

# WHAT IT TAKES TO ROLL OUT A NEW TREATMENT REGIMEN: LESSONS FROM DR-TB

*Dr Norbert NDJEKA*

MD, DHSM (Wits), MMed (Fam Med) (MED), Dip HIV Man (SA)  
*Director Drug-Resistant Tuberculosis, NDoH, South Africa*



health




Department:  
Health  
**REPUBLIC OF SOUTH AFRICA**

# OUTLINE




- Background: DR-TB situation in RSA and the impact of Covid-19
- Introduction of MDR-TB Shorter Treatment Regimen:
  1. Interaction with regulatory authority
  2. Interaction with Experts Committees
  3. Training of health care workers
  4. Coordination with other Government sections (pharmaceutical, finance, academia)
  5. Partnerships
- Challenges encountered
- Progress report
- Conclusion

# DR-TB BURDEN: SOUTH AFRICA AND GLOBAL CONTEXTS

## GLOBAL

 Incidence	<b>465,000</b> RR and MDR-TB estimated in 2019	
 Treatment	<b>177,099</b> RR and MDR-TB initiated during 2019	<b>57 %</b> <b>2017</b> RR and MDR-TB success rate
	<b>38 %</b> of MDR-TB cases are initiated on treatment	
 XDR	<b>47 %</b> Success rate of those started on second-line treatment in 2016	

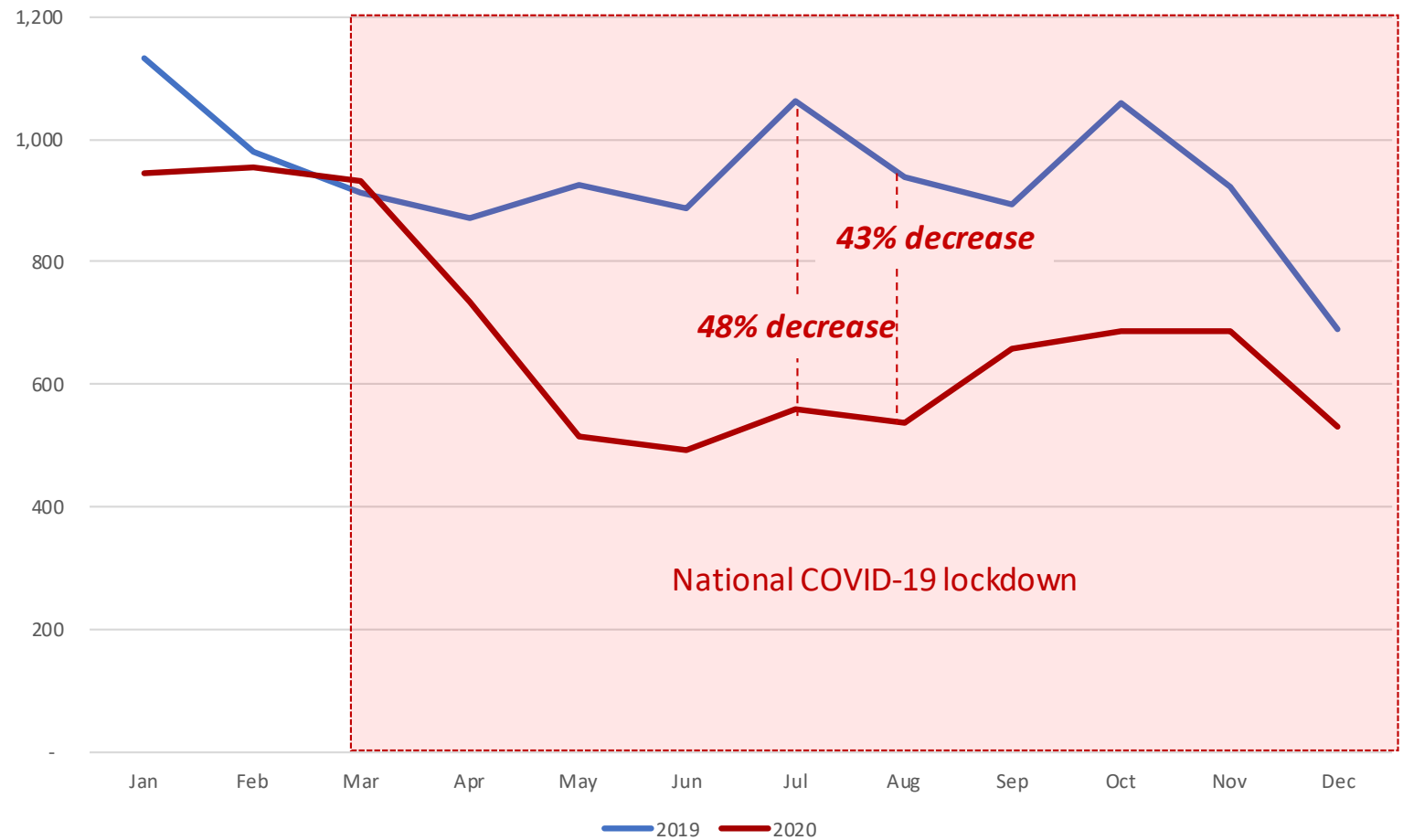
## SOUTH AFRICA

 Incidence	<b>13,005</b> RR and MDR-TB diagnosed in 2019	
 Treatment	<b>9,040</b> RR and MDR-TB initiated in 2019 (incl. 406 XDR-TB)	<b>60 %</b> <b>2017</b> RR and MDR-TB success rate (n= 9,798)
	<b>70 %</b> of DR-TB cases are initiated on treatment in 2019	
 XDR	<b>60 %</b> Success rate of those started on second-line treatment in 2016 (n=604)	

South Africa has one of the **highest DR-TB burdens** in the world but **outperforms the global standard of treatment initiations** almost two-fold

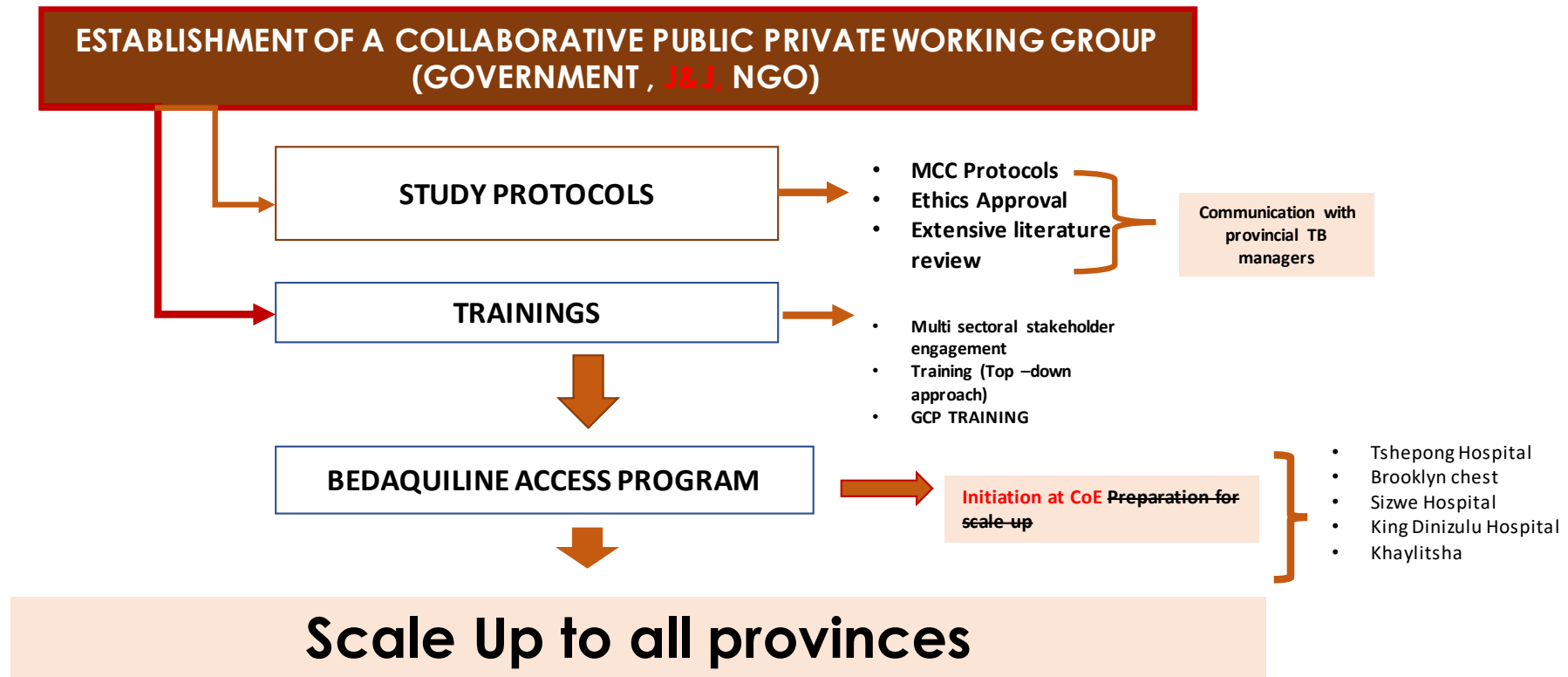
# DR-TB CASE-FINDING DURING COVID-19

Month	2019	2020	% change
Jan	1,132	945	-17%
Feb	979	955	-2%
Mar	912	932	2%
Apr	870	736	-15%
May	925	514	-44%
Jun	886	492	-44%
Jul	1,063	558	-48%
Aug	939	536	-43%
Sep	895	657	-27%
Oct	1,060	688	-35%
Nov	922	686	-26%
Dec	691	530	-23%
<b>Grand Total</b>	<b>11,274</b>	<b>8,229</b>	<b>-27%</b>



DR-TB Case-finding has declined considerably since the onset of the COVID-19 epidemic (Source: EDRweb, 2021) 4

# PLANNING AND IMPLEMENTING BEDAQUILINE CLINICAL ACCESS PROGRAMME IN SOUTH AFRICA: FROM 2011 TO 2015.



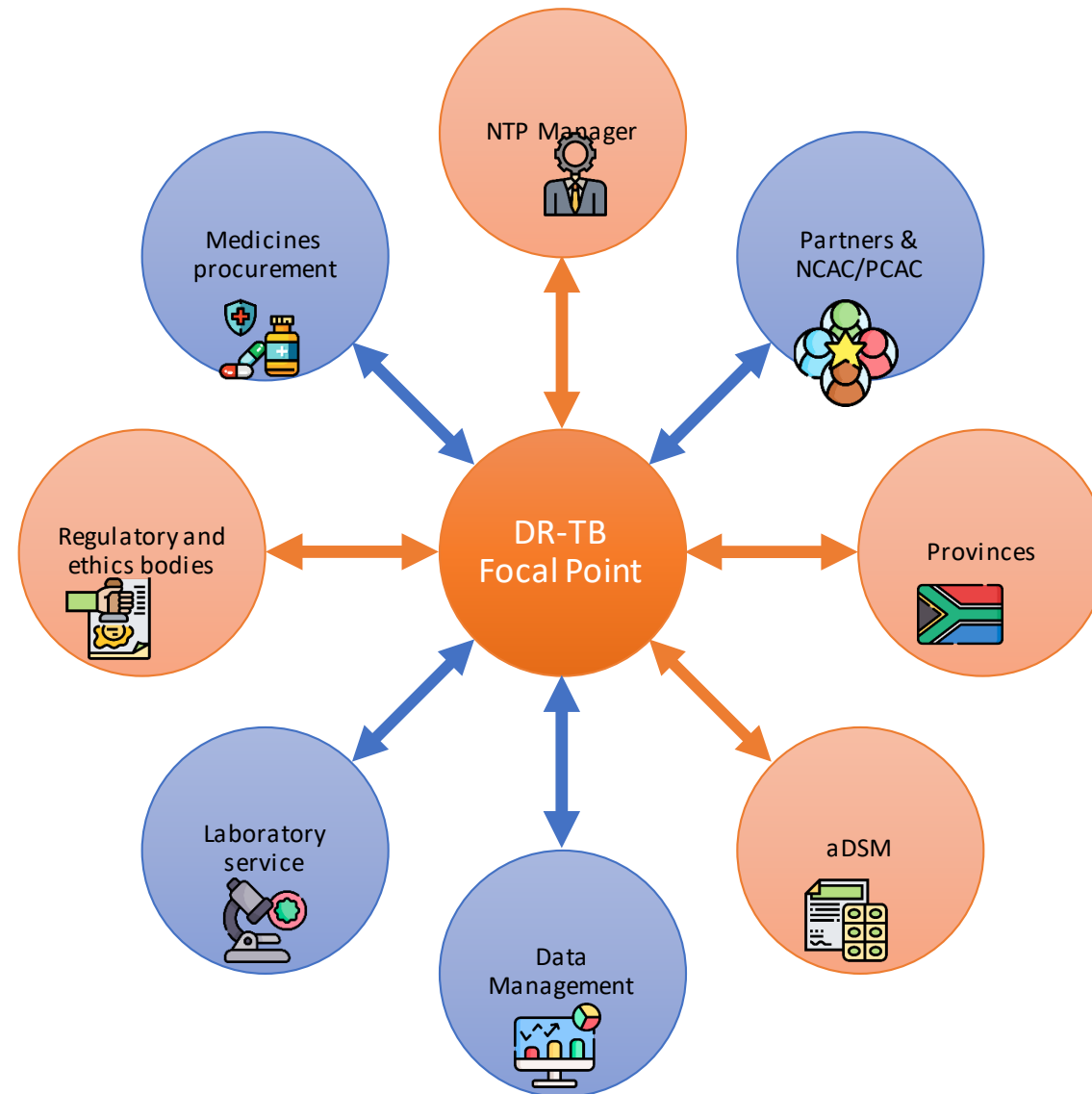
## LEGEND:

**NGO:** Non-Governmental Organization    **MCC:** Medicines Control Council    **GCP:** Good Clinical Practice

## Source:

**Ndjeka N**, Hughes J, Reuter A, Conradie F, Enwerem M, Ferreira H, Ismail N, Kock Y, Master I, Meintjes G, Padanilam X, Romero R, Schaaf HS, Riele JT, Maartens G. **Implementing novel regimens for drug-resistant TB in South Africa: what can the world learn?** Int J Tuberc Lung Dis. 2020 Oct 1;24(10):1073-1080. doi: 10.5588/ijtld.20.0174. PMID: 33126942.

# INTERACTIONS REQUIRED



# TRAINING OF HEALTH CARE WORKERS

- Treatment guidelines need to be revised to accommodate new drugs and regimens
- Tools to be aligned with revised guidelines
- Training needs assessed
- Detection of Aes using ECG, audiometers
- Implementation of training to be monitored e.g. pre and post-tests

COORDINATION  
WITH OTHER  
GOVERNMENT  
SECTIONS  
(PHARMACEUTICAL,  
FINANCE and  
ACADEMIA)

Political commitment is required

Finances and other resources are required

Support from pharmaceutical section for  
procurement/supply chain

Technical assistance from NGOs and Academia to support  
provinces and districts and roll out was decentralised

The local Academia is also very helpful in providing  
technical assistance



# PARTNERSHIPS

Establishment of a network to help diagnose and manage adverse events

- ototoxicity i.e. provision of audiometers and training
- Provision of equipment (ECG)

Improve recording and reporting tools i.e. EDR Web upgrade

Funding for training of staff

# KEY SUCCESS FACTORS



Functional national committee with clinical and programmatic sub-teams



Effective coordination of the work between the NTP and Expert Committee



Cooperation from the regulatory authority and other governance structures



Acquisition of medicines



Ensure there is a functional data system



Effective laboratory services



Availability of funds to hold events (e.g. training, best practice sharing)

# CHALLENGES



Securing buy-in (and managing resistance to change) from key stakeholders at early stages



Regulatory authority approval (18 months for regulatory approval of BDQ; 18 months waiting period to get DCAP approved)



Quantification and stock management (scale-up of BDQ and run-down/write-off of KM stock)

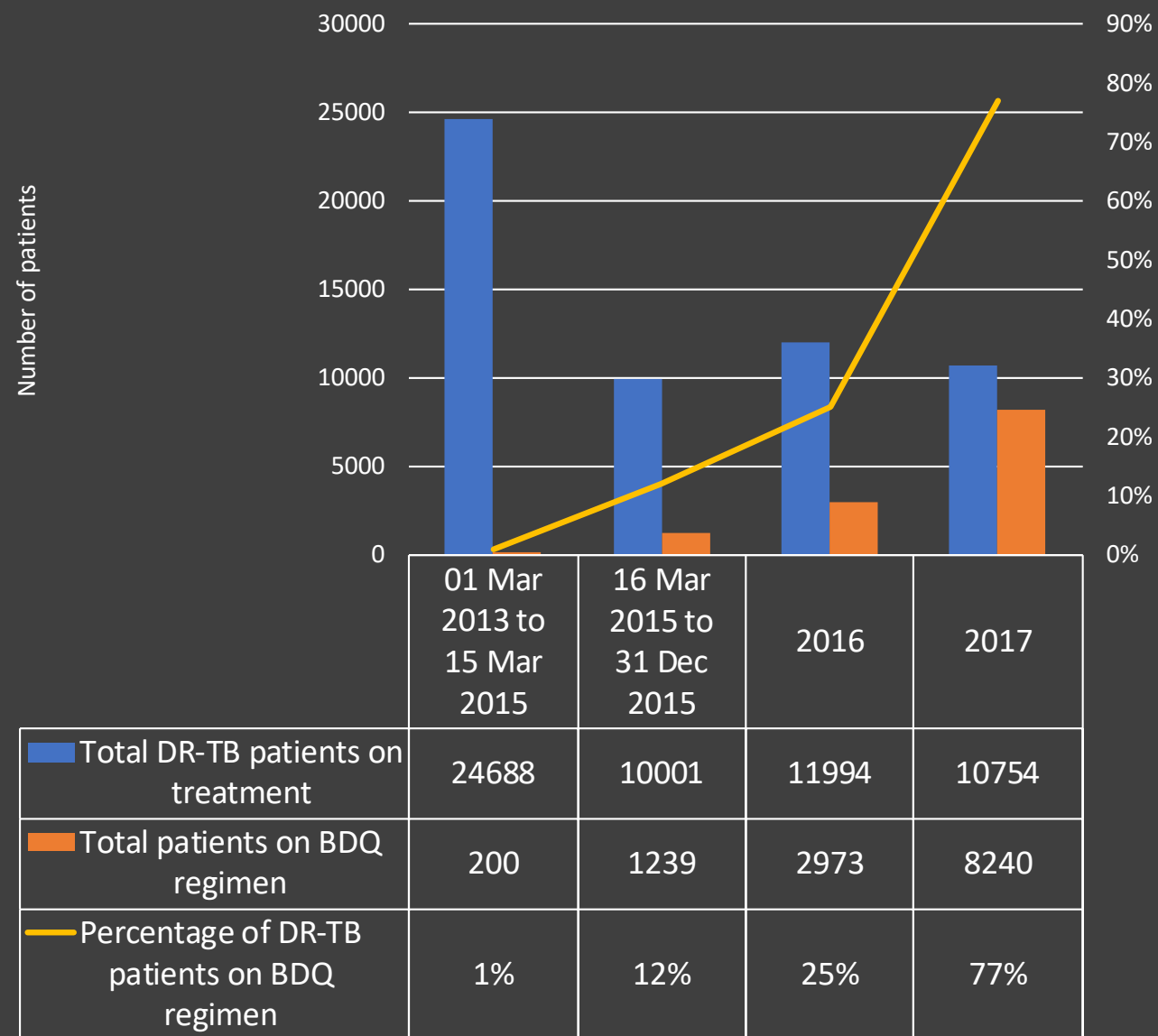


Tracing patients being unnecessarily initiated on injectable-containing regimens



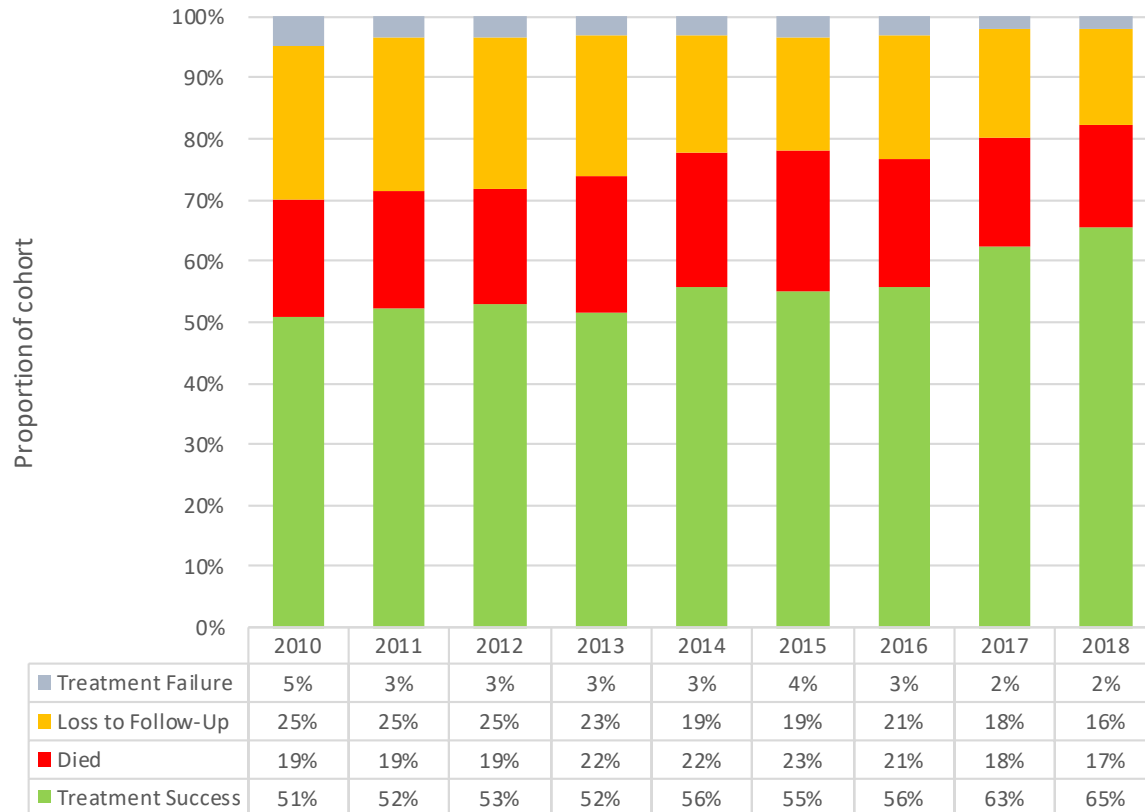
COVID-19 lockdown has impacted patient attendance/presentation for care; difficult to bring them back

# INTRODUCTION OF BEDAQUILINE

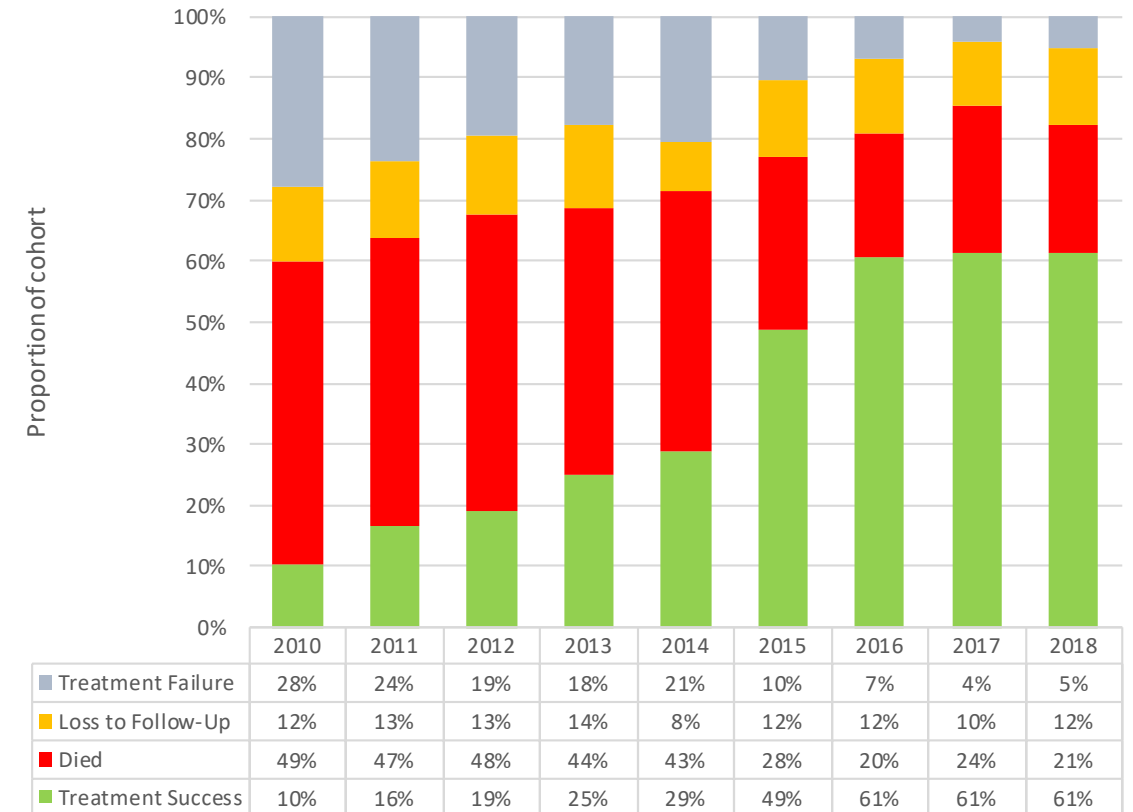


# Treatment outcomes

## Treatment Outcomes (MDR TB)

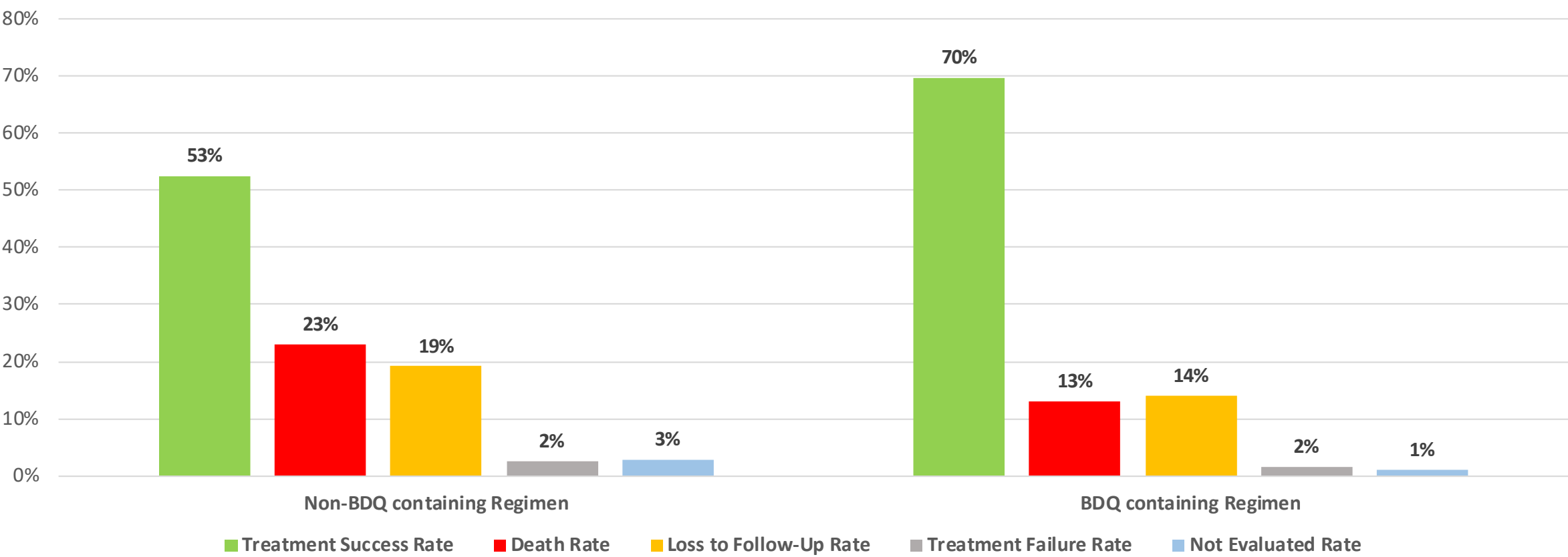


## Treatment Outcomes (XDR-TB)



# 2017 COHORT: NON-BDQ VS BDQ CONTAINING REGIMEN (LONG & SHORT REGIMEN)

2017 Cohort: Non-BDQ vs BDQ containing regimen



# CONCLUSION

- Planning is critical
- Interaction with various Government structures responsible for acquisition of drugs, laboratory supplies, equipment
- Meeting regulatory authority requirements
- Strong partnerships with academia, with NGOs and private sector
- National Team that supports clinical and programmatic activities
- Revision of treatment guidelines
- Training of health care workers
- To sum up everything, I would say INNOVATION IS KEY