MEDECINS SANS FRONTIERES
FIELD RESEARCH

The Impact of a Tick-Sheet in Improving Interpretation Accuracy of Chest Radiographs by Non-Specialists in an HIV positive cohort

Item Type	Other
Authors	Kosack, Cara; Mesic, Anita; Spijker, Saskia; Bonnet, Maryline; Joekes, Elizabeth
Rights	These materials can be used, adapted and copied as long as citation of the source is given including the direct URL to the material. This work is licensed under a Creative Commons Attribution 4.0 International License: http://creativecommons.org/licenses/by/4.0/ https://i.creativecommons.org/l/by/4.0/88x31.png
Download date	05/08/2021 16:29:51
Link to Item	http://hdl.handle.net/10144/619246

Version   February 02, 2013
                           Médecins Sans Frontières and Epicentre

FINAL PROTOCOL

The Impact of a Tick-Sheet in Improving Interpretation Accuracy of Chest Radiographs by Non-Specialists in an HIV positive cohort

Study protocol

MSF International
MSF Holland
Epicentre

2013

Study Protocol: The Impact of a tick-sheet in Improving Interpretation Accuracy of Chest Radiographs by Non-specialists in an HIV-positive cohort

Study sites	Shan State, Myanmar Médecins Sans Frontières - Holland
Methodology	Medecins Sans Frontieres and Epicentre
Collaboration	Ministry of Health, Myanmar Epicentre, Paris, France Médecins Sans Frontières - International Médecins Sans Frontières - Holland
Principle Investigator	Cara Kosack Médecins Sans Frontières - International
Investigators	Medical Coordinator or HIV/TB Advisor (Anita Mesic) Médecins Sans Frontières - Holland Saskia Spijker Médecins Sans Frontières - International Maryline Bonnet Epicentre
Development study protocol	Cara Kosack, Médecins Sans Frontières - International Maryline Bonnet, Epicentre Saskia Spijker, Médecins Sans Frontières - International Anita Mesic, Médecins Sans Frontières - Holland Elizabeth Joekes, LSTM, UK
Scientific committee	Elizabeth Joekes, LSTM, UK

Emails

Cara Kosack	cara.kosack@amsterdam.msf.org
Saskia Spijker	saskia.spijker@amsterdam.msf.org
Maryline Bonnet	maryline.bonnet@geneva.msf.org
HIV Advisor (Anita Mesic)	msfh.myanmar.hivadv@googlemail.com
Elizabeth Joekes	e.joekes@liverpool.ac.uk
MedCo Myanmar (Dr Khin Nyein Chan)	myanmar-medco2@oca.msf.org

Glossary

AFB	Acid-Fast Bacilli
AUC	Area Under the Curve
CRRS	Chest Radiograph Reading and Recording System
CXR	Chest X-ray
DIWG	Diagnostic Imaging Working Group
HIV	Human Immunodeficiency Virus
MDR TB	Multidrug-Resistant Tuberculosis
MoU	Memorandum of Understanding
MSF	Médecins Sans Frontières
ROC	Receiver Operating Characteristic
RLS	Resource-Limited Settings
TB	Tuberculosis

Table of Contents

1   Introduction and background

Tuberculosis (TB) is a major health hazard and diagnosis is especially challenging in resource-limited settings (RLS). Chest x-ray (CXR) is a useful tool in the diagnosis and monitoring of pulmonary *M. tuberculosis* infection and forms part of diagnostic protocols and management guidelines from both WHO and MSF. However, studies have shown that error rates due to under or over-reading CXRs can be as high as 20%[1,2] As the characteristics of TB on CXRs are non-specific, CXRs are therefore prone to high subjectivity with regards to interpretation and show high inter-observer variability in non-radiologists and other non-experts. CXRs are therefore inaccurate as an exclusive diagnostic tool for the diagnosis of TB.[3,4]

The ability of a CXR to be suggestive of pulmonary TB infection depends on the presentation of the disease,[5] which in turn is influenced by a range of other factors such as HIV status and sex of the patient,[6] as well as the technical quality of the radiograph.[2]

Diagnosing TB in HIV positive patients is particularly challenging due to higher rates of smear-negative results. No single or combination of clinical or radiographic criteria has been shown to reliably diagnose smear-negative pulmonary TB among HIV-infected patients with unexplained cough in a low-income setting.[7] The CXR is therefore an important contribution to the combined criteria for diagnosing TB in such a patient group and is endorsed by the WHO for use in HIV infected patients.[8] According to data from four African studies, the sensitivity of CXRs for TB screening in HIV positive patients can range from 27% to 81%[9]. CXRs have the advantage of immediately available results in contrast to TB culture which can take weeks before a result is known. This is a crucial advantage for HIV/TB co-infected patients where treatment should not be delayed.

One major factor in diagnostic accuracy of CXRs is the interpretation skill of the reader, which renders results subjected to intra- and inter-reader variation. One study on x-ray classification in which 1,100 films were read by 90 experienced physicians and radiologists found up to 34 % disagreement on the question: "is the film normal?" and a 28 % disagreement on the question: "Is there a cavity present?".[2]

High reader variability in interpreting CXRs directly correlates with low diagnostic performance. When a standardised set of CXRs was interpreted by 162 radiologists and residents, the group with the highest diagnostic accuracy also showed the smallest inter-reader variability.[10] Reducing the reader variability in CXR interpretation therefore has the potential to improve diagnostic performance.

It has been shown that reader variability is generally less discrepant when readers were more experienced or trained,[1,7] In this regard, it has also been shown that in the clinical diagnosis of TB based on patient history, CXR results and acid-fast bacilli (AFB) smear results, nurses have been as good as TB physicians in diagnosing TB when provided with correct radiographic readings.[11] These results imply that non-radiologists would be able to diagnose more accurately if they were able to improve their ability to interpret CXRs more accurately.

Apart from the provision of training, one other effort to reduce reader variability includes the utilisation of a chest radiograph reading and recording system (CRRS) in order to standardise description and thus potentially improve the diagnostic validity of chest radiography. The CRRS transforms observed radiological patterns into categorical forms and has demonstrated satisfactory inter- and intra-reading agreement.[12,13] For example, for two clinicians with experience in radiology but not a formal radiology accreditation, the

application of CRRS showed an acceptable level of agreement in detecting major categories of abnormality of TB CXRs.[12] A similar study also demonstrated good agreements between two CRRS certified observers in reporting TB-related abnormalities on CXRs using the CRRS system.[13]

However, the direct impact of the CRRS application was not investigated in both studies because reader variability without CRRS application was not determined.[12, 13] This is difficult to determine, as the course not only educates on the use of a standardised form but also provides three days of training in CXR interpretation, confounding the impact. Subsequent use of the CRRS in screening asymptomatic HIV-infected adults however, showed levels of sensitivity and specificity comparative to other studies that did not use standardised reporting.[14] Furthermore, the CRRS application was developed for prevalence surveys and no study has focused on the impact of training and a standardised recording system on CXR interpretation accuracy by non-specialists, or in a clinical setting. Clinical officers have been shown to achieve an acceptable level of screening CXRs for 'any abnormality' regardless of their relevance for TB when doing a sensitive reading for screening purposes, however not in the specific clinical setting of diagnosing smear-negative TB when bacteriological testing is unavailable.[15]

This particular focus on non-radiologist performance in CXR interpretation is of high importance for MSF projects where CXR reading is usually not conducted by accredited radiologists but rather by general physicians. The diagnosis of TB infection based on laboratory results, clinical presentation and CXR results therefore depends partly on the ability of physicians to correctly interpret CXRs. Previous findings of low variability (as an indicator for quality) resulting from the application of a CRRS, lead to the hypothesis that a simplified version of a reading and recording system in a form of a tick sheet (see Annex 6.1) could potentially improve the accuracy of CXR interpretation by non-specialists.

This study aims to formally detect the impact of a four hour CXR reading training, using a tick-sheet for documentation, in improving the interpretation accuracy of CXRs by non-specialists.

2   Study rationale

The reason for conducting this study is to improve the interpretation accuracy of CXRs used in the diagnosis of TB infection by non-specialists.

In MSF settings, the interpretation of CXRs is usually not done by radiologists or specialists but rather by a medical officer or general physician, which is a group that is less trained in the interpretation of CXRs in comparison to a radiologist. In order to improve the diagnosis of TB, approaches to improve CXR interpretation is an important factor to consider. The utilisation of a tick-sheet has the possibility to reduce variability and improve diagnostic accuracy through standardisation and is therefore a potentially useful tool in improving TB diagnostics. The reason for conducting this study is to determine whether reading a CXR using a tick-sheet and a short four hour training session, improves clinicians CXR interpretation accuracy compared to an expert reference standard, whether it reduces inter-reader variability, and improves the accuracy of a diagnosis of active TB.

3   Study objective

3.1 Primary objective

To determine if the application of a tick-sheet after four hour training on its use and on CXR interpretation, improves the interpretation accuracy of CXRs for active TB, by non-specialists, in an HIV-positive cohort.

3.2 Secondary objective

To determine whether the application of a tick-sheet reduces the inter-reader variability of CXR interpretation in a group of non-specialists by comparing the inter-reader agreement before and after intervention.

4   Methods

4.1 Study Design

Diagnostic study measuring the diagnostic accuracy and inter-observer agreement of CXR reading before and after introduction of a recording sheet, in CXRs retrospectively collected from clinical files of adult TB suspects.

4.2 Reference Standard

The reference standard will be the consensus of the readings by two independent expert radiologists with a third if discrepancies between the initial two occur.

4.3 Sample Size

We used the Receiver Operating Characteristic (ROC) diagnostic accuracy table proposed by Obuchowsky[16] for Area Under the Curve (AUC) with the following estimations: expected AUC of CXR reading before the use of the tick-sheet of 0.75; an expected moderate difference of AUC of the reading after introduction of the tick-sheet compared to the baseline reading of 10%; 25% frequency of x-ray TB suggestive x-rays among TB suspects; a moderate observer variability; a correlation of 0.47 between the two readings approaches; a 5% risk alpha and 80% power.[16] Therefore, the table indicates a recommended sample size of 133 patients (x-rays) for 6 observers.

4.4 Study Site and Duration

The study will be conducted in an MSF project in Shan state, Myanmar. Myanmar is among the highest TB burden countries in the world with an estimated 525 cases per 100 000 reported in 2010.[18] The HIV/AIDS burden in Myanmar is among the most serious in Asia; in 2011 an estimated 216,000 adults and children were living with HIV.[19] The vulnerability of populations to TB and MDR TB is further exacerbated by this significant HIV burden.

MSF signed memorandum of understanding (MoU) with Myanmar Ministry of Health in 1993 and has been working in Shan state since 2001 delivering high quality comprehensive HIV treatment and care. MSF recruited medical, paramedical including nurses and counsellors and other support staff in the project areas and has implemented the activities in parallel to the MoH via two MSF clinics: Lashio and Muse Clinic. MSF set up its own laboratory in the area for diagnosis of HIV and opportunistic infections and also procure and import medicines, laboratory reagents, and medical and laboratory equipment.

Although the activities are implemented in parallel, MSF has been working in close collaboration with national programs/MoH. MSF is also one of the members of the Country Technical Strategic Group providing support to the Myanmar - Country Coordination Mechanism (M-CCM), chaired by the Minister of Health.

As of November 2012, MSF has been providing ART treatment to 3,996 patients in Shan State project through vertical clinics.

International actors such as the International Union Against Tuberculosis and Lung Disease are collaborating with the Ministry of Health in Lashio in order to address this epidemic.

The target population in the project area is over 5 million people. Shan state is traditionally known for its large representation of HIV high-risk groups (sex workers, intra-venous drug users etc.); however the epidemic has now spread to the general population and is no longer limited to only these high-risk groups.

Integration of HIV and TB services is a priority within MSF; therefore in addition to providing HIV/AIDS treatment and care, MSF also aims to ensure that TB treatment is provided where indicated. Prior to enrolling in ART services, all HIV positive patients are screened for TB following standard MSF algorithm (see Annex 6.2). Included in this algorithm is a routine CXR for all HIV positive patients where their medical history and physical examination raises a suspicion of TB, and where it is believed that the CXR will add additional valuable diagnostic information.

The reasons for choosing this site for the study are:
- HIV positive cohort
- High TB prevalence
- Reasonably good quality of CXR images from two referral sites
- Questionable quality of x-ray interpretation by specialist supplied with CXR from referral sites
- Reliable medical records of patient data including CXRs storage

The intersectional radiographer will select the sample CXRs from retrospective cases and will arrange reading sessions for the physicians. The training will then take place and images will be re-read by participating physicians using the tick-sheet.

4.5 Study Population

Physicians without a specialisation who interpret CXRs on a routine basis and are willing to participate will be included in the study. Currently, Lashio clinic has 4 physicians and Muse has 3 physicians.

CXRs of TB suspects aged ≥ 15 years who attended either clinic will be retrospectively collected and read by the physicians before and after the training.

4.5.1 Inclusion Criteria

All physicians who work at the Lashio Clinic and Muse Clinic in the Shan project of the Myanmar mission will be invited to participate in the study and written informed consent will be obtained.

4.5.2 Exclusion Criteria

The following reasons are considered exclusions for physicians participating:
1. Withdrawal of consent
2. Absence during training and reading period

4.5.3 Sampling of CXRs

133 CXRs of adults will be randomly sampled using predetermined randomisation list provided by Epicentre among consecutive patients who came to either clinic for TB screening within the last 12 months.

4.6 Study Procedures

7 physicians from the Lashio Clinic and Muse Clinic will participate in the study. This is one more physician than required by the sample size to ensure final sample sized is met.

133 CXRs of adults will be retrospectively collected and all 7 clinicians from the project will be asked to record in writing any radiological features they detect and whether the CXR is normal, abnormal and suggestive of TB, or abnormal but not suggestive of TB. The physicians will be blinded to each other's findings by a request not to discuss cases prior to making a conclusive report.

The physicians will then be trained in a group session in interpretation of chest x-rays over a four hour period where basic imaging principles and important features for diagnosing TB will be explained as well as presentation of cases studies. In addition, tick-sheets for the interpretation of chest x-rays will be presented and explained for use.

Then all previously read radiographs will be read in a random order once again taking the teaching into account and utilising the tick-sheet after a period of at least 1 month to avoid recall.

Three consultant radiologists will read the same sample set of images. All films will be digitised with a digital camera following MSF Protocol (Annex 6.2), then anonymised and sent via internet to the expert panel who will read the films digitally.

Both the radiologists and non-specialist physicians will be blinded towards lab results, clinical findings and the previously made diagnosis. However, all readers will be aware that all films are from TB suspects.

4.7 Outcomes, Data Entry and Analysis

4.7.1 Outcomes

The initial and post-intervention reports will be compared against the reference standard. CXR reading endpoints will be: normal, abnormal and TB suggestive and abnormal but not TB suggestive.

Initial report forms for the non-specialist readers will be designed to allow for open documentation of findings. One of the three categories ('normal', 'abnormal but not TB suggestive', or 'abnormal and TB suggestive') can be concluded by the reader.

For the accuracy analysis, the reference standard will be positive if the expert readers interpret the x-ray as 'abnormal and TB suggestive' and negative if interpreted as 'normal' or 'abnormal but not TB suggestive'. The same definition will be used for the x-ray interpretation by the non-specialist physicians.

For the non-specialist reader agreement analysis, reports for each finding and overall diagnosis of TB will be graded as ''agree'' (i.e. either both positive or both negative) and ''disagree''. Disagreements will be graded as "diagnostic of TB" or "positive but not diagnostic of TB".

4.7.2 Data Entry

Data will be double-entered using EpiData 3.1 software (EpiData, Odense, Denmark).

4.7.3   Analysis

Analysis will be carried out using STATA version 11 (StataCorp, College Station, Texas, USA).

For the main analysis, sensitivity, specificity, positive and negative predictive value will be estimated independently for each non-specialist reader against the reading consensus of the expert readers, both before and after the intervention. ROC curves will be plotted, and AUC values will be estimated for the x-ray reading before and after intervention.

The inter-reader agreement among non-specialists before and after the intervention, will be assessed using kappa statistics. The maximum attainable kappa, which represents the greatest possible agreement, and the prevalence index, that expresses the influence of the TB prevalence on the kappa coefficient, will be calculated for the interpretation of the kappa coefficient. [20] Regarding the ordinal classification of x-ray reading, because the disagreement between "normal" and "abnormal not TB suggestive" is of less concern than a disagreement between "abnormal TB suggestive" and "normal" or "abnormal TB suggestive" and "abnormal not TB suggestive" weighted kappa will be considered. The following will be proposed to define the strength of agreement for the kappa coefficient: [21]

> < 0.21 = poor agreement
> 0.21-0.4 = fair agreement
> 0.41-0.6 = moderate
> 0.61-0.8 = good
> 0.81-1.0 = very good

4.8 Ethical Considerations

The study will be initiated after formal approval by the MSF Ethical Review Board. On a local level the Department of Medical Research at the Ministry of Health will be asked to approve the study.

The study will be carried out in accordance with the Declaration of Helsinki concerning medical research in humans. All enrolled clinicians will sign an informed consent (annex 6.5) and participation will be voluntary. Each clinician will be assigned a study number for identification in the study and the final results will not be linked to an individual physician.

CXRs that will be used in this study derive from patients who already received a diagnosis and or treatment. Therefore patient informed consent is not required. Should the re-interpretation by the consensus expert panel lead to a different diagnosis than that which was previously made, the findings will be communicated to the responsible physician and follow-up of the patient will be initiated. Thus, the study has the benefit for the patients of having their CXRs re-interpreted by a radiologist. In addition, the community is expected to benefit from improved capacity for x-ray reading by medical staff after training sessions.

An information letter on the notice board of each clinic will inform the patients on the objectives of the study (annex 6.4).

If the tool proves effective, MSF will roll out the intervention in our other programs in Myanmar and elsewhere. Results will be also actively disseminated to Ministry of Health partners, also with the checklist and training package.

4.9 Financing of the study

The study has been granted funding by the MSF Innovation Fund that will pay for all material and personnel required in the mission and at head quarters level.

5 References

1. Toman K (1980). Tuberculosis case-finding and chemotherapy: questions and answers. *World Health Forum,* I (1, 2): 153-158.

2. Van Cleeff MRA, Kivihya-Ndugga LE, Meme H, Odhiambo JA, Klatser PR. (2005)*.* The role and performance of chest X-ray for the diagnosis of tuberculosis: A cost-effectiveness analysis in Nairobi, Kenya. *BMC Infectious Diseases,* 5: 111.

3. Du Toit G, Swingler G, Iloni K (2002). Observer variation in detecting lymphadenopathy on chest radiography. *The International Journal of Tuberculosis and Lung Disease*, 6 (9): 814-817.

4. Swingler GH, du Toit G, Andronikou S, van der Merwe L, Zar HJ (2005). Diagnostic accuracy of chest radiography in detecting mediastinal lymphadenopathy in suspected pulmonary tuberculosis. A*rchives of Disease in Childhood*, 90 (11):1153-1156.

5. World Health Organisation. (2004) TB/HIV: a clinical manual*. Pages:* 2–44.

6. Kivihya-Ndugga LE, van Cleeff MR, Ng'ang'a LW, Meme H, Odhiambo JA, Klatser PR (2005)*.* Sex specific performance of the routine TB diagnostic tests. *The International Journal of Tuberculosis and Lung Disease*, 9 (3):294–300.

7. Davis JL, Worodria W, Kisembo H, Metcalfe JZ, Cattamanchi A, Kawooya M, Kyeyune R, Den Boon S, Powell K, Kello R, Yoo S, Huang L (2010). Clinical and radiographic factors do not accurately diagnose smear-negative tuberculosis in HIV-infected inpatients in Uganda: a cross sectional study. *Plos One,* March, Vol. 5, Issue 3, e9859.

8. WHO. (2007). Improving the diagnosis and treatment of smear-negative pulmonary and extrapulmonary tuberculosis among adults and adolescents. Recommendations for HIV prevalent and resource-constraint settings. Available at: http://www.who.int/tb/publications/2006/tbhiv_recommendations.pdf [Accessed 30th August 2012].

9. Agizew T, Arwady MA, Yoon JC, Nyirenda S, Mosimaneotsile B, Telda Z, Motsamai O, Kilmarx PH, Wells CD, Samandari T (2010). Tuberculosis in asymptomatic HIV-infected adults with abnormal chest radiographs screened for tuberculosis prevention. *The International Journal of Tuberculosis and Lung Disease*, 14(1): 45-51.

10. Potchen EJ, Cooper TG, Sierra AE, Aben GR, Potchen MJ Potter MG, Siebert JE (2000). Measuring performance in chest radiography. *Radiology,* 217:456-459.

11. Lam PK, LoBue PA, Catanzaro A (2009). Clinical diagnosis of tuberculosis by specialists and non-specialists. *The International Journal of Tuberculosis and Lung Disease,* 13(5): 659-661.

12. Den Boon S, Bateman ED, Enarson DA, Borgdorff MW, Verver S, Lombard CJ, Irusen E, Beyers N, White NW (2005)*.* Development and evaluation of a new chest radiograph reading and recording system for epidemiological surveys of tuberculosis and lung disease. *The International Journal of Tuberculosis and Lung Disease*, 9(10): 1088-1096.

13. Dawson R, Masuka P, Edwards DJ, Bateman ED, Bekker L-G, Wood R, Lawn SD (2010)*.* Chest radiograph reading and recording system: evaluation for tuberculosis screening in patients with advanced HIV. (2010) *The International Journal of Tuberculosis and Lung Disease*, 14(1): 52-58.

14. Agizew T, Bachhuber MA, Nyirenda S, Makwaruzi VZSAM, Telda Z, Tallaksen RJ, Parker JE, Mboya, JJ, Samandari T (2010). Association of chest radiographic abdormalities with

tuberculosis disease in asymptomatic HIV-infected adults. *The International Journal of Tuberculosis and Lung Disease*, 14(3): 324-331.

15. Hoog AH, Meme HK, van Deutekom H, Mithika AM, Olunga C, Onyino F, Borgdorff MW (2011). High sensitivity of chest radiograph reading by clinical officers in a tuberculosis prevalence survey. *International Journal of Tuberculosis and Lung Disease*, 15(10): 1308-1314.

16. Obuchowski NA. (2000). Sample size tables for receiver operating characteristic studies. *AJR*;175:603–608.

17. Rockette HE, Campbell WL, Britton CA, Holbert JM, King JL, Gur D (1999). Empiric assessment of parameters that affect the design of multiobserver receiver operating characteristic studies. *Acad Radiol*; 6:723–729.

18. WHO. (2012). Myanmar. Tuberculosis profile. Available at: <https://extranet.who.int/sree/Reports?op=Replet&name=/WHO_HQ_Reports/G2/PROD/EXT/TBCountryProfile&ISO2=MM&outtype=html> [Accessed 30th August 2012].

19. UNAIDS. (2012). Global AIDS Response Progress Report. Available at: < http://www.unaids.org/en/dataanalysis/knowyourresponse/countryprogressreports/2012countries/ce_MM_Narrative_Report.pdf > [Accessed 15th January 2013].

20. Sim J, Wright CC (2005). The kappa statistic in reliability studies: use, interpretation, and sample size requirements. *Phys Ther* 85: 257-268.

21. Landis JR (1997). The measurement of observer agreement categorical data. *Biometrics*. 1997; 33: 159-174.
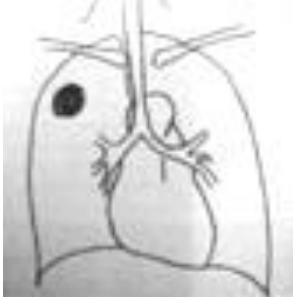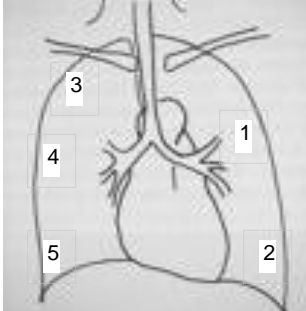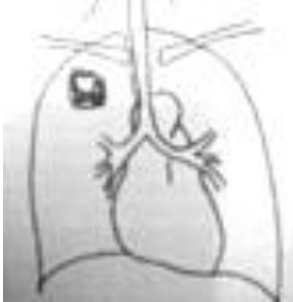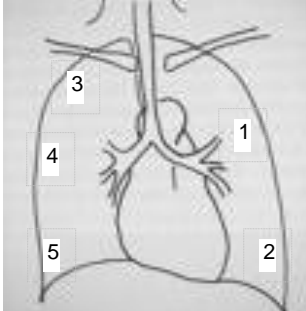
6   Annex
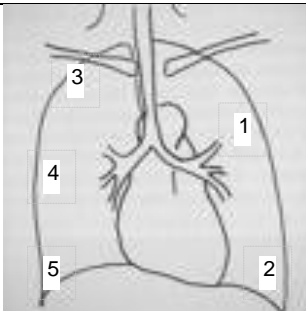
6.1 Tick sheet
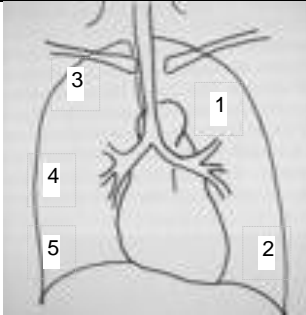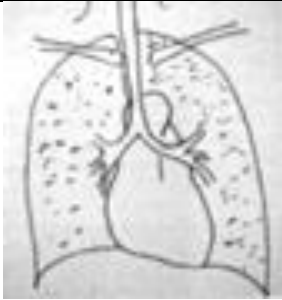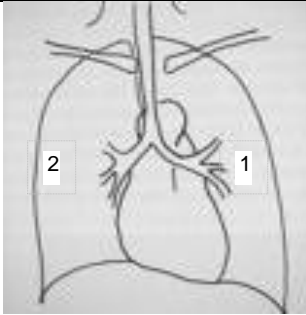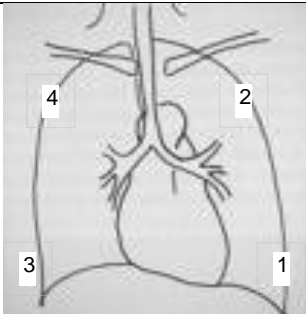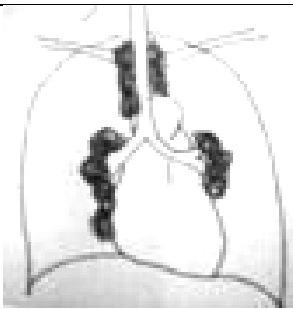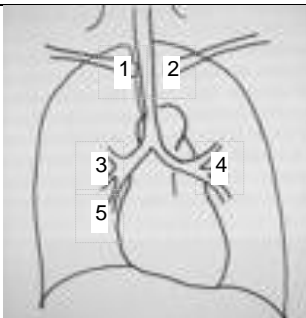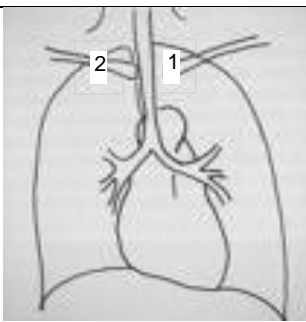
Radiograph Reporting for TB Research Studies in MSF / Epicentre

Name clinic:_____   Patient ID: _____   Date x-ray taken: __/__/____

Reviewer code:_____   Date of review: __/__/_____

Overall quality of radiograph		yes	no
Good quality	No radiographic faults		
Not good but readable	Some faults but readable		
Poor quality: unreadable	Not readable and must be repeated		
Specific quality of radiograph		**yes**	**no**
Too dark	Cannot see peripheral vessels		
Too light	Cannot see vertebral ends behind the heart		
Rotated	Medial clavicles different distances from spinous process		
Under-inspired	Less than 9-10 posterior ribs at diaphragm		
Parts cut off	E.g. costophrenic angles		
Artefacts seen	Any dots, lines, metal, clothing that is not anatomy or disease		
Motion artefact	Like a moving photo e.g. loss of sharp edges		

	Diagram example	Please record	Distribution Zones (1,2,3,4,5)	
Granuloma oval lesion			1	
			2	
			3	
			4	
			5	
Cavitation (within a granuloma, consolidation or infiltrate)			1	
			2	
			3	
			4	
			5	
Broncho-pneumonic pattern, infiltration			1	
			2	
			3	
			4	
			5	

Consolidation		3, 1, 4, 5, 2	**1**	
			2	
			3	
			4	
			5	
Milliary nodular pattern		2, 1	**1**	
			2	
Pleural effusion		4, 2, 3, 1	**1**	
			2	
			3	
			4	
Lymph-adenopathy		1, 2, 3, 4, 5	**1**	
			2	
			3	
			4	
			5	
Apical fibrocystic change: scarring and cysts		2, 1	**1**	
			2	

CXR normal		Other diagnosis	
CXR abnormal – suggestive of active TB			
CXR abnormal – non-suggestive of active TB			

6.2 TB algorithms used in Myanmar

Diagnosis of pulmonary and pleural TB in HIV positive patients <u>with danger signs</u>

Suspicion of TB and with danger signs[1]

↓

Clinical assessment, sputum for AFB, +/- CXR[2]

- AFB (+)ve[*]
- AFB (-)ve/CXR specific of TB[*]
- AFB (-)ve & CXR not specific of TB or No CXR

[3]Parental or broad spectrum antibiotics + PCP Rx

- No response after 5 days
- Response after 5 days

Xpert MTB/RIF

- TB, R- resistant
- TB, No resistant
- No TB

Liquid Culture and DST to NTRL

Xpert MTB/RIF

- TB, No resistant
- TB, R- resistant
- No TB

No TB → Other cause

Liquid Culture and DST to NTRL

Start TB Rx, complete antibiotics and PCPRx

↓

Access evolution under TB Rx after 2 mths and/or CXR improvement

- Improvement
- No clinical and CXR improvement

[4]Consider other diagnosis

Full 1st line TB Rx

[*]Consider using broad spectrum antibiotics in addition to anti-TB treatment if clinical judgement guides having superadded bacterial infections

[1] Danger signs: respiratory rate >30/min and fever >39 degrees C and/or pulse rate >120/min and/or unable to walk

[2] +/- CXR: with or without CXR depending on availability in individual setting

[3] E.g. ceftriaxone for 7 days and a macrolide such as erythromycin or azithromycin **(no aminoglycoside)**

[4] In the absence of clinical improvement (i.e. no weight gain, no improvement in TB signs & symptoms such as cough, chest pain, fever off and on, etc) and no clinical improvement after 2 months of a well controlled TB Rx (i.e. good adherence to treatment), diagnosis and treatment should be reconsidered

Diagnosis of pulmonary and pleural TB in HIV positive patients <u>without danger signs</u>

```
                    Suspicion of TB and without danger signs[1]
                                    │
                    Clinical assessment, sputum for AFB, +/- CXR[2]
                                    │
        ┌───────────────┬───────────────────────┐
        │               │                       │
    AFB (+)ve    AFB (-)ve/CXR        AFB (-)ve & CXR not specific
                 specific of TB       of TB or No CXR
                                              │
                               [3]Oral broad spectrum antibiotics or PCP Rx
                                              │
                               ┌──────────────┴──────────────┐
                    No or partial response          Response after 7 days
                    after 7 days
                            │
    Xpert MTB/RIF      Xpert MTB/RIF
```

Xpert MTB/RIF
- TB, R- resistant
- TB, No resistant
- No TB

Xpert MTB/RIF
- TB, No resistant
- TB, R- resistant
- No TB → Other cause

TB, R- resistant → Liquid Culture and DST to NTRL

TB, No resistant → Start TB Rx, complete antibiotics and/or PCPRx

TB, R- resistant → Liquid Culture and DST to NTRL

Start TB Rx → Access evolution under TB Rx after 2 mths and/or CXR improvement
- Improvement
- No clinical and/or CXR improvement → [4]Consider other diagnosis
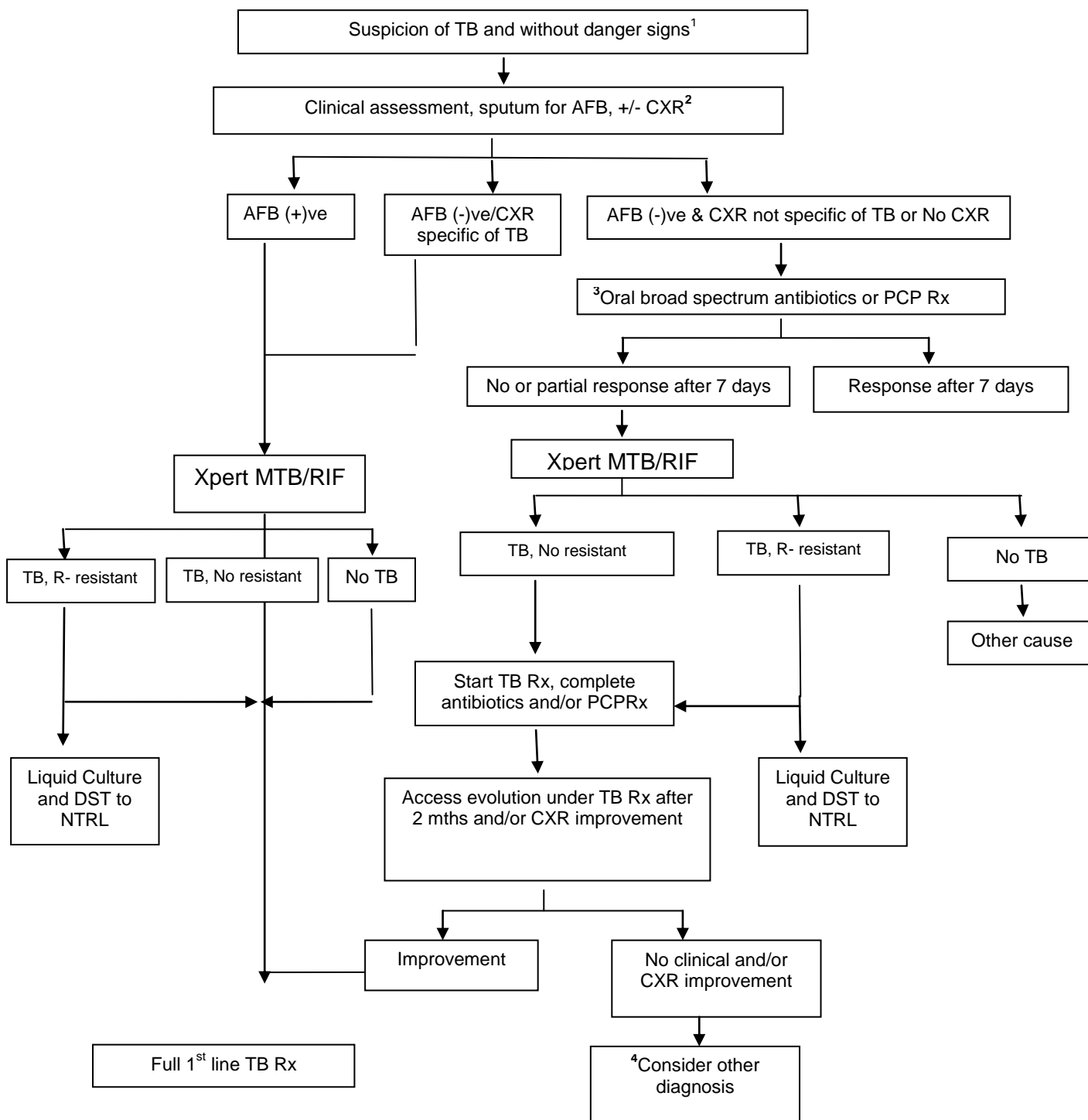
Full 1st line TB Rx

[1] Danger signs: respiratory rate >30/min and fever >39 degrees C and/or pulse rate >120/min and/or unable to walk

[2] +/- CXR: with or without CXR depending on availability in individual setting

[3] Oral antibiotics - e.g. Amoxicillin +/- erythromycin for 7 days (**no fluoroquinolone**). If patient is clinically stable, repeat sputum for AFB and do CXR if not done on Day 1. According to clinical signs, response to antibiotic and/or PCP Rx, depending on repeated sputum result, consider TB treatment.

[4] In the absence of clinical improvement (i.e. no weight gain, no improvement in TB signs & symptoms such as cough, chest pain, fever off and on, etc) and no clinical improvement

after 2 months of a well controlled TB Rx (i.e. good adherence to treatment), diagnosis and treatment should be reconsidered.

6.3 Digitising x-rays: MSF protocol

1. Camera selection

The minimum megapixel requirement needed for this purpose is 3.5 megapixels.
In addition, the camera should have an optical image stabilization mode or any kind of Motion Detection Technology that helps to prevent blurred photos.

2. Camera settings

- *Megapixels*

As most compact digital cameras these days have far higher resolution, set the picture size to a lower megapixel value of approximately 3.5 - 4 megapixels. If the resolution is too high, it makes the image file larger and more difficult to send via slower email connections without improving the quality of the photo of the radiograph.
The setting procedure will be slightly different for each camera but there is normally a menu option called 'Picture Size', or similar.

- *Compression*

Set the compression option to 'high'. The procedure will be slightly different for each camera but there is normally a menu option called 'Quality', or similar.

- *Focus*

Set the camera focus function to autofocus and always ensure that the camera has focused properly before making the exposure.

- *Zoom*

Set the optical zoom to approximately the midpoint and then make minor adjustments to fit each film. Adjustments should be made until the radiograph fills the entire frame as best as possible without cutting off relevant anatomy. If required, place the radiograph sideways on the light box to better match the frame of the camera viewer (i.e. position the film in landscape if it was taken portrait).

- *Exposure*

For photographing chest x-rays, adjust the exposure compensation setting manually to +1.3 EV. The procedure will be slightly different for each camera but there is normally a menu option called 'Exposure', or similar. Using the auto exposure function will result in the lungs being too dark. Adjusting the setting manually will brighten the lungs so that disease is more apparent.
For photographing other anatomical areas, the exposure compensation setting may be kept to zero. Ensure that the flash is set to OFF.

- *Motion*

To avoid motion while taking the photo, make use of the self-timer setting. This ensures that the camera has time to stabilize before the exposure is made and will reduce motion artifact.

3. X-ray set up

- *Light box*

X-rays should be placed on a standard medical light box for viewing and photography. Ensure that the light is well diffused over the entire light box and that the illumination is uniform. If the light is uneven, it is possible to correct it by checking that the wattage of the bulbs or by replacing the cover with some partially opaque white plastic.
Each light box requires 2-3 vertically mounted 15 W (437 mm long) fluorescent tubes with a colour temperature in the range of 3600 - 4000 K°.

- *Black out*

Extraneous light around the edges of the radiograph should be blocked out by using any opaque object. What is often easiest is to use is a blackened x-ray film. Take an unexposed sheet of x-ray film

out of the darkroom and expose to light for a few minutes. Then fully develop the film; it will come out black. You can cut the film into strips and use the strips of blackened film to create a frame that will serve to block the extraneous light around the edges of the radiograph.

- *Tripod*

The use of a small tripod is best to avoid motion blur of the photograph. The optimal distance to place the tripod is at approximately 70 cm from the light box. It is critical to position the camera exactly perpendicular to the film to avoid parallax image degradation that occurs when the camera is placed at an angle to the film. If a tripod is not available, then take the photo using a fast exposure setting, such as 1/500 second.

4. Transmission

- *Transmission to computer*

Transfer the images to a computer via the memory card or by using the cables that are provided with the camera. Create a new directory for each patient.

The following instructions relate to the XnView program, which is a standard MSF program and is available at all field sites:

1. Open the XnView program and locate the image file via the directory on the left hand side of the viewer.
2. Highlight the image thumbnail.
3. In the viewer along the bottom, click on 'Properties' and take note of the 'File size'.
4. The number given will be in bytes (i.e. 315 000 Bytes = 315 kB).
5. Double click on the image to open it in its own window.
6. Go to 'File' and then to 'Save As'.
7. A 'Save picture' window will open; select 'Options' at the bottom.
8. An 'Options' window will open; select the 'Write' tab.
9. You will see a scroll bar called 'Quality' which has options from 'Lowest' to 'Best'.
10. The lower the quality, the smaller the image size will be.
11. Reduce the quality to between 25% and 50% and click 'Ok'.
12. You will be brought back to the 'Save picture' window. Change the 'File name' so that the reduced quality image is saved as a new file.

Go back to the 'Browser' tab and you will see your new file.
Repeat step 3 to check new file size. Aim for approximately 200 – 300 kB.
Open the new file and ensure that the image has not lost too much quality and can still be considered suitable for interpretation. For example, check for over-pixilation and loss of lung markings on a CXR.

5. Transmission via internet
On the computer hard drive, locate the file to be emailed. The file is now ready to be sent to the teleradiology service provider.

6.4 Information letter for patients

To be translated into the local language.

Study on x-ray interpretation at Lashio and Muse Clinic

Médecins Sans Frontières is currently undertaking a study that measures the impact of x-ray interpretation training on the reading skills of their physicians. Several physicians at this clinic have agreed to participate in this training to improve their x-ray reading skills.

In order to be able to measure the impact of this training, some x-rays taken of patients in these clinics will be read by consultant radiologists who are specialist in the interpretation of x-rays. To make this possible, we will digitize some x-rays and send them overseas via the internet for these specialist readings.

In the case that one of your x-rays has been sent overseas and the consultation from the radiologist suggests a different diagnosis than the one you previously received, your physician will discuss the result and what it means for your treatment with you at your next follow-up visit.

Privacy and confidentiality

The x-ray will not be labeled with your name so that your privacy remains guaranteed. The radiologist will only receive an x-ray with the date the x-ray was taken and an identification number, which is also used here at the clinic.

If you have any additional questions regarding the study, please do not hesitate to ask your treating physician.

The Lashio and Muse clinic team

6.5 Informed consent participating clinicians

Study on x-ray interpretation at Lashio and Muse Clinic

Médecins Sans Frontières is currently undertaking a study that measures the impact of x-ray interpretation training on the reading skills of their physicians. Several physicians at this clinic have agreed to participate in this training to improve their x-ray reading skills.

In order to be able to measure the impact of this training, some x-rays taken of patients in these clinics will be read by consultant radiologists who are specialist in the interpretation of x-rays. To make this possible, we will digitize some x-rays and send them overseas via the internet for these specialist readings.

In the case that one of your x-rays has been sent overseas and the consultation from the radiologist suggests a different diagnosis than the one you previously received, your physician will discuss the result and what it means for your treatment with you at your next follow-up visit.

Privacy and confidentiality

The tick-sheet form will be labeled with code given to you. By giving you a 'code' we will be able to measure the impact of the training. In addition, we will be able to give you individual feedback on the interpretation of the x-rays you read during the study. The detailed feedback will solely be made available to you and not to the other study participants or your supervisor so that your privacy remains guaranteed.

However, an overall agreement between each participants 'code' and radiologists will be shown in the report.

Voluntary participation

Your participation to this study is voluntary. If you do not wish to participate, you do not have to, and you do not have to give a reason. You can also withdraw your consent at any time during the study. Your decision to participate or not has no influence to your current or future employment with MSF. There will not be any financial expenses for you to participate in the study. You will also not be paid to participate.

Benefits

If participate in the study you will receive a special training prepared for using as systematic way (i.e. with a tick-sheet) for the interpretation of chest x-rays. In addition, every x-ray you will read during the study will also be ready by consultant radiologists. You will receive the consultants' readings after the study is finalized so that you can compare your readings to theirs to have a maximum learning effect.

If you agree to participate in the study, we will ask you to fill in and sign the form below in 2 copies. One copy will be kept by us and one copy is for you.

For additional information, you can ask a member of the investigator team.

The investigator team

I have read or listened and understand the above information. I have been advised of the goals and procedures of the study, and the benefits and risks of participating in the study.

I hereby give my consent to participating in the study.

_____

Name of physician   Date   Signature

Witness

I certify that the person named above has been given an opportunity to understand the above given information and ask questions, that he or she understands the issues discussed, that his or her decision to participate in the study is an informed and voluntary one, and that I have witnessed his or her signature.

_____

Name of witness   Date   Signature

_____

Name study coordinator   Date   Signature