GDF Key Updates, Achievements, and Remaining Challenges

Dr Brenda Waning
Chief, Global Drug Facility, Stop TB Partnership

Stop TB Coordinating Board, 12 December 2019
Jakarta
GDF One-Stop-Shop: Product Catalog Updates & Plans

**REMOVED**

**Medicines**
- Kanamycin
- Capreomycin
- Rifampicin/INH 150mg/150mg
- Ethionamide 125mg
- Pyrazinamide 150mg

**Diagnostics**
- Omnigene-Sputum

**ADDED**

**Medicines**
- SMX/TMP
- Levoflaxacin
- Moxifloxacin
- Clofazimine
- Etambutol 100mg
- Pyrazinamide 150mg
- Ethionamide 125mg
- Isoniazid 100mg
- Pretomanid
- Rifaxipine/INH 300/300mg FDC

**Diagnostics**
- Pure drug linezolid
- GeneXpert Edge
- IGRA (QFT-Plus)

*Pending WHO Recommendation*
GDF SLD Price Reductions

60% Decrease in SLD Prices

Past WHO-Recommended Regimens

2018 WHO-Recommended Regimens

Up to 29% Decrease in SLD Prices in 2019
# GDF Savings of ~$84 Million over 2018-2019

## $52 Mn Savings from GDF SLD Tenders

<table>
<thead>
<tr>
<th></th>
<th>2018</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estimated*</td>
<td>$33 million</td>
<td>$16.5 million</td>
</tr>
<tr>
<td>Actual</td>
<td>$36 million</td>
<td>TBD</td>
</tr>
</tbody>
</table>

*Estimated at tender award based upon forecast, supplier allocation, price; Does not include savings from 2018 BDQ price decreases post-donation

## $32 Mn Savings from GDF’s Order Management & Flexible Procurement Systems

<table>
<thead>
<tr>
<th>Intervention</th>
<th>2018</th>
<th>Q1-Q3 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-order Adjustment</td>
<td>$9,188,953</td>
<td>$10,939,181</td>
</tr>
<tr>
<td>Order Cancellation</td>
<td>$1,158,120</td>
<td>$1,122,467</td>
</tr>
<tr>
<td>Order Reallocation</td>
<td>$2,807,372</td>
<td>$1,333,269</td>
</tr>
<tr>
<td>Order Postponements</td>
<td>$4,644,673</td>
<td>$975,184</td>
</tr>
<tr>
<td>Subtotal</td>
<td>$17,799,118</td>
<td>$14,370,101</td>
</tr>
<tr>
<td>Total</td>
<td><strong>$32,169,219</strong></td>
<td></td>
</tr>
</tbody>
</table>

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*Estimated at tender award based upon forecast, supplier allocation, price; Does not include savings from 2018 BDQ price decreases post-donation.
Trends in Countries Procuring via GDF with Non-Global Fund Financing

- **Domestic Funding**
- **Other non-GF**

Including ~20 Clinical Trials

Expanding GDF Client Base for Diagnostics Procurement
## 2019 GDF Client Satisfaction*

<table>
<thead>
<tr>
<th>Category</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Simple procurement process</td>
<td>96%</td>
</tr>
<tr>
<td>Timely &amp; clear communication</td>
<td>97%</td>
</tr>
<tr>
<td>Products arrived at date agreed</td>
<td>93%</td>
</tr>
<tr>
<td>Satisfied with product quality</td>
<td>99%</td>
</tr>
<tr>
<td>No damage to product or package</td>
<td>94%</td>
</tr>
<tr>
<td>Shipment documentation complete &amp; accurate</td>
<td>100%</td>
</tr>
<tr>
<td>GDF responsive &amp; flexible</td>
<td>98%</td>
</tr>
<tr>
<td>GDF service compared to other orgs</td>
<td>97%</td>
</tr>
<tr>
<td>Will use GDF services again</td>
<td>99%</td>
</tr>
</tbody>
</table>

*Annual client satisfaction survey as per ISO Standard Operating Procedures*
### TPMAT Results: WHO-GF-GDF Harmonization using TB Medicines Dashboard

#### 2018-2019 Changes:
- **GDF Catalog:** 7 products removed, 15 added
- **Essential Medicines List:** 35 changes
- **WHO Prequal EOI:** 20 changes
- **Global Fund ERP EOI:** 5 priority products approved

#### Table of Medicines

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Capreomycin 500mg vial</td>
<td><img src="#" alt="Green Circle" /></td>
<td><img src="#" alt="Green Circle" /></td>
<td><img src="#" alt="Grey Circle" /></td>
<td><img src="#" alt="Blue Circle" /></td>
</tr>
<tr>
<td>Capreomycin 1000mg vial</td>
<td><img src="#" alt="Green Circle" /></td>
<td><img src="#" alt="Grey Circle" /></td>
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<td><img src="#" alt="Blue Circle" /></td>
</tr>
<tr>
<td>Clofazimine 50mg tablet/capsule</td>
<td><img src="#" alt="Green Circle" /></td>
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<td><img src="#" alt="Green Circle" /></td>
<td><img src="#" alt="Green Circle" /></td>
</tr>
<tr>
<td>Cycloserine 125mg capsule</td>
<td><img src="#" alt="Green Circle" /></td>
<td><img src="#" alt="Green Circle" /></td>
<td><img src="#" alt="Grey Circle" /></td>
<td><img src="#" alt="Green Circle" /></td>
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[Visit the TB Medicines Dashboard](http://www.stoptb.org/gdf/medicinesdashboard/)
**Equitable Allocation of USAID-Janssen Bedaquiline Donation**

**Donation Timeline**

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mar 2015</td>
<td>30,000 treatments over 3 years</td>
</tr>
<tr>
<td>May 2018</td>
<td>30,000 treatments added, extended to 4 years</td>
</tr>
<tr>
<td>Feb 2019</td>
<td>30,000 treatments added</td>
</tr>
<tr>
<td>Mar 2019</td>
<td>15,000 treatments added for 5 Mar 2019 deadline</td>
</tr>
<tr>
<td>TOTAL</td>
<td>105,000 treatments over 4 years</td>
</tr>
</tbody>
</table>

- Rapid situational analyses of >80 countries
- Triangulation of inventory, enrolment, existing orders to meet demand ACROSS ALL COUNTRIES thru Jun 2020

**Monthly Bedaquiline Orders**

- >42,000 treatments to 55 countries in < 5 weeks
- >15,000 treatments to 32 countries in 5 days

<table>
<thead>
<tr>
<th>Month</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mar</td>
<td>203</td>
<td>257</td>
<td>4,087</td>
<td>6,779</td>
<td>4,225</td>
</tr>
<tr>
<td>Jul</td>
<td>203</td>
<td>257</td>
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<tr>
<td>Jan</td>
<td>4,225</td>
<td>4,225</td>
<td>4,225</td>
<td>4,225</td>
<td>4,225</td>
</tr>
</tbody>
</table>
TB Markets: Inherently Small and Fragmented; Require Global Coordination

MEDICINES
- **Small Market Size:**
  - Fraction of the size of HIV or Malaria
- **Markets Fragmented Across:**
  - >20 DR-TB regimens & >50 products
  - Quality Status: Internationally QA’d & locally QA’d products
  - Buyers (GDF, domestic) for Internationally QA’d products
- **Suppliers:**
  - Don’t see TB as high profit
  - Medicines “made to order”; no stock held leading to long lead times
  - Supply security is main priority

DIAGNOSTICS
- Three suppliers hold virtual monopolies for the three main TB diagnostic tests
- No consensus among main donors and buyers on best approach to improve service and maintenance or warranty costs
- **Small volumes** for many products
- Unknown quality of generic lab supplies procured by some programs
Domestic Procurement of TB Medicines and Diagnostics 2017 – Q3 2019

- 16 failed tenders
- Failed deliveries, despite successful tenders, due to lack of product registration
- 35 countries procured medicines of unknown quality
- 10 countries procured products that are not WHO-recommended
- High prices paid through local agents & distributors for certain medicines and diagnostics
- 25 countries experienced medicine stock-outs or shortages
- Slow uptake of new regimens, medicines, formulations

National distributor prices for Xpert cartridges

- Concessional, ex-works price
  - LMI Asian country: $17
  - UMI African country: $16
  - Two UMI Asian countries: $20-30
  - Four UMI EECA countries: $20-70
  - Two UMI Latin American countries: $50-80
  - National distributor price for Xpert cartridges: $9.98
Rifampicin: Demand vs Supply Imbalance

- Imbalance Due To:
  - Temporary global API supply constraint
  - Unexpected domestic procurement via GDF

<table>
<thead>
<tr>
<th>Country Demand</th>
<th>Supply</th>
<th>Backlog (cumulative)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>10,000</td>
<td>20,000</td>
</tr>
<tr>
<td>30,000</td>
<td>50,000</td>
<td></td>
</tr>
<tr>
<td>70,000</td>
<td>90,000</td>
<td></td>
</tr>
<tr>
<td>100,000</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2016  | 2017  | 2018  | 2019  |

Rifampicin API, Kilograms
GDF’s Response & Results During FLD Supply Constraint

2018 Imbalance*

2.9 Mn Treatments (Demand)

2.1 Mn Treatments (Supply)

GDF Response

- Weekly prioritization & rationing of orders for countries with high-risk of stockout
- Sending lots of smaller shipments instead of large shipments
- Monthly production planning with suppliers
- Addition of FLDs to GDF Strategic Rotating Stockpile
- Interventions to address API shortage

GDF Results

- All clients got what they needed
- 594 shipments to 86 countries
- Accommodated requests for emergency orders
  - Delivered to 19 countries in <60 days
- **No stockouts** in GDF client countries
- >65 stockouts averted

*Nov 2017 – Oct 2018

[Diagram showing the imbalance and response/results]
Challenges Going Forward

- Insufficient visibility on demand; suppliers unable to plan in advance to meet 2020 needs
  - No means to anticipate large orders from domestic buyers
  - Increase in GF procurement via GDF at end-of-grant cycle in 2020; and,
- Increased use and production of rifapentine likely to further complicate coordination and production planning of FLDs

Approaches to Address Challenges

- Add FLDs to GDF Strategic Rotating Stockpile (SRS)
- Work with GF to get end-of-grant procurement estimates & timelines for top 10 countries
- Encourage pooled procurement of rifapentine is conducted by GDF
- Establish ProCureTB Network of large domestic buyers
- Move discussion towards uninterrupted access and sustainable supply. Don’t just focus on price.
ProCureTB Network

Composition
Procurement officials from key countries with high burdens of TB (high demand)

Aim
Provide a peer-to-peer platform to support national & global procurement of TB medicines & diagnostics and ensure suppliers are able to meet TB medicine needs of all buyers.

Objectives
• Coordinate timing of orders to suppliers;
• Share information on price, availability, and product quality issues; and,
• Develop global demand forecasts.

Logistics
• Stop TB Partnership’s Global Drug Facility (GDF) will serve as the Secretariat;
• In-person meetings will be held on the side of the Stop TB Collaborating Board meetings
Paediatric DR-TB – Setting the Context

The numbers:
- ~25,000 children < 15 years old become newly sick with Drug-Resistant TB every year
- No data on # young children (<5 yo); estimates 10-12,000 get DR-TB every year, with only 500 receiving treatment
- UNHLM Target: Treat 115,000 children with DR-TB by 2022, including ~47,000 young children < 5 yo

The products:
- Until now, young children were treated with injections and suboptimal adult formulations that needed to be crushed or broken and have a bitter taste
- In 2018, the world’s first-ever, child-friendly formulations for DR-TB were developed
Stop TB’s GDF Pediatric DR-TB Initiative

Funded by the Government of Japan and USAID

- Develop clinical and technical support materials for countries
- Find & quantify demand, then provide grants for procurement of medicines
- Plan production to match demand; Conduct pooled procurement
- Generate & disseminate evidence on use (e.g., acceptability) of new formulations
Clinical & Technical Support Materials

February 2019 Update of Sentinel Project Field Guide

- Drug Information Materials
- Standard Operating Procedures for Administration (English, French, Russian)
Results to Date

GDF negotiated substantial price reductions of 30% to 85%

56 countries procured these new formulations: 16 in 2018, 40 in 2019

1,100 pediatric DR-TB were procured: 2-times the annual # of kids treated globally
56 Countries Procuring Child-Friendly DR-TB Formulations

1. Afghanistan
2. Angola
3. Armenia
4. Azerbaijan
5. Bangladesh
6. Belarus
7. Benin
8. Botswana
9. Burkina Faso
10. Cambodia
11. Cameroon
12. Chad
13. Côte d'Ivoire
14. DRC
15. Eswatini
16. Ethiopia
17. Georgia
18. Ghana
19. Guinea
20. Haiti
21. India
22. Indonesia
23. Kazakhstan
24. Kenya
25. Kyrgyzstan
26. Laos
27. Lesotho
28. Liberia
29. Malawi
30. Mongolia
31. Morocco
32. Mozambique
33. Myanmar
34. Namibia
35. Niger
36. Nigeria
37. Pakistan
38. Papua New Guinea
39. Republic of Moldova
40. Rwanda
41. Senegal
42. Sierra Leone
43. Somalia
44. South Africa
45. Sri Lanka
46. Tajikistan
47. Tanzania
48. Thailand
49. Timor-Leste
50. Turkmenistan
51. Uganda
52. Ukraine
53. Uzbekistan
54. Viet Nam
55. Zambia
56. Zimbabwe
Introduction of New Pediatric TB Formulations

- **1st Pedi FDC for DS-TB**: 36
- **2nd Pedi FDC for DS-TB**: 40
- **New Pedi Meds for DR-TB**: 56

**# Countries Ordered in First 15 Months:**

- **1st Pedi FDC for DS-TB**: 36
- **2nd Pedi FDC for DS-TB**: 40
- **New Pedi Meds for DR-TB**: 56
It’s Time to End Drug-resistant TB in Children

The Pediatric DR-TB Initiative **is only possible** thanks to the support provided by USAID and the Government of Japan.
Thank you!
ありがとうございました！
Terima kasih!

Dr Brenda Waning
brendaw@stoptb.org