Improving Access for Quality-Assured TB Medicines + Diagnostics

Update on GDF
New Strategic Direction

Achievements, Challenges & Perspectives

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GDF Special Adviser

Stop TB Coordinating Board - Ottawa - July 2013
What is the Global Drug Facility?

An initiative of the Stop TB Partnership (2001), mainly funded by USAID and CIDA, with projects supported by Unitaid & Koweit Fund, hosted in WHO and managed by the Stop TB Partnership secretariat.

An operating mechanism to support the Stop TB Strategy:

• expanding access to quality-assured first (FLD) and second-line TB drugs (SLD) and diagnostics,
• contributing to the development of sustainable procurement and supply management for countries in need.

GDF began supplying FLDs in 2001, and in 2008 added the supply of SLDs, pediatric TB medicines and diagnostics and is a major source for GeneXpert.
What is GDF Mandate today?

GDF is more than a traditional procurement mechanism – it is a **one-stop access for provision of medicines and diagnostics** through:

- **Emergency one year grants** - bridge TB program gaps for FLDs
- **Grants for FLDs to continue for 1 more year to allow for proper phase-out**
- **Grants for SLDs:** under discussion with donors
- **Direct procurement (DP)** – TB program buys FLDs, SLDs, Diagnostics through GDF
- **In-country technical assistance** in procurement and supply chain management
A total of 128 different countries received the benefits from the procurement system and the multiple advantages offered by GDF across the years

Source: GDF OMS Data / June 2013
Total Patient Treatments Supplied 2001-2012
First Line Drugs

Live Report June 2013
Total Patient Treatments Supplied 2001 - 2013
Second Line Drugs

Live Report June 2013
Scale-Up of MDR-TB treatment supply with GDF medicines over the years

Scale-Up of MDR-TB treatment supply over the years
SLD Patient treatments supplied by GDF and current projections for 2013

* Estimated, based on constant 2012 value and 15675 DR-TB treatments planned for India

Note: Method 6 months intensive phase injectables up to 2011, 8 months from 2012
Value of Orders Placed 2012 (mUSD)

- FLD: 58
- MDR: 74
- New Diag: 16

89 M in 2013 till June 2013
GDF order placed value all inclusive – By Product Line
July 3, 2013

Live Report July 2013
http://gva1swamphion/sree/Reports?op=vs&path=/WHO_HQ_Reports/G1/PROD/INT/Shared/All+inclusive+values+of+products+ordered+by+Line+and+Country&userid=GDF_ro&password=gdfread1
GDF order placed value all inclusive – By financial service
June 3, 2013

Live Report June 2013
http://gva1swamphion/sree/Reports?op=vs&path=/WHO_HQ_Reports/G1/PROD/INT/Shared/All+inclusive+values+of+products+ordered+by+Line+and+Country&userid=GDF_ro&password=gdfread1
Patient Treatments Supplied per Year
First Line Drugs

Live Report June 2013
GDF FLD Market Share of Notified Cases

Live Report June 2013
Percentage of FLD Treatments Supplied per Year by Service

Live Report June 2013
Patient Treatments Supplied per Year
Second Line Drugs

Live Report June 2013
Patient Treatments Supplied per Year by Service
Second Line Drugs

Live Report June 2013
GDF SLD Market Share of Notified Cases

Live Report June 2013
Universal access for quality assured TB medicines and diagnostics for GDF clients

Partner Linking

Services and Products

Product Quality Assurance

Evidence from Countries

Market Shaping

New TB Tools

Capacity Building

Market Research & Forecasting

GDF Strategic Direction and Framework (2013-2016)
Main GDF Achievements since last Stop TB CB

Key Milestones

1. Focus on services delivery & Operations => Results

> M US$ 89 since 2013 (vs M US$ 151 in 2012)

New Pas / LTAs signed
TRC 28 finalized / TRC 29 planned

X 2,4 # suppliers / 2009
X 3,2 # products / 2009

SLD treatment price reduced up to 27% (2012 vs 2013)

Lead times decreasing

Support to TBREACH, TBEXPERT and EXPANDTB
GDF Impact on SLD Dynamics: 2011 vs. 2013 treatment cost comparison / High end regimen

2011/2013 Drug Breakout for 12 Cm Pto Cs Mxf PAS/ 12 Pto Cs Mfx PAS

- Capreomycin: $2,880.00 (2011), $2,250.00 (2013)
- Cycloserin: $1,276.34 (2011), $928.80 (2013)
- Moxifloxacin: $1,209.60 (2011), $1,029.60 (2013)
- PAS Acid: $2,208.00 (2011), $2,207.52 (2013)

Legend:
- Blue: 2011 USD Drug Breakout for 12 Cm Pto Cs Mxf PAS/ 12 Pto Cs Mfx PAS
- Red: 2013 USD Drug Breakout for 12 Cm Pto Cs Mxf PAS/ 12 Pto Cs Mfx PAS same suppliers than 2011
- Green: 2013 USD Drug Breakout for 12 Cm Pto Cs Mxf PAS/ 12 Pto Cs Mfx PAS best prices
GDF Impact on SLD Dynamics: 2011 vs. 2013
treatment cost comparison / High end regimen

2011/2013 Cost of treatment
12 Cm Pto Cs Mxf PAS/ 12 Pto Cs Mfx PAS

<table>
<thead>
<tr>
<th>Year</th>
<th>Cost of Treatment</th>
<th>Decrease (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011 USD Drug</td>
<td>$7,890.60</td>
<td>-14.5%</td>
</tr>
<tr>
<td>Breakout</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2013 USD Drug</td>
<td>$6,746.40</td>
<td>-26.2%</td>
</tr>
<tr>
<td>Breakout</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Same suppliers</td>
<td>$5,822.21</td>
<td></td>
</tr>
<tr>
<td>Best prices</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

TOTAL COST PER PATIENT FOR 24 months:
- 2011 USD Drug Breakout for 12 Cm Pto Cs Mxf PAS/ 12 Pto Cs Mfx PAS
- 2013 USD Drug Breakout for 12 Cm Pto Cs Mxf PAS/ 12 Pto Cs Mfx PAS same suppliers than 2011
- 2013 USD Drug Breakout for 12 Cm Pto Cs Mxf PAS/ 12 Pto Cs Mfx PAS best prices
Update on specific medicines

• Group 5 Medicines now available through:
  – Linezolid
  – Clofazimin
  – Imipinem /cilastatin

• Rifabutin currently being added to GDF catalogue
• Partial regimens now available to countries
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2. Moving ahead with the new strategic framework implementation

- Closer country monitoring & support (New RSOs + New quantification tools)
- Merging FLDs/SLDs/Diag.
- Concept note on the global strategic stockpile + flexible procurement fund + discussions engaged with donors
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- ISO 9001 status maintained
- New ordering system being developed
Translate the key data of # of months of stock on hand into the country classification:

• Reaching 8 months or Less than 8 months: Red alert (urgent imminent risk of shortage: immediate action taking for new drugs supply)

• Between 8 and 12 months: orange alert (action taking is required to ensure next supply will meet current needs, and revising stock levels is urgently needed)

• 12 months or more supply: green light situation - smooth supply guaranteed for more than 1 year
Strategic interventions & new tools to avoid stockouts

- On-going discussion for a flexible Procurement Fund and Strategic Stockpile for FLDs + SLDs + Diagnostics with TGF and donors

- **New Forecasting Tools + Early Warning Stockout System**: GDF and its partners are developing new forecasting systems to quantify needs for the coming years and these systems are continuously being improved upon, esp. for SLDs

- **Promoting M&E systems inter-operability** for better data exchange and SLDs consumption at country and global level

- **Information sharing and in country partners leveraging**: closer monitoring model of in country supply chains information being implementing with RSOs, and partners collaboration (WHO, rGLCs, Donors funded programs like TB CARE, Technical Agencies, NGOs, Regional Association, Private sector...
GDF commits to 3 main quality objectives:

1. **Product quality**
   - Quality assurance & control
     - Fast deliveries
     - Satisfied clients
     - Technical assistance

2. **Service quality**
   - Pooled procurement

3. **Lowest Prices**
GDF ISO 9001 QMS = Quality & transparency

GDF commits to transparency & improvement

1. Systemic
2. Live
3. Comparable

→

Transparency
Improvement
Performance
GDF Operations-Lead time order to delivery

http://gva1swamphion/sree/Reports?op=vs&path=/WHO_HQ_Reports/G1/PROD/INT/Shared/Delivery_dashboard_order_placed_to_delivery_rev1&userid=GDF_ro&password=gdfread1
Median increase of Lead time due to production difficulty with TB REACH Supplier – which affect all lead times.

Issue was resolved in March 2013.

Source web report: 2007-2013 on June 3 2013
http://gva1swamphion/sree/Reports?op=vs&path=/WHO_HQ_Reports/G1/PROD/INT/Shared/Delivery_dashboard_order_placed_to_delivery_rev1&userid=GDF_ro&password=gdfread1
GDF ISO 9001 – Client satisfaction by Service Categories

* June 2013
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   - Consultancy on stock-outs root causes – on-going
   - Consultancy on SSP+FPF (final stage of selection)
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TB Supply Chain Process

GDF procurement process is only a small share of the overall procurement system.

NTP Procurement & Funding planning
12 to 24 months
75%

NTP Procurement planning

NTP assess stocks & shelf life
NTP calculates theoretical drugs requirements
NTP assess surveillance data collection: enrollment rates, etc
NTP funding plan & request
NTP calculates theoretical drugs requirements

NTP Final Drug Quantification + Payment Mechanism

GDF supply chain = 1/4
From 1 to 12 months
25%

If Drugs in stock + immediate payment
If late payment, delayed PO => production
Current TB Supply Chain Process

Order is placed and Payment received → Order is processed by manufacturer → Product is manufactured → Product is inspected → Product is dispatched → Country receives product

~6 months

Limited quantities of medicines are available in the Strategic Revolving Stock for emergencies
GDF delivers emergency orders from SLD *stockpile* in 33-50 days

Source web report: 2007-2012
http://gva1swamphion/sree/Reports?op=vs&path=/WHO_HQ_Reports/G1/PROD/INT/Shared/Delivery_dashboard_order_placed_to_delivery_rev1&userid=GDF_ro&password=gdfread1
Stock-outs root causes: Main findings

• From a total of 65 reported stock outs from 2007-2013:
  – 54 were confirmed by different documents
  – 10 were confirmed as Non-stock-outs
  – 1 report was related with laboratory material - no to medicines procurement.
Percentage of Countries with Stock-outs (2007 – 2013)

- No reported Stock-outs: 71%
- Reported Stock-outs (all causes): 29%
Number of Countries Receiving Services from GDF and Number of Stock-outs per Year
Countries with Stock-outs per Primary Cause (%)

- Funding Issues, 41
- Country Management Issues, 49
- Supplier/PA, 3
- S1 shortage, 5
- Unknown, 3
- Unknown, 3
Number of Countries with Stock-outs per Year

- 2007: 3
- 2008: 1
- 2009: 9
- 2010: 10
- 2011: 17
- 2012: 8
- 2013: 2

Year
Percentage of FLD Treatments Supplied per Year by Service

Live Report June 2013
Lessons Learned so far…

• Funding availability is key but technical support and close monitoring are crucial to implement a good management system at the country level to avoid stock outs.

• Standardized methods for information collection, data management and close monitoring + early information sharing with stakeholders / in country partners at all cycle steps are key to avoid stock-outs
Lessons Learned so far...

- Efficient planning at country level and stakeholder coordination should help to align the different processes for the supply chain and to maintain a healthy buffer stock.
- Flexible Procurement Fund and Strategic Stock Pile are key interventions to implement to avoid stock-out risks.
- GDF will continue to invest with partners in strategic research / data / market dynamics monitoring as a basis for reshaping operations.
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4. Aligning forces & partners for anticipating future demand / supply landscape
   - Discussion for rational introduction models for new TB drugs (bedaquiline / Delamanid)
   - Stakeholders Meeting suppliers & donors& partners
   - Strategic meetings with WB – PAHO on harmonization and capacity building / landscape
   - Linking GF portfolios
   - Managers/grant Mngt\n
Cooperation’s agreements being concluded: with CHAI (SLDs), TB Alliance and STPHI (paediatrics)
Update on GDF main achievements: cost efficiency data

EXPENDITURE TRENDS: ACTIVITY VRS PROCUREMENT

<table>
<thead>
<tr>
<th>Year</th>
<th>GRANT (US$'000)</th>
<th>DP (US$'000)</th>
<th>ACTIVITY (US$'000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004</td>
<td>8,000</td>
<td>6,613</td>
<td>1,918</td>
</tr>
<tr>
<td>2005</td>
<td>28,367</td>
<td>13,433</td>
<td>2,980</td>
</tr>
<tr>
<td>2006</td>
<td>41,344</td>
<td>6,165</td>
<td>3,368</td>
</tr>
<tr>
<td>2007</td>
<td>36,847</td>
<td>12,500</td>
<td>3,565</td>
</tr>
<tr>
<td>2008</td>
<td>52,098</td>
<td>15,463</td>
<td>4,421</td>
</tr>
<tr>
<td>2009</td>
<td>22,134</td>
<td>47,979</td>
<td>5,804</td>
</tr>
<tr>
<td>2010</td>
<td>44,598</td>
<td>87,254</td>
<td>6,494</td>
</tr>
<tr>
<td>2011</td>
<td>58,164</td>
<td>96,672</td>
<td>7,329</td>
</tr>
<tr>
<td>2012</td>
<td>30,631</td>
<td>117,252</td>
<td>7,051</td>
</tr>
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Key Milestones

- Paediatric Grants at risk (Unitaid $ ending 2013)
- FLDs Grants / Emergency Gaps at risk
- SLDs grants ending (Unitaid $ ending 2013)
- GDF remains highly understaffed (13 vs 24)
- Urgent need of hiring LT staff for current vacant LT positions

Remaining Challenges

- In country supply chain issues still a barrier
- Context of current GF procurement
- Strategic Stockpile and Flexible procurement fund urgently needed
- SLDs still fragmented and fragile market
- Innovative actions required on demand + supply side
- GeneXpert /Diagnostic monitoring is key for accurate forecast
SUPPLY DEMAND

GDF

• Quantification
• Planning

Data Mngt

• Information Systems
• Early Warning Stock-out System

Scale-Up

• Access Strategies
• Public + Private Sector

TA

Expand Market

• Scale-UP
• Public + Private

Standardize Demand

• Standard Products with Harmonized Regimens
• Reduce regulatory burden / bottlenecks

Access Strategies

• New products
• Higher volumes

Procurement Fund + Strategic Stock Pile

Avoid payment delays
Reduce lead times
Increase orders size
Allow better planning
Reduce costs
Easier Forecast
Smother demand

Support

• Supplier engagement / Meetings
• Demand visibility / Volumes APC

Monitor

• API monopoly situation / capacity
• Vertical integration risks

Foster

• New API sources – PreQ of API and FFP
• New products / forms / packaging

GDF

Diagnositics

Orders trends

Global Forecast

DEMAND

SUPPLY

SLDs challenges + partners
SLD supply vulnerabilities: demand versus risk

Demand: Low  |  Medium  |  High  |  Very High

- More than 2 suppliers for each FFP
- 1 supplier for FFP

API risk: monopoly, quality or capacity of API

- High Risk
  - Kanamycin
- Medium Risk
  - Capreomycin
  - Ethionamide/Prothionamide
  - Cycloserine
- No risk
  - PAS Acid
  - Amikacin
  - PAS Sodium
  - Moxifloxacin
  - Levofloxacin
  - Terizidone
  - PAS Sodium
  - Ethionamide/Prothionamide
  - Cycloserine
  - Moxifloxacin
  - Levofloxacin
  - Terizidone
New approaches with Unitaid: GDF potential contribution to the paediatric TB drugs market

- On-going study commissioned to assess current status of last advice uptake by countries
- New formulations projected to be only available Q2 2016
- Expected that GF will incorporate paediatrics into new grants
- GDF potential contribution to Global TB Alliance project
  - Innovative packaging / kits
  - Support to countries with new tools for planning / forecast uptake and roll-out at country level
  - Pool procurement and prices decrease / market shaping activities
  - 5 Year project > 1.ground work/2.planning/3.uptake/4.implementation/5.ME/transitioning
New approaches with Unitaid: involving private sector to drive demand for IQA SLDs

- Donor-supported market only provide access to 19% of MDR-TB burden, mainly via the public sector

- Private sector is using drugs of unknown quality + not WHO recommended regimens

- Private sector is accountable for an important segment of SLDs drugs / BRICs like India, Russia - countries like Philippines, Vietnam, Indonesia currently scaling-up their MDR-TB programs with PPM interactions

- Attracting this segment by offering subsidized IQA SLDs to private clinics to drive demand for IQA SLDs is a possible exploratory pilot intervention
Main recommendations for the way forward (1)

1. Staffing GDF with the right mix of skills (FT and ST staff)
2. Empower a manager with acting capacity to conduct reforms
3. Focus and engage on the 2 interventions considered as of high impact by suppliers and countries:
   Strategic Stock Pile + Flexible Procurement Fund
   These interventions require donors multi-year high level commitment and a sustainable coordinated support from partners to bring results:
   – Role of GF => major funding agency to countries for drugs procurement
   – Role of other donors like Usaid, CIDA, Kuwait Fund, Unitaid (sustain initial projects) => operational sustainability
   – Role of GDF and partners: Development of innovative management model with situation room / Early Warning Stock-out system + disseminating country monitoring framework
Main recommendations for the way forward (2)

5. Ensure gaps / short falls for FLDs/SLDs/Paediatrics will be covered through grants for countries still depending on GDF / donors => shared responsibility
   - GF grants to cover all medicines (including some buffer)
   - Other donors to ensure emergency grants => available

6. Continue to explore new mechanisms for new TB drugs introduction => markets

7. GDF to continue as a catalyst/platform for leveraging synergetic partners activities

8. Keep current “open” agenda with partners on market research, producing evidences and data from countries
Discussion

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