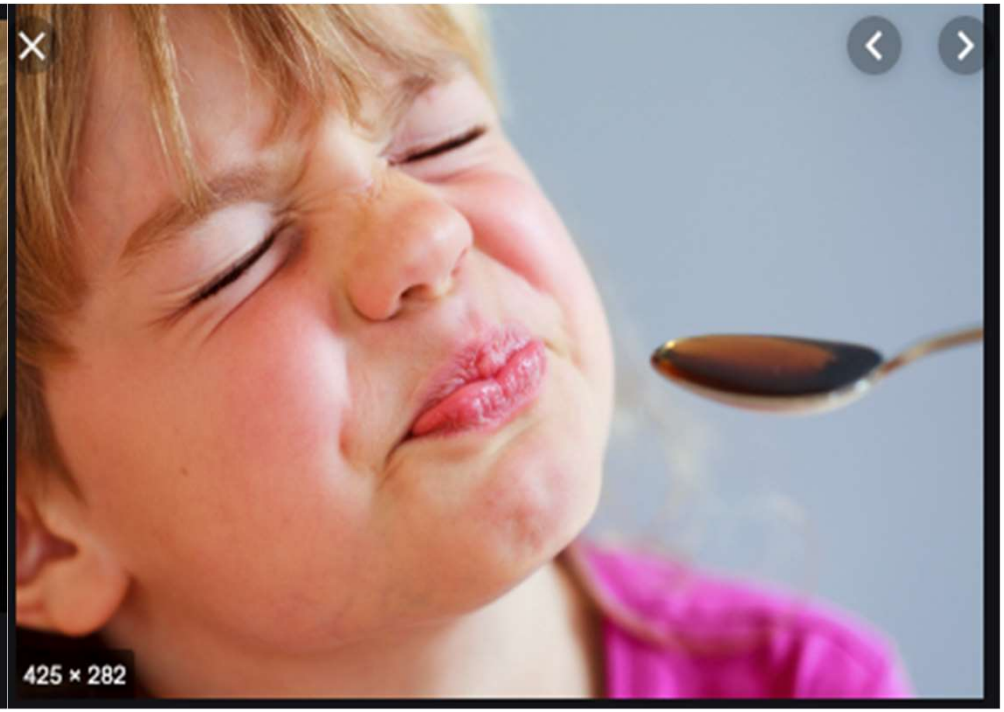
Barriers to treatment 1

- Taste Formulation tablet vs liquid , volume , tablet size…….
- Will FDC solve this?


HOW TO GIVE YOUR CHILD
LIQUID MEDICINES
AT HOME
aboutkidshealth.ca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- 15 kg 3 yrold
- Rifampicin 15mg/kg : 11.25 ml
- Isoniazid 10mg/kg : 15ml
- Pyrazinamide 35mg/kg : 7 ml
- Ethambutol 20mg/kg : 6ml
- Pyridoxine only tablets
- Vit D

- 5 children
- 2 x1 yrolds, 3 yrold 5 yrold 9 yrold
- Mum dad and granny also all on medication
- Sticky bottles
- Mum also on iron replacement
- English not first language
- 5 and 9 yrold on tablets
- shortage of rifinah 150/100 so dispensed separate Rif & INH from new pharmacy..that didn’t match previous dosing chart

- Liquid preparations are available but reduced stability (<4 weeks)
- Move to standardize strength across UK
- All standard TB drugs can be crushed and given with small amount food
- If crushed do within 30 min of dose
- Rifampicin from capsule? Irritant
- IF mixed with food (or liquid) make sure whole dose taken
- Mix with water … suspension or dissolves
- INH not stable in sugary liquids

- Are FDC the solution?

Statement on the use of child-friendly fixed-dose combinations for the treatment of TB in children

In December 2015, the World Health Organization (WHO) and the Global Alliance for TB Drug Development (TB Alliance), with support from UNITAID, launched child-friendly fixed-dose combinations (FDCs) for the treatment of drug-susceptible tuberculosis (TB) in children weighing less than 25 kg.

The formulations available are as follows:

- **For the intensive phase of treatment.** 3 FDC (rifampicin 75 mg + isoniazid 50 mg + pyrazinamide 150 mg).
- **For the continuation phase of treatment.** 2 FDC (rifampicin 75 mg + isoniazid 50 mg).

The child-friendly FDCs were developed in line with the revised dosing to achieve the appropriate therapeutic levels, which was published in the WHO *Guidance for national tuberculosis programmes on the management of tuberculosis in children*, second edition (2014) (see table below).

Medicine	**Dosage (mg/kg)[a]**
Isoniazid (H)	10 (range 7–15)
Rifampicin (R)	15 (range 10–20)
Pyrazinamide (Z)	35 (range 30–40)
Ethambutol (E)	20 (range 15–25)

[a]As children approach a body weight of 25 kg, adult dosages can be used.

Weight band	Numbers of tablets	
	Intensive phase: RHZ 75/50/150[a]	**Continuation phase: RH 75/50**
4–7 kg	1	1
8–11 kg	2	2
12–15 kg	3	3
16–24 kg	4	4
⩾25 kg	Adult dosage recommended	Adult dosage recommended

[a]Ethambutol should be added in the intensive phase for children with extensive disease or living in settings where the prevalence of HIV or of isoniazid resistance is high.

The FDCs are obtainable from the Global Drug Facility. For more information, please consult www.stoptb.org/gdf

- Variety of FDC available … but not easy to access in UK
- Still issues with : bioavilability / bioequivalence
- Variety of formulations
- Drug availability varies with host genetics , age, pathophysiology, environment
- Evidence of risk under dosing in some young infants

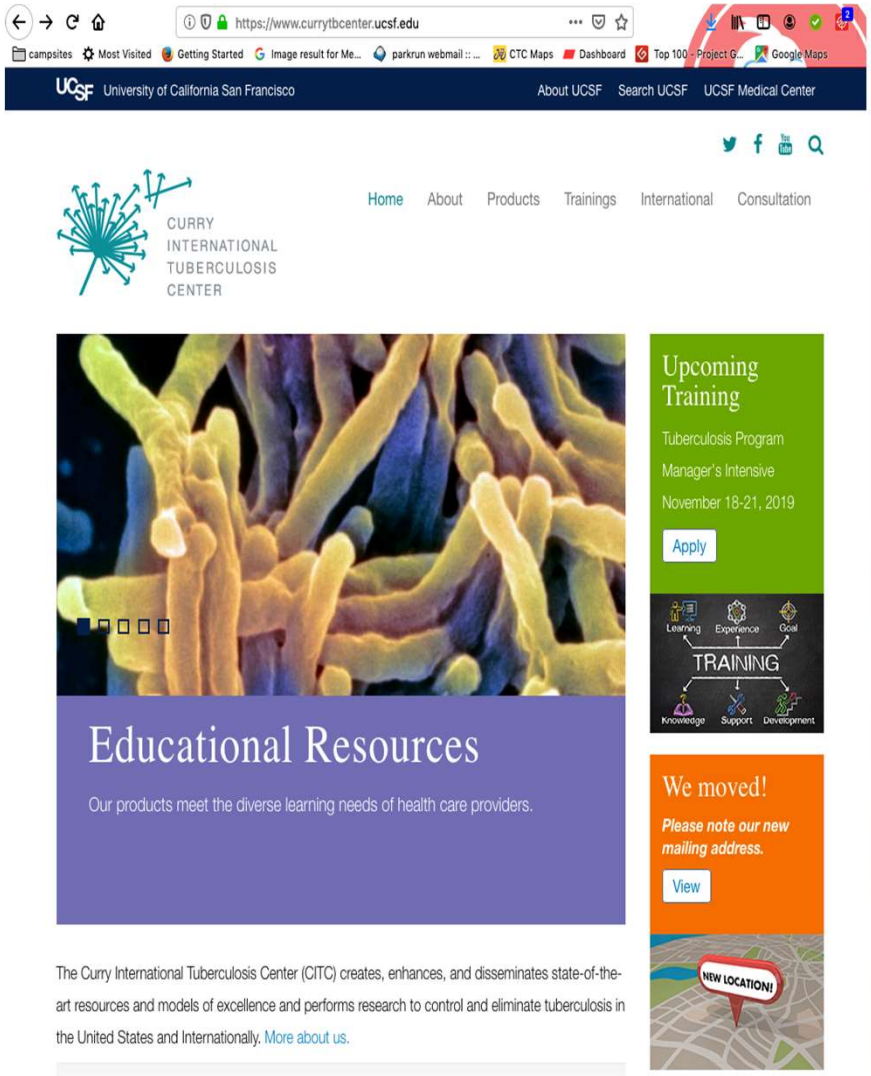
- SHINE study : RCT Africa and Asia

FDC 4 vs 6 months in “mild TB “ in children

Due to report 2020

- More info about FDC in real life

- UK experience:
- Units that have used: needs large volume liquid to make palatable
- Aston University Birmingham trial currently ongoing improved formulation
- PTBNET paper in progress pooling experience so far across Europe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The Curry International Tuberculosis Center (CITC) creates, enhances, and disseminates state-of-the-art resources and models of excellence and performs research to control and eliminate tuberculosis in the United States and Internationally. More about us.
Upcoming Training
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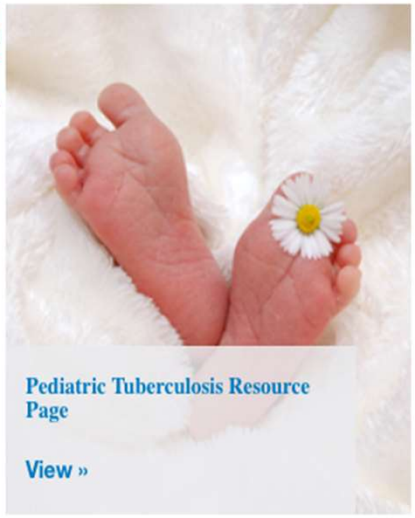
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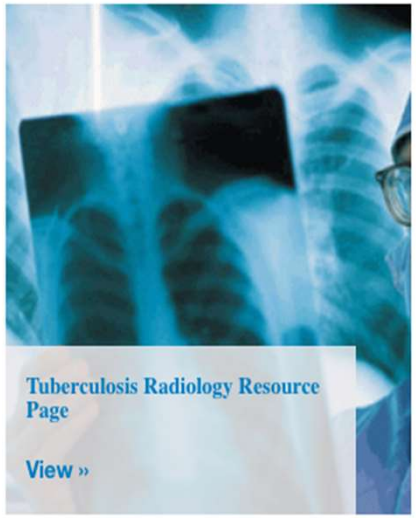
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TB COE
Four Regional TB Centers of Excellence (COE) for Training, Education, and Medical Consultation serve the health care community across the U.S.
Learn more »


CITC Newsletter
Summer 2019 Edition
View »


Homelessness and TB Toolkit
An online Toolkit and resource guide to assist both public health programs and homeless service agencies
Learn more »

- Who is the best person to give medication?
- Would somebody else be more effective giving eg other family member
- Other route ? NG
- Crush tablet
- Mix with food or liquid
- Jelly, marmalade, Nutella, peanut butter ice cream, yoghart

- Potential impact on absorption/ availability in crushed or liquid medication mixed with food or liquid

- If Vomits > 30 minutes after no need to repeat dose

Barrier 2

- Compliance…. Remembering or wanting to take it (give it)
- Compliance with many long term medications poor in adults and children
- Improved by understanding need for treatment
- ? Improved if you know you are unwell
- Latent vs active TB ? Where might compliance be worse
- Compliance reduced if feeling unwell from condition or medication side effect
- Reduced if concern about toxicity
- Reduced if you .. Or family members don’t think you need it
- Reduced if other complex social / life issues

- DOT variable evidence of improving out come in active disease but consensus should be offered (WHO 2017)
- 3x a week DOT no longer recommend (WHO 2017)
- DOPT Directly observed preventative therapy – Compliance with latent TB may be 50%
- ESAT enhanced self administered therapy
- VOTs visually observed therapy : some UK experience in children ? adolescents

Recommendations

2.1.1 Health education and counselling on the disease and treatment adherence should be provided to patients on TB treatment (Strong recommendation, moderate certainty in the evidence)

2.1.2 A package of treatment adherence interventions[25] may be offered to patients on TB treatment in conjunction with the selection of a suitable treatment administration option[26] (Conditional recommendation, low certainty in the evidence)

2.1.3 One or more of the following treatment adherence interventions (complementary and not mutually exclusive) may be offered to patients on TB treatment or to health-care providers:

a) tracers[27] and/or digital medication monitor[28] (Conditional recommendation, very low certainty in the evidence)

b) material support[29] to patient (Conditional recommendation, moderate certainty in the evidence)

c) psychological support[30] to patient (Conditional recommendation, low certainty in the evidence)

d) staff education[31] (Conditional recommendation, low certainty in the evidence).

Recommendations

2.1.4 The following treatment administration options may be offered to patients on TB treatment:

a) Community- or home-based DOT is recommended over health facility-based DOT or unsupervised treatment (Conditional recommendation, moderate certainty in the evidence).

b) DOT administered by trained lay providers or health-care workers is recommended over DOT administered by family members or unsupervised treatment (Conditional recommendation, very low certainty in the evidence).

c) Video observed treatment (VOT) may replace DOT when the video communication technology is available and it can be appropriately organized and operated by health-care providers and patients (Conditional recommendation, very low certainty in the evidence).

- Education and counselling: In TB clinic:

Clinician, Nurses, Pharmacist

- Psychology….
- Material support ….. Encourage parent to bribe/ reward children?
- Digital medication monitors
- Doset boxes
- Compliance charts
- Colour coding for medication
- Labelling syringes

- BE HONEST and Encourage families to BE HONEST
- Explain and re-explain why they or their child needs this

- Busy clinic
- Families late and seeing multiple family members
- Interpreter not available or missed time slot

- Simple medications but easy to make mistakes
- Time for family education not easily available
- Pharmacy important role

- Parent may not be taking their own medication
- Importance of collaborative working with adult services

Sheffield Children's NHS Foundation Trust

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Pharmacy Department

MEDICINE INFORMATION SHEET

Name:

NHS number:

Date of birth:

This chart helps you to make sure all medicines are given at the right times.

MEDICINE	Midday  (12pm-2pm)
RIFINAH 150/100 (Rifampicin 150mg/ Isoniazid 100mg tablet)	Give …… tablets
Pyrazinamide 500mg tablet	Give …… tablets
Ethambutol 400mg Tablet	Give …… tablets
Pyridoxine 10mg Tablet	Give …. tablet

Prepared by: Checked by: Date:

Sheffield Children's NHS Foundation Trust

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Pharmacy Department

MEDICINE INFORMATION SHEET

Name:

NHS number:

Date of birth:

This chart helps you to make sure all medicines are given at the right times.

MEDICINE	Morning (10am) 	Mon	Tue	Wed	Thur	Fri	Sat	Sun
Rifampicin 150mg/ Isoniazid 100mg tablets (Rifinah)	Give ….. tablets							
Pyrazinamide 500mg tablet	Give …… tablets							
Ethambutol 400mg/100mg tablet	Give ….. tablets							
Pyridoxine 10mg tablet	Crush and disperse **HALF** a tablet in a small amount of water							

- How do we people currently decide who merits DOTS?
- Do we always get it right?
- Does anybody use DOTS in Latent TB currently?

- WHO LTBI 2018 : “ interventions to ensure adherence should be tailored to specific needs and local context. This may include similar support to that used in active disease”

- Do all children need DOTS?....

- Who can give DOTS?
- Health care professionals: OPAT, TB nurse, community nursing team Community pharmacy
- Non healthcare professionals *“with training”*
- ? School
- ? Social care

- Who gives DOTS in your area

- Any experience with?
- School
- Social care
- Community pharmacy

What training was put in place?

How was compliance monitored ?

- Problems with medication is often a family thing….

Barrier 3 side effects / Toxicity

- 60% of adult may have flu like symptoms with LTB rx
- Advise families about possible more serious side effect : loss of appetite nausea/ vomiting, yellowing of skin , skin rashes
- Increased number of children with abnormal LFT since new WHO dosing
- Cytopenias less common but can occur with standard TB meds
- Opthalmology & Ethambutol: base line eye test recommended in all children … practical national guidance in progress
- Allergic drug reactions

- Raised AST /ALT “not uncommon at initiation of treatment”

(in adults)

Repeat at 2-4 weeks into treatment ? All case ? Just active disease

ALL children need monthly clinical assessment (WHO, CDC)

* MDR treatment need monthly LFT , U & E, FBC, other monitoring dependant on drug

- Stop treatment if > 5x normal or > 3 x normal and symptomatic
- Unless severe active disease (substitute other medication) stop all treatment till LFT normalized
- Gradual introduction
- If drug identified may impact on duration of Rx +/- need to consider other drugs

TB DRUG MONOGRAPHS

Home | Baseline & Ongoing Monitoring Tests | Drug Monographs | For Patients | More...

A UK based resource to support the monitoring and safe use of anti-tuberculosis drugs and second line treatment of multidrug-resistant tuberculosis.

NB: WHO have issued a rapid guidance in August 2018 with substantive changes to all treatment groups in the last 2016 MDR guidance ***advising that capreomycin and kanamycin should not be used in MDR TB. Amikacin is still within their guidance but this is now downgraded to a group C medication with Bedaquiline now being upgraded to a group A drug****. However given that these new guidelines need to be agreed to be implemented locally and nationally, individual cases should still be managed with expert MDR advice and also in conjunction with the BTS MDR Clinical Advice Service review*

FULL GUIDANCE: PDF Last Updated AUGUST 2018

mdrtb_adr_monitoring_guidance_august_2018.pdf
Download File

USEFUL LINKS

Table A8.2. Protocol for reintroducing TB drugs after DILI or grade 1–3 rash (adapted from a reintroduction protocol for cutaneous reactions [23])

Day	Isoniazid (mg)	Rifampicin (mg)	Pyrazinamide (mg)
1	50		
2	150		
3	300		
4	300	75	
5	300	150	
6	300	300	
7	300	450 <50 kg; 600 >50 kg	
8	300	450/600	250
9	300	450/600	500
10	300	450/600	1000
11	300	450/600	1500 <50 kg; 2000 >50 kg
12	300	450/600	1500/2000
13	300	450/600	1500/2000

British Association of Paediatric TB (BAPT)

- *4Th Annual National Education Meeting*

8th Feb 2020 Newcastle

- Established 2017
- Open to any professional involved in paediatric TB
- Improve access to and provision of care for children and familes with TB
- Forum for Education and Guideline development
- Identify paediatric priorities for TB Action plan 2020-2025

Draft proposals to be finailised

- Implement actions to reduce active cases of TB and child transmission
- Treatment outcomes and data collection for active and latent TB in children
- Engage with Community paediatrics and Unaccompanied / Assylum seeking support services
- Ensure funding for paediatric TB networks and virtual clinics
- Support for standardized pathways of care in paediatric TB around a hub and Spoke model
- Training and support for all healthcare worker managing children with TB

- **** pTB net: European / International collaboration paediatric TB***