

# Clinical decision-making

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# Clinical decision-making



Contextual, continuous, evolving,  
data driven process in consultation  
with the patient



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# Clinical decision-making – Example

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- In a country where Bdq, Dlm, Lzd and Cfz were available in routine use, a patient was diagnosed with RR-TB and started on standard second-line treatment
- Baseline first- and second-line DST received 3 months later showed FQ-R and the clinician decided to add PAS and continue with the same regimen
- Patient remained continuously positive without any change in the regimen.
- DST performed at 12 month of treatment showed patient infected with XDR strain
- Unfortunately patient's brother (age=20) and sister (age=11) attended the facility with symptoms and were also later found to also have XDR-TB



**Poor clinical practice!**



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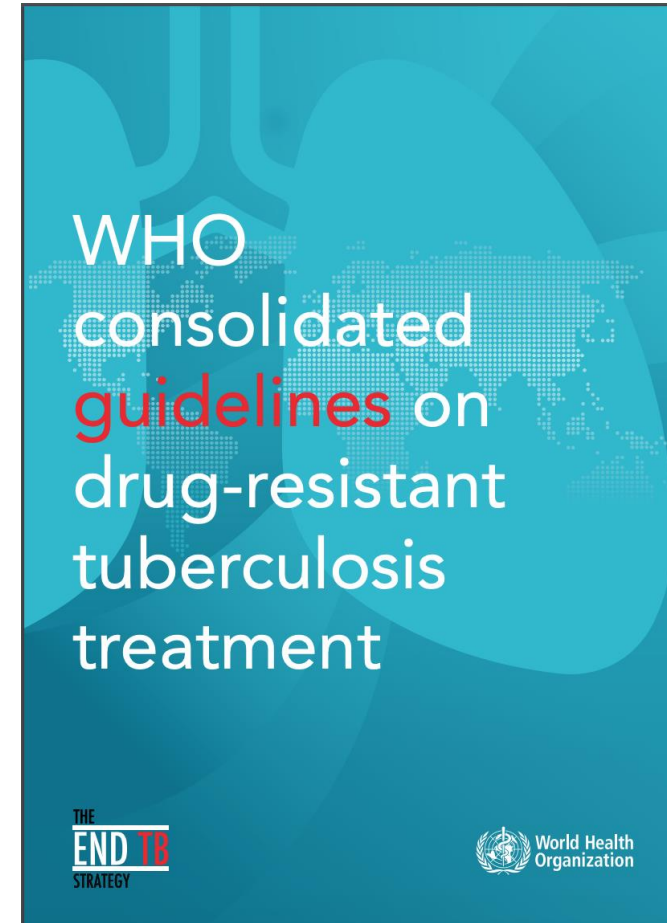
# Clinical decision-making!

## Resources – clinical guidance

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### WHO consolidated updated guidelines

- Changes in drug hierarchy; Bdq and Lzd moved up in Group A, injectables moved down to Group C
- Recommendation for all-oral longer regimens
- Recommend use of AOS regimen in OR conditions



# Resources - endTB website

[www.endTB.org/resources](http://www.endTB.org/resources)



endTB clinical  
guide



Forms



E-learning modules



Reports



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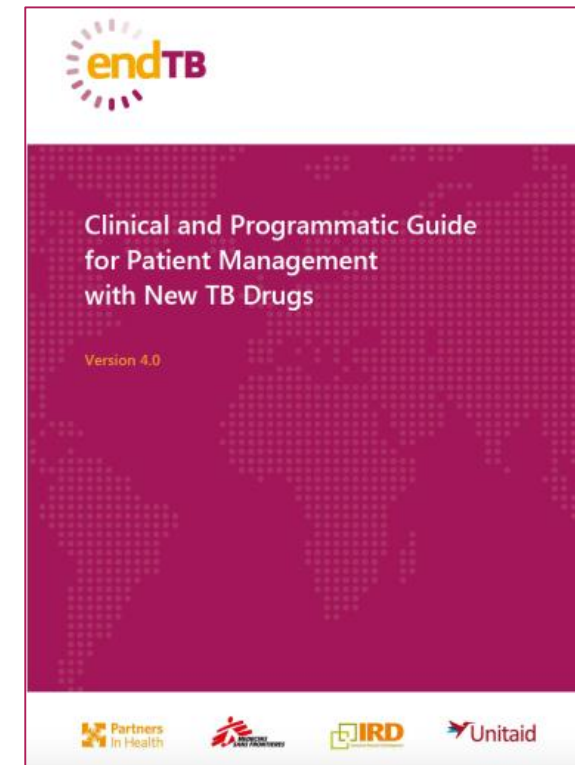


# Resources – clinical guidance

## endTB clinical and programmatic Guide for Patient management

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- Guidance on regimen design, treatment duration, drug interactions, safety monitoring and management
- Used by clinicians and programs
- Dynamic document, incorporates learnings from the field, last version 4.0
- Available in different languages – English, Russian and Spanish
- **v5 will be online soon!**



# Resources – clinical guidance

## Clinical Guide for all-oral shorter regimen (AOS)

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What is different from the endTB clinical guide?

- Guidance on operational research on all-oral shorter regimen; adapted from endTB clinical guide and can be adapted to your local setting
  - Eligibility criteria, considerations to design AOS, duration of treatment, drug interactions, minimum requirements for safety monitoring and management
  - Practical considerations on failures or impending failures, slow clinical response and what to do in case of drug toxicity
  - OR on AOS in special populations
  - Considerations for recurrence and Relapse: outcome and post treatment follow-up and post-treatment outcome

# Resources – clinical guidance

## Management of Multidrug-Resistant Tuberculosis in Children: A FIELD GUIDE

- Only guide put together by pediatric MDR experts in conjunction with WHO
- Focused on specific management principles of young children including use of newer drugs
- Specific pediatric monitoring and AE management (e.g. monitor for PN etc.)



## Management of Multidrug-Resistant Tuberculosis in Children: **A FIELD GUIDE**

Fourth Edition: February 2019  
Cover photo courtesy of Marcela Tommasi



Guides are not enough!



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# Expert Advise

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- Local experts and clinical committees
- External committee of experts
- Consider including external experts who may volunteer on local committees (e.g ESwatini)

# Expert Committees

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## Advantages

- Advise on:
  - difficult cases; e.g. regimen design in hard to treat patients
  - Special populations; children, pregnant women, co-existing conditions
- Direct access to international experts
- Help in capacity building

## Disadvantages

- Different opinions, depending on setting can be obstructive
- Delay in start of treatment
- Continuous dependency; clinicians not empowered to make independent clinical decisions
- Older, conventional ways hinder inclusion of newer approaches to treatment of MDR-TB



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# Expert Advise

## External medical committee

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### **endTB medical committee:**

- Active since 2015, 16 MDR-TB experts
- >500 cases reviewed from 20 countries
- Accessible to PIH, MSF and IRD projects
- PIH: Michael Rich  
email: [mrich@pih.org](mailto:mrich@pih.org)
- MSF: Cathy Hewison  
email [cathy.hewison@paris.msf.org](mailto:cathy.hewison@paris.msf.org)
- IRD: Uzma Khan  
email [uzma.khan@ird.global](mailto:uzma.khan@ird.global)

### **Sentinal project for guidance on children:**

Contact: [tb sentinelproject@gmail.com](mailto:tb sentinelproject@gmail.com) or [jenniferfurin@gmail.com](mailto:jenniferfurin@gmail.com)



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# Expert Advice

## Knowing when you need it and when you don't!

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Example 1: 24 year old patient on previous MDR regimen, failed treatment that included one drug and you want support in a salvage individualized regimen



on previous MDR regimen, failed treatment that included one drug and you want support in a salvage individualized regimen

Example 2: 16 year old patient with FQ-S MDR-TB started on Z-Bdq-Lfx-Cfz-Lzd has late bacteriologic response, culture negative at month 5, is clinically responding – still not gain, asymptomatic, adhering to treatment, no adverse events. The clinician wants to ask the expert committee whether to extend treatment or not.



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# Use of data for clinical monitoring and decision-making

**EndTB Patient Dashboard**  
Patient Summary

Nida Yaqoob (PAK-001-00018-01) | Female | 20 Years 7 months 22 days

**TREATMENT INFORMATION**  
Treatment start date: 15 Aug 16  
Current month of treatment: 6.4

**CASE DEFINITION**  
WHO registration group: Treatment After Failure  
Disease site: Pulmonary  
Drug resistance profile: Confirmed drug resistant TB  
Sub-class of drug resistance profile: Confirmed MDR

**SEROLOGY STATUS**  
HIV: Negative  
Hep B ag: Non-reactive  
Hep C ab: Non-reactive  
Baseline HIV: Negative  
Hepatitis B: No  
Hepatitis C: No

**CO-MORBIDITIES**  
No Co-morbidities for this patient

**IMPORTANT DATES**  
Treatment start date: 15 Aug 16

**PAST TB TREATMENT INFORMATION**  
Year first TB treatment: 2016  
Drug-Susceptible TB Treatment in the Past: No  
Drug-Resistant TB Treatment in the Past: Yes  
How Many Drug-Resistant TB Treatments: 1  
Past TB drugs > 1 month: Cycloserine (Cs), Pyrazinamide (Z), Amikacin (Am), Levofloxacin (Lfx), Ethionamide (Eto)

**PREVIOUS TB TREATMENT TABLE**

Start date of past TB treatment	End date of past TB treatment	Type of treatment	Regimen type	Past TB outcome
03 Feb 16	05 Aug 16	DR-TB	Cat 4	Failed

**DST RESULTS**

Mo nth	Date	H 0.2	H 1.0	R	E	S	Z	Of x	Lfx	Mf x 0.5	Mf x 2.0	A m	K m	C m	E t o	Cs	PA S	Bd q	DI m	Lz d	Ctz	
-8.4	06 Dec 15		Re s	Re s	Re s	Re s	Su s	Su s				Su s	Su s	Su s	Su s							
-0.3	05 Aug 16		Re s	Re s	Re s	Re s	Re s	Su s			Su s	Su s	Su s	Su s	Su s							

- Standardized data collected at all sites
- Can be used for clinical monitoring and helps improve clinical practice
- Using patient summaries and customized reports

# Technical support for designing AOS OR protocol, data management, experience sharing and capacity building

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# Summary

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- Important to empower clinicians to make independent decisions
- Good clinical monitoring for toxicity essential for all drugs and regimens
- Resources that should be routinely available, need to be accessible to programs for decision making (e.g. second-line LPA, screening for PN and VA etc.) but absence should NOT stop us from using good clinical judgement
- Always use the best regimen as the initial choice of treatment not leave as a last resort!



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