bactec MGIT liquid culture
- Solid culture
- SD BIOLINE (Abbott) TB Ag MPT64 and Tauns Capilia TB-Neo rapid MTB identification tests
- DST: pure drug substances and BD lyophilized vials

**Microscopy**
- LED/light microscopes, reagents, consumables
- GDF microscopy kits
  - Reagents and consumables for 1,000 ZN smears
  - Reagents and consumables for 1,000 LED/auromine smears
  - Starter kit for microscopy

**Specimen transport supplies**
- OMNIgene·SPUTUM, transport boxes

**General laboratory supplies**
- Sputum containers, pipettes, centrifuges, glassware, etc.

**Biosafety and waste management**
- Respirators
- Latex, nitril gloves
- Laboratory coats, surgical gowns, goggles, shoe and hair covers
- Disinfectants for floors, BSC surfaces, instruments, hands
- Biosafety cabinets, class II, 2 or 3 filters
- Thermic anemometer
- Smoke sticks to visualize air flow
- Autoclaves and supplies
- Waste containers for solids, liquids, sharps
Recent/planned additions to the GDF catalog

- Linezolid and clofazimine pure substances for DST
- OMNIgene-SPUTUM reagent for preserving clinical specimens
- Qiagen QFT-Plus and Oxford Immunotec T-SPOT.TB IGRA
- Cepheid GeneXpert EDGE
- Nipro LPA for detection of INH, RIF resistance and NTMs
- Fujifilm LAM
- Roche COBAS
- Abbott m2000
- Hain Fluorotype
- BD BDMAX
- Bioneer AccuPower
- Molbio TrueNat
- Xpert XDR cartridge
- QFT-Access
- GeneXpert Omni
- Digital X-ray, treatment adherence technologies, container labs, connectivity softwares and global SIMs, devices for pediatric sputum collection and stool processing,…

Q4 2018

Q2-3 2019

Pending WHO 2019/2020 recommendations

Reviewing in 2019 for potential expansion
GDF-served countries for diagnostics

69 countries procured diagnostics from GDF in 2018
• In 2017, GDF procured 4.6 million of the 11.3 million Xpert MTB/RIF cartridges (41%) procured globally by the public sector under concessional pricing.

• Of 122 countries that bought GeneXpert cartridges globally in 2017, 53 countries (43%) bought them through GDF.

Annual number of Xpert MTB/RIF cartridges procured under concessional pricing

- Cartridges procured by the rest of the world
- Procured by GDF
- Cartridges procured by India
- Cartridges procured by South Africa

Data: Cepheid

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Supply trends for 2007-2018: Value of GDF orders delivered to countries (all fee included)

US$ millions


1st-line medicines 2nd-line medicines Diagnostics

US$ 57 million
GDF’s value-add in facilitating procurement and access

• One-stop shop for procurement of TB medicines & diagnostics
  • Trusted source of quality-assured products at low prices
  • Ability of countries to easily buy many products at once, including an entire package of equipment, reagents, consumables and ancillary products
  • Buying through GDF allows countries to avoid distributors that may mark-up prices
    • Distributors of one manufacturer are known to have prices 3-8 times higher than GDF
• Access to GDF’s Flexible Procurement Fund
  • When country regulations do not allow payment until after delivery of products, this fund acts as a bridge for GDF to place orders with manufacturers
• Strong customer service via dedicated country supply officers (CSOs)
GDF’s value-add in facilitating procurement and access

• Ensuring uninterrupted supply of products
  • A network of regional technical advisors (RTAs), CSOs and pool of consultants with strong competency in procurement and supply chain management
  • Development of quantification and inventory management tools, to assist with forecasting and order planning
  • Agreements with manufacturers to ensure availability of supply according to negotiated KPIs, with continuous engagement for improvement
GDF’s value-add in facilitating procurement and access

• Beyond procurement and technical assistance
  • Access to Stop TB’s convening power and advocacy at the highest levels
  • Demand generation by promoting new products
    • Series of GDF Technical Information Notes on: LAM test, LAMP test, Xpert Ultra, microscopy kits
      • Includes guidance on procurement, including supply information and package of required and optional ancillary products
    • How to calculate and budget order sizes
  • Access to grant funding for introduction of new products (e.g., UNITAID EXPAND-TB and TBXpert projects for introduction of MGIT, LPA, GeneXpert)
  • 2019 webinar series on GDF diagnostics (GDF catalog and tools, how to order, procurement and supply cycle, and more): http://stoptb.org/gdf/drugsupply/resource_materials.asp
GDF market-shaping and partner coordination

• Creation & Chair of the **TB Procurement & Market-Shaping Action Team (TPMAT)**

• Composed of procurers, donors, implementers, international organizations & civil society

• Aim to address existing challenges of TB medicines and diagnostics markets in a coordinated manner

• Areas of work include:
  
  • Alignment on identification of key market issues limiting access and interventions to address them, including for new product introduction

  • Expansion of concessional prices for diagnostics

  • Improved service & maintenance terms for diagnostic equipment
    
    • GDF led development of a model Service Level Agreement for enhanced service of GeneXperts under cartridge surcharges: countries are using it as a foundation for negotiations with Cepheid and their service providers, ensuring optimal terms and accountability

  • Identification of interventions to reduce risks around domestic procurement
Facilitating access to affordable diagnostics

• GDF objective: lowest possible, sustainable prices should be made available to all low- and middle-income countries (~152 countries)
  • Certain manufacturers provide reduced costs to eligible buyers in eligible countries
    • Eligible buyers: Public sector, not-for-profit entities
      • Unfortunately private sector is usually excluded, with some exceptions
    • Eligible countries: Most low- and middle-income countries, though with variability
      • Cepheid, Eiken/Human: 145 countries; Hain: 138 countries; BD: 85 countries
  • GDF has negotiated concessional pricing with DNAGenotek for Omnigene-Sputum reagent, to allow access to all low- and middle-income countries, plus some high-income (161 countries total)
  • GDF, UNDP and FIND worked with BD in 2017 to expand its concessional price list from 40 to 85 countries
**Trends in domestic procurement of TB medicines & diagnostics**

- Push across many donors for countries to assume increasing responsibility for financing TB care
  - Encouraging countries to finance first-line TB drugs and some laboratory commodities
  - Progressive co-financing requirements over 2018-2020 for all countries, regardless of income
    - Countries with high-TB burden have most aggressive requirements given TB prevalence in MICs
    - Examples:
      - Lower-middle income Central Asian country: 50% of Xpert, MGIT, LPA procurement in 2020 not funded by Global Fund. 100% microscopy and culture not funded in 2018
      - Lower-middle income East Asian country: all Xpert procurement starting in 2018 not funded by Global Fund

- When countries finance TB care, domestic procurement reverts to national systems and policies
  - Absence of donor levers used to require procurement of quality-assured, WHO-recommended products

- Will countries be able to afford new diagnostics? Will some revert to microscopy and solid culture?
- Will manufacturers of new diagnostics pursue a global market without sustainable international financing?
GDF’s Early Observations on Domestic Procurement

**Experience varies greatly across countries**

- Some countries procure just as they did with donor financing; business as usual
- Some countries face challenges that were common prior to massive donor investments
  1. Failed tenders
  2. Suboptimal procurement outcomes
     - Procurement of non-quality-assured / non-WHO-recommended medicines & diagnostics
     - High prices paid
     - Inability to access concessional prices for diagnostics through in-country distributors
  3. Increase in number of first-line drug stockouts
  4. Inability to mobilize domestic financing in a timely manner; risk of new diagnostics being rationed and use reduced
GDF work to support countries as they assume financing & procurement of TB products

- Continue selling medicines & diagnostics to NTPs buying w/ domestic funds (42 countries in 2018)
- Explore **GDF applying to national tenders** via UNOPS country offices
- Addition of first-line medicines to **GDF’s strategic rotating stockpile**
- Increase size of GDF’s **Flexible Procurement Fund**
- Systematic monitoring of country challenges & successes; incorporate into all GDF missions
- **TPMAT** focus area: dashboard to monitor readiness/capacity to procure; identify & address challenges at global and national levels
Conclusions

• As the largest buyer of TB diagnostics globally, GDF plays a significant role in facilitating procurement and access
  • One-stop shop for quality-assured products at concessional prices
  • Guiding countries in procurement, including generating demand for new products
  • Aiming for widest access to concessional prices for diagnostics
  • Shaping the market and coordinating partners
• GDF is able to procure for all countries and with any funding source
  • GDF is adapting to a new global funding landscape and supporting countries using domestic financing
Thank you

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