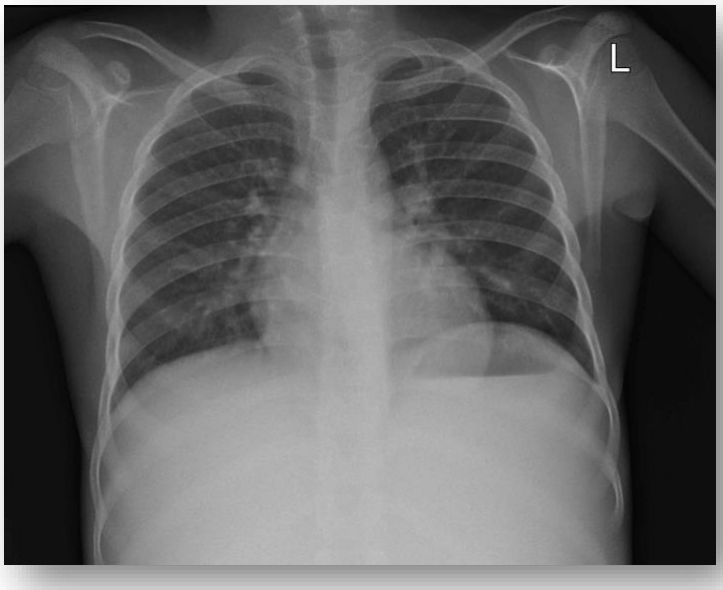

The Impact of digital X-ray with Teleradiology on Case Management in Mweso, Democratic Republic of Congo

Study protocol

Médecins sans Frontières (MSF) – Holland

Ministère de la Santé Publique de la République Démocratique du Congo

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Study site	Mweso, Democratic Republic of Congo
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Abbreviations

ART	Antiretroviral Therapy
CR	Computed Radiography
CXR	Chest X-ray
DRC	Democratic Republic of Congo
DD	Differential diagnosis
IPD	In-Patient Department
LRTI	Lower Respiratory Tract Infections
MSF	Médecins Sans Frontières
MTL	Medical Team Leader
OR	Odds Ratio
PCP	*Pneumocystis carinii* pneumonia
RDT	Rapid Diagnostic Test
RLS	Resource-Limited Settings
TB	Tuberculosis
URTI	Upper Respiratory Tract Infections
WHIS-RAD	World Health Imaging System - Radiography
WHO	World Health Organization

1. Introduction and Background

1.1 Humanitarian and Health situation in DRC

The long conflict in the Democratic Republic of Congo (DRC) has caused suffering for civilians, with estimates of millions affected either directly or indirectly as a result of the fighting. [1,2] The situation in DRC is portrayed as a recurrent humanitarian crisis with both acute health needs and limited access to humanitarian assistance. In particular, high morbidity and mortality are observed in areas affected by conflict where the institutional health systems have been disrupted. [1-4]

Médecins Sans Frontières Operational Centre Amsterdam (MSF-OCA) has been present in the eastern provinces of North and South Kivu since the early 1990's. The populations in these areas have very little access to health care even in stable times due to a lack of health care infrastructure and the limited presence of other actors providing assistance.

The project at Mweso hospital provides access to free primary and secondary level health care to a target population of approximately 145 000 including more than 25 000 internally displaced persons (IDP's). In 2013 over 138 000 OPD consultations were carried out, with approximately 48 000 in patients below 5 years of age. Nearly 6000 patients were admitted to the hospital in 2013, 3900 of which were below 5 years of age. The main pathologies seen are malaria, acute upper and lower respiratory tract infections (URTI and LRTI), acute watery diarrhoea, malnutrition and sexually transmitted infections.

Health care is provided in collaboration with the local Ministry of Health (MOH) in existing fixed structures including one hospital and four Health Centers: Kashuga, Kalembe, Mpati and Bibwe. Outpatient care is provided with an integrated nutritional program, TB treatment (only follow up, except for Mweso where diagnosis and treatment are performed and Kashuga where sputum smear preparation and Ziehl-Nelson is also done), reproductive health, cholera treatment and a mental health program.

The Hospital MSF is supporting has a 180 bed capacity, but throughout the year the Bed Occupancy Rate is higher than 100% with even peaks of >150%. The inpatient service provided includes Internal Medicine, Paediatric care, very basic neonatology ward, reproductive health, emergency caesarean sections, nutrition, Mental Health care including psychiatry, and surgery including orthopaedic surgery.

In addition to this, MSF actively supports the National TB program. In 2013, 432 patients were admitted for treatment of drug sensitive TB (DSTB) plus 1 patient for drug resistant TB (DRTB). There were 405 new cases of which 107 were diagnosed with extra pulmonary tuberculosis (EPTB). 24 patients were undergoing re-treatment, 4 had relapsed, 11 failed to finish the course of treatment.

Diagnostic means for differential diagnosis for chest infections (including TB) and other diseases are basic and rely on patient history, clinical examination, and basic laboratory examinations. The differential diagnosis of dyspnoea and cough, including pulmonary TB, is often virtually impossible, especially in HIV infected patients. This may lead to potentially harmful empirical treatment or simple, and possibly excessive, co-medication in an attempt to treat 'all' possible underlying causes.

1.2 X-ray equipment and digital imaging

X-ray imaging is a core diagnostic service in preventative and curative medicine. Good quality imaging can provide increased diagnostic accuracy and help to guide effective medical decision-making. X-ray services offer additional diagnostic value to comprehensive patient management for both adults and children, especially in the differential diagnosis of chest infections and other co-morbidities in patients with acute abdomen, as well as malnutrition, severe malaria, unknown cause of fever and with orthopaedic fractures.

However, often in resource limited settings (RLS), X-ray units are old or broken and have not received sufficient supply and maintenance. Formal radiographic education is also often not available, thus untrained staff perform radiographic procedures potentially resulting in images of poor quality. In addition, there is somewhat limited capacity of medical staff to interpret radiographs correctly, coupled with insufficient guidance and experience to act on the relevance of the findings.

There are many options for X-ray units in RLS but the most suitable for reliable operation is the World Health Imaging System – Radiography (WHIS-RAD) developed by the World Health Organization (WHO). The WHIS-RAD X-ray unit is straight-forward to use for technicians with limited training, has proven reliability under adverse environmental conditions, is easy to install, is low cost, has proven design for excellent radiation safety, and can be performed for all routine general radiographic examinations.

While access to digital X-ray technology is rapidly increasing in western settings, the majority of health care centres in RLS are still developing radiographs using the traditional method of film and chemistry. Film and chemistry, however, has proven to be one of the greatest challenges to achieving acceptable diagnostic image quality. It is for this reason that there is a global shift towards computed radiography (CR) technology which records images digitally. The CR digital image receptor system is a separate component to the X-ray unit itself. It consists of digital cassettes, a cassette reader and a computer viewing station. Instead of cassettes that hold X-ray film, the CR system uses cassettes holding digital plates made from phosphor. These plates are passed through a cassette reader and viewed on a computer monitor. Digital images have the added advantage that they are immediately ready for transmission for remote teleradiology reporting.

1.3 Teleradiology

The continuing advancement in telecommunication technologies has allowed for greater access to health care services in RLS through the capture and transmission of medical information in digital form. Radiology is a medical specialty that adapts particularly well to this advancing technology.

Unfortunately, those populations who can most benefit from improved technologies in health care often have the least access.[5] There is an ethical imperative to provide the best possible health care service, and teleradiology can improve access to specialised care in an environment where resources are constrained. Medical practice in RLS should not be considered as under-developed medicine, but rather medicine with restricted means occurring in a different environment.[5] In such environments, where specialists are not otherwise available, the expert knowledge of a radiologist is likely to improve the quality of interpretation.

Teleradiology is defined as the electronic transmission of radiologic images from one location to another for the purposes of interpretation and/or consultation.[7] Teleradiology is one area of telemedicine that has become a mainstream option globally for reading medical images and is gradually being considered borderless.[5] As clinical management of a patient can be largely based on the findings of diagnostic imaging, facilitating timely interpretative services in order to support patient care is a core goal of teleradiology.

The introduction of digital imaging and teleradiology therefore provides two new features: firstly the availability of high quality radiographic images, and secondly specialist reading of these images. Additional advantages of teleradiology services include efficient and economical use of resources, increased speed of diagnosis and management, and reduced stress on health care systems.[6] Last but not least; regular reports of radiologists do have a training effect on the treating clinicians.[8]

MSF has decided intersectionally to work towards implementation of teleradiology in selected sites.

MSF Telemedicine System

In 2010 MSF introduced a store-and-forward telemedicine system to provide doctors in MSF field sites access to a network of specialists, including radiologists.

The multilingual platform requires users to log onto a secure website and upload the case details including any anonymised images (such as X-rays). Radiologists on the system all voluntarily provide their specialised skills interpret the images and return their findings.

2. Study rationale

Several senior physicians within MSF have raised concerns that quality of care in projects is often compromised by the limited availability of diagnostic means. This lead to the consideration of the potential benefit of radiology services to further contribute to quality of care given to patients.

Without X-ray services physicians rely on clinical signs and symptoms alone, for which the sensitivity and specificity are known to be low. The availability of a radiologic device is expected to increase diagnostic accuracy, which in turn allows for more precise and targeted therapy, but to what extent is unknown. At the same time, the installation and maintenance of radiologic device is resource intensive. In settings with many competing priorities it is important to ensure that the investment pays off not just in terms of improved diagnosis but also in improved patient management. Thus, this study aims to formally evaluate the impact of digital X-ray with teleradiology on case management.

The reasons for choosing Mweso Hospital in DRC as study site is that it provides both primary and secondary health care with a broad scope of services such as OPD, IPD, surgery (including orthopaedic), reproductive health, nutrition, and TB and HIV.

The community will benefit from improved capacity for X-ray reading, improved patient management, and medical staff will receive education in diagnostic imaging, especially by learning through case studies.

In addition, knowledge about the added value of digital X-ray with teleradiology in Mweso will guide informed decision-making about the introduction of digital X-ray with teleradiology in other locations, not only for MSF but also health policy makers.

3. Study objectives

3.1 Primary objective

To demonstrate the extent of change in patient management through the availability of digital X-ray with teleradiology consultation.

3.2 Secondary objectives

a) To demonstrate the extent of change in patient diagnosis through the availability of digital X-ray with teleradiology consultation.

b) To demonstrate the extent of change in patient diagnosis and management in the subgroup of patients with chest pathologies through the availability of digital X-ray with teleradiology consultation.

c) To estimate if the extent of change in diagnosis and management is different in patients < 5 years of age versus ≥5 years of age.

4. Methods

4.1 Study design

Paired before-after study to determine the therapeutic impact of an add-on diagnostic test.

4.2 Sample size

The primary objective of the study will estimate the proportion of patients whose treatment plan is altered as a result of the X-ray diagnosis compared to the treatment decision based on clinical diagnosis.

A change in treatment in 10-20 % of patients (being the additional therapeutic yield) would be considered clinically and programmatically useful, so 15% has been used for the estimated change.

With 80 % power (β=0.8) and a significance level of 5 % (α=0.05), a sample size of 500 patients will allow an estimate of the proportion of patients with a changed treatment plan of 15 % ± 5 %.

For the secondary objectives:

a) The same sample size applies to assessing change in diagnosis (rather than management) in all patients.

b) We estimate that approximately 80 % of X-rays will be for chest pathologies, which would be ~400 patients of the sample of 500. For this sample size we would be slightly less sure of our estimate of change (15 % ± 5.5 %).

c) We estimate that approximately 40 % of X-rays will be for patients aged <5 years (based on proportions of adults and children seen in OPD and IPD in 2013). To be able to confidently estimate whether the proportion of change in management (or diagnosis) is different for patients aged <5 years compared to in those aged ≥5 years, a larger sample size is needed. To detect a difference between a change in management of 20 % in patients aged <5 years compared to 10 % in those aged ≥5 years (from the upper to the lower limit of the range of estimated useful change) with 80% power, a sample size of 180 patients aged <5 years and 270 patients aged ≥5 years is needed. Assuming some loss of usable data, a total of 500 patients should allow a valid comparison.

4.3 Study site and duration

The study will be conducted in Mweso, Democratic Republic of Congo.

The duration of the study will be *approximately* 20-24 months after study start the site:

- 10-12 months study phase to reach sample size of 500

This is based on an expected case load 60 x-ray cases/month of which an estimated 80 % get sent for a teleradiology consultation.

= 48 teleradiology cases per month

= 10-12 months until completion (500 cases total).

- 6 - 12 months for analysis and report writing. Publication will follow.

The above duration is only a prediction of the number of patients who may be referred for imaging per month based on genuine clinical need. Strict referral criteria may result in fewer number of cases referred per month than stated above, in which case the study phase will be longer. Patients will not be referred for imaging in order to fulfil the predicted study duration.

4.4 Study population

4.4.1 Sampling frame

All adult and paediatric patients presenting at Mweso Hospital who are assessed by a physician and where it is considered that an X-ray with a teleradiology consultation may offer additional clinical value (above the benefit of the physicians own interpretation of the X-ray).

4.4.2 Inclusion criteria

If the treating physician requests an X-ray, the patient will be offered to participate in the study.

Those providing written informed consent (by the patient or legal guardian), after explanation of the purpose and potential benefit of the study, will be enrolled. It will be made clear to patients that they are still eligible for X-ray and a teleradiology consultation even if they do not consent to use of their medical data in the study. The number of refusals to participate will be documented. The process of participant recruitment and inclusion is explained in more detail under 4.5 study procedures.

4.4.3 Exclusion criteria

Potential participants will be excluded from the study if they refuse or subsequently withdraw consent for participation.

4.4.4 Sampling

All X-ray examinations of consecutive patients meeting the inclusion criteria will be included in the sample until the total of 600 is reached.

4.5 Study procedures

Each patient will be diagnosed by the current standard methods (i.e. clinically and with laboratory procedure where indicated) without X-ray. A preliminary management and treatment plan will be based on this diagnosis and will be clearly documented.

The decision to request an X-ray will be made by the treating expatriate physician only. An X-ray will be requested when it is expected that the result may influence the therapeutic decision. The treating physician must have been trained in identifying clinical indications for requesting an X-ray (Annex 6.5).

All X-ray examinations will be requested in writing on a standard X-ray request form, which will indicate the examination required and the underlying diagnostic question in order to justify the use of x-radiation (see Annex 6.2).

The treating physician will send to the radiology department the X-ray request form and the form of preliminary clinical diagnosis and treatment plan (see Annex 6.3). The X-ray technician carries out the requested X-ray(s). The study is then sent for teleradiology (by the X-ray technician or expatriate physician) with the clinical information entered into the system in English.

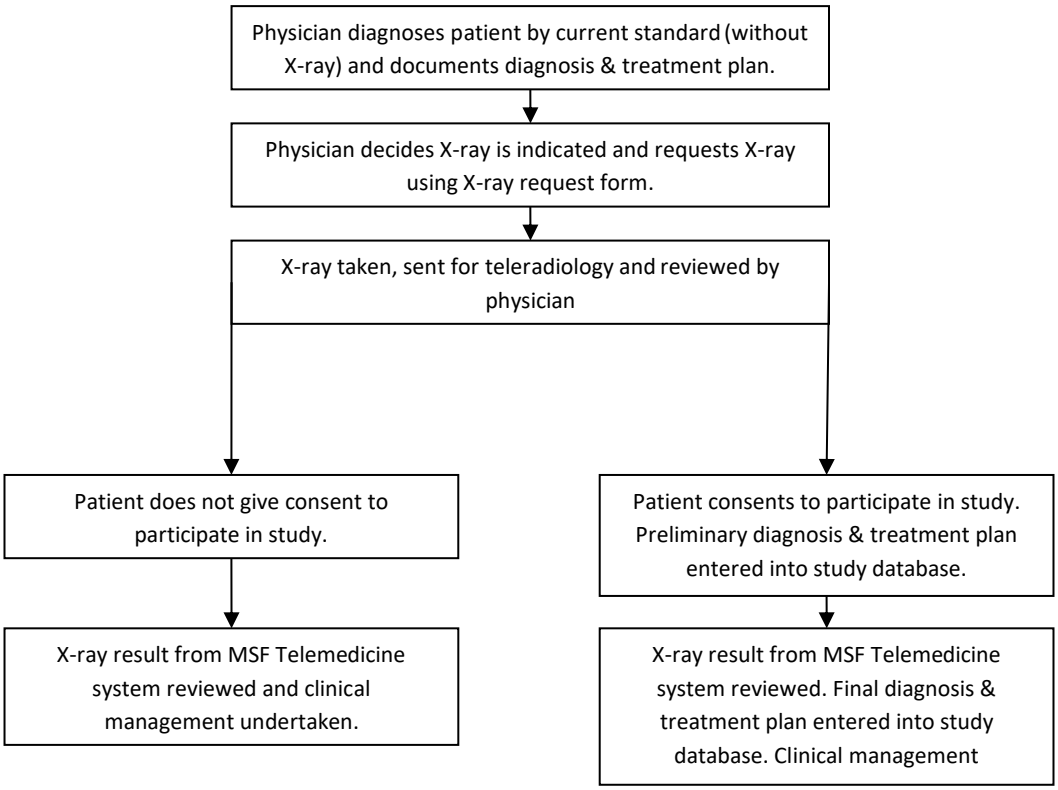
The X-ray technician (or expatriate physician) will explain to the patient the study objectives and seek consent to participate in the study. If the patient consents, the X-ray technician will enter the preliminary diagnosis and treatment plan from the physician (see Annex 6.3) into the study data entry system. If the patient does not want to participate in the study, the images will still be sent for teleradiology, and the patient will still benefit from the teleradiology consultation. The MSF Telemedicine system will send back the findings within 24 hours for most cases (median response time of approximately 6 hours). [9]

The same expatriate physician (who created the original management plan) must review the findings of the teleradiology consultation. If any adjustments to the treatment plan are required, (i.e. if the treatment/management of the patient has changed with the additional information from the X-ray and teleradiology) the patient must be notified. If for any reason it is not possible for the same expatriate physician to review the findings and complete the after X-ray treatment plan, the patient must be excluded from the study with these details recorded.

IPD patients can be notified of the findings of the X-ray and teleradiology consultation on the ward. OPD patients can wait for the results, be scheduled to have a follow-up appointment 2-3 days after the X-ray has been taken or be given a tracing consent to be contacted to review their treatment plan and receive results of the teleradiology consultation.

The final diagnosis and treatment plan will be recorded on the patient file and study form (see Annex 6.4). The study form (after X-ray) will be given to the X-ray technician to be entered into the study data entry system.

Figure 1: Process of recruitment of potential study participants



4.6 Outcomes, data entry and analysis

4.6.1 Outcomes

Primary outcome

In order to address the primary objective of the study (i.e. change in patient management) each case will be examined and graded either as

- 'Change in patient management' (i.e. X-ray & teleradiology lead to a change in patient management)
- 'No change in patient management' (i.e. X-ray & teleradiology did not lead to a change in patient management).

Secondary outcomes

a) Each case will be examined and graded either as
    - 'Change in patient diagnosis' (i.e. X-ray & teleradiology lead to a change in patient diagnosis).
    - 'No change in patient diagnosis' (i.e. X-ray & teleradiology did not lead to a change in patient diagnosis).

b) The above grading for diagnosis and management, will be used for sub-analyses using additional data routinely recorded on the forms:
    - Site of X-ray (chest X-ray versus other body parts)
    - Age (age <5 years versus ≥5 years) and
    - X-ray (first X-ray for diagnosis versus follow-up X-ray)

4.6.2 Data collection and entry

Information on study participants

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

The EpiData file on study site will contain following variables:

a) Study identification number
b) Age in years
c) Sex
    - Female
    - Male

- Unknown

d) Initials of requesting physicians: to be determined

e) Suspicion of TB
    - Yes
    - No
    - Unknown

f) Type of X-ray
    - Thorax
    - Abdomen
    - Pelvis
    - Extremity upper (right, left)
    - Extremity lower (right, left)
    - Spine (cervical, thoracic, lumbar, complete)
    - Other, to specify

g) X-ray timing
    - First X-ray of this particular body part (X-ray for diagnosis)
    - Follow-up X-ray

h) Clinical indication for X-ray
    - Differential diagnosis (DD) respiratory illness
    - DD for surgical vs. conservative management – orthopedically (e.g. fractures)
    - DD for surgical vs. conservative management – thorax
    - DD for surgical vs. conservative management – abdomen
    - Follow-up X-ray for treatment response
    - Other, please specify

i) Preliminary Dx without X-ray and teleradiology
    - Respiratory illness – bacterial (excl. TB)
    - Respiratory illness – pulmonary TB
    - Respiratory illness – viral
    - Respiratory illness – non-infectious
    - Pleural effusion
    - Foreign body - thorax
    - Foreign body - abdomen

- Bowel obstruction
- Fracture upper extremity
- Fracture lower extremity
- Fracture spine
- Fracture pelvis
- Other, please specify

j) Preliminary management
- Conservative
- Antibiotics
- TB treatment
- Explorative thoracic surgery
- Explorative abdominal surgery
- Transfer to another facility
- Other

k) Preliminary drug 1
- Name of drug
- Dosage per day
- Duration

l) Preliminary drug 2
- Name of drug
- Dosage per day
- Duration

m) Preliminary drug 3
- Name of drug
- Dosage per day
- Duration

n) Preliminary drug 4
- Name of drug
- Dosage per day
- Duration

o) Final Dx with X-ray and teleradiology report

(Do not include new diagnosis which occurred after taking the x-ray)

- Respiratory illness – bacterial (excl. TB)
- Respiratory illness – pulmonary TB
- Respiratory illness – viral
- Respiratory illness – non-infectious
- Pleural effusion
- Foreign body - thorax
- Foreign body - abdomen
- Bowel obstruction
- Fracture upper extremity
- Fracture lower extremity
- Fracture spine
- Fracture pelvis
- Other, please specify

p) Final management

(Do not include new treatment changes which related to a condition that developed after taking the x-ray)

- Conservative
- Antibiotics
- TB treatment
- Explorative thoracic surgery
- Explorative abdominal surgery
- Orthopaedic intervention: e.g. cast, reduction
- Other, please specify

q) Final drug 1

- Name of drug
- Dosage per day
- Duration

r) Final drug 2

- Name of drug
- Dosage per day
- Duration

s) Final drug 3

- Name of drug
- Dosage per day
- Duration

t) Final drug 4

- Name of drug
- Dosage per day
- Duration

Additional variables which will be classified by study team in Europe, after study file is completed:

a) Change in patient's management:

- Yes
- No
- Unknown

b) If yes, why?

- X-ray confirmed diagnosis but changed treatment duration (same treatment – different duration)
- X-ray excluded or added diagnosis with a therapeutic consequence (change in treatment)
- Approach was changed from curative to palliative or vice versa
- Other, specify:

c) Change in patient's diagnosis:

- Yes
- No
- Unknown

4.6.3 Analysis

Analysis will be carried out using STATA version 10 (StataCorp, College Station, Texas, USA), using for the primary and secondary outcome a binomial test of the proportion of patients with changed management compared to a hypothesised proportion (15 %). The proportion of patients who fit into specific reasons for change or no change in patient management will be calculated with 95% confidence intervals.

The primary (change in patient management) and secondary (change in patient diagnosis) outcome analysis will be assessed in the following groups:

- Chest radiographs only
- Children <5 years of age versus patients ≥5 years of age

4.7 Ethics considerations

The study will be initiated after formal approval by the MSF Ethical Review Board as well as local written approval by the ethical committee in the Ministry of Health in Goma. The study will be carried out in accordance with the Declaration of Helsinki concerning medical research in humans. However, it is important to acknowledge that the study is not an interventional study, but rather an evaluation of the availability of X-ray with teleradiology. The indication for an X-ray examination is purely clinical and radiology would be used in the very same way with or without this study in place.

Consent: All enrolled patients will sign or fingerprint the informed consent. Minors below the legal age of consent in the study country will only be included if their legal guardian consents to the study. Participation will be voluntary.

Patient risks: The main risk to patients is loss of anonymity which will be minimised though transmitting all cases without any patient identifying information. Images will only be identifiable by the patient study number allocated to each case.

Benefits: Individuals will benefit through the installation of the X-ray unit and teleradiology in decision making in the management of their care. By extension the community will also benefit from the access to greater diagnostic capabilities and the increased education and training of hospital staff. The results of the study will not influence the continuation of the X-ray and teleradiology service to the community after the study completion. The unit will already be installed and the MSF Telemedicine system will remain available to all MSF projects. The study results will influence however the prioritisation of resources for communities in DRC and other MSF settings where the equipment and service is not currently available.

Bias: A weakness of a before-after study design is considered to be a potential bias towards overestimating the impact of the new test (here the X-ray and radiologist report). Nonetheless it is the most appropriate approach to this study, and to maximise strength of the study and limit the chance for bias, the protocol has been developed with reference to methodological quality reviews (see 6.5).[10,11]

Community involvement: The study will be discussed and agreed with the Ministry of Health in Goma. In addition, it will be discussed with community leaders in Mweso to ensure that the objectives are well understood and that the community leaders are supportive. Information about the study will also be posted in the hospital in written form. Upon completion of the study, the results will be communicated to the community and the Ministry of Health.

4.8 Financing of the study

The study has been granted funding by MSF's Innovation Fund which will pay for all material and personnel required in the field and at headquarters.

4.9 Responsibility of MSF - Holland

- Will bear the overall responsibility for the conduct of the trial including the scientific, financial, legal, ethical and administrative aspects and coordinate all activities related to the trial.
- Be principally responsible for the trial design, in consideration of input from other trial investigators and from the relevant ethical review boards/committees.
- Will install the X-ray unit with a suitable internet connection to submit images for teleradiology.
- Run and manage the trial at the site according to the current trial protocol.
- Develop the trial database.
- Be responsible for the trial data management for such data as is generated at the site;
- Analyze the trial data at the end of the trial.
- Be in charge of writing the trial report and trial manuscript's preparation for a peer-reviewed journal.

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6. Annex

6.1 Informed consent (English)

To be translated by local staff and back-translated by someone external from the study and read to the patient in the local language. Patients will then be asked for consent by signature or fingerprint. A record of their consent will be kept.

INFORMED CONSENT FOR PATIENTS: IMPACT OF DIGITAL X-RAY WITH TELERADIOLOGY ON CASE MANAGEMENT IN CENTRAL AFRICAN REPUBLIC

The physician or doctor has diagnosed you as usual and planned your treatment. The physician/doctor decided that taking an X-ray is beneficial to diagnose your illness. We want to investigate whether taking an X-ray and sending it to a specialist doctor for reading X-rays helps to optimize your treatment and to help us decide whether this could help other patients in future, which might include your or your family.

When the report of your X-ray is available, your diagnosis and treatment plan will be reviewed by your doctor. You will be informed of the results of the teleradiology consultation and if the treatment plan has changed.

If you are not hospitalized, there is a separate tracing consent form to be signed and you can indicate how you prefer to be traced. Alternatively we will schedule a follow-up appointment with you 2-3 days after the X-ray has been sent to an X-ray film interpretation specialist, so that we can inform you if we have to adjust your treatment.

All of this will happen whether or not you agree to be part of the study. The reason we are asking your agreement is that if you agree to participate in the study, the results of your X-ray and information from your medical record will be shared with the study team.

Privacy and confidentiality

The X-ray will not be labeled with your name so that your privacy will be guaranteed. Study records will be labelled with an identification code but will NOT show individual names.

Voluntary participation

Your participation in 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. Your decision to participate or not has no influence on your further treatment.

It will not cost you anything to have the X-ray or the reading of the X-ray by the specialist doctor.

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 doctor of this hospital.

CONSENT PAGE

IMPACT OF DIGITAL X-RAY WITH TELERADIOLOGY ON CASE MANAGEMENT IN DEMOCRATIC REPUBLIC OF CONGO

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Email: drc-medco@oca.msf.org

Mobile number: +243 8171 00002 / +243 971 185 212

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

I understand that I am undergoing this X-ray examination purely for clinical reasons and not just for this study.

I hereby give my consent to participating in the study.

_____ _____

Name of client Date Signature/Thumb print

Witness

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

_____ _____

Name of witness Date Signature

_____ _____ _____

Name of study nurse/doctor Date Signature

TRACING CONSENT – PATIENTS

Study number: _____

Participant name: _____

Local contact: _____

Phone number: _____

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

If my treatment plan changes as a result of the X-ray and teleradiology consultation I hereby give my consent to be traced;

O by phone (phone number): _____

O at my house (provide address): _____

O or another location (please provide details):

_____ _____

Name of client Date Signature/Fingerprint

_____ _____

Name of study nurse/doctor Date Signature/Fingerprint

6.2 X-ray request from

MEDECINS SANS FRONTIERES	**X-ray request form** **Mweso Hospital**
Patients identification number: …… **Last name: ……** **First name: ……** **Age : ……. Gender: ……** **HIV status:** ❑ positive ❑ negative ❑ unknown **Timing X-ray:** ❑ First X-ray (X-ray for diagnosis) ❑ Follow-up X-ray	**Date: ……** **Department/Ward :……** **Name requesting physician : ……** **Radio number (given by X-ray technician):……** **Study number (given at data entry stage):……**
Type of X-ray requested (tick where appropriate) ❑ Thorax (PA) ❑ Abdomen (supine + erect) ❑ Pelvis (AP) ❑ Upper extremity (AP + lat) : ❑ Right ❑ Left Location: …… ❑ Lower extremity (AP + lat) : ❑ Right ❑ Left Location: …… ❑ Spine (AP + lat) ❑ Cervical ❑ Thoracic ❑ Lumbar ❑ Complete ❑ Other: ……	**Additional information:** Suspicion of TB ❑ Yes ❑ No ❑ Unknown
Clinical information for teleradiology	
Signature requesting physician	**Signature X-ray technician**

6.3 Clinical diagnosis and treatment plan BEFORE X-ray

<table>
<tr><th colspan="2">Clinical Dx and treatment plan BEFORE X-ray</th></tr>
<tr><td>Clinical indication for X-ray
❑ DD respiratory illness
❑ DD surgical vs. conservative – orthopedic
❑ DD surgical vs. conservative – thorax
❑ DD surgical vs. conservative – abdomen
❑ Follow-up after treatment – response check
❑ Other, specify_____</td><td>Preliminary Dx - without X-ray
(based on history, clinical exam and laboratory results)
❑ Respiratory illness – bacterial (excl. TB)
❑ Respiratory illness - pulmonary TB
❑ Respiratory illness – viral
❑ Respiratory illness – non infectious
❑ Pleural effusion
❑ Foreign body – thorax
❑ Foreign body – abdomen
❑ Bowel obstruction
❑ Fracture upper extremity
❑ Fracture lower extremity
❑ Fracture spine
❑ Fracture pelvis
❑ Other, specify_____</td></tr>
<tr><td>Treatment plan before X-ray & teleradiology:
❑ Conservative (no medication/treatment)
❑ Antibiotic (excl. TB)
❑ TB treatment
❑ Explorative thoracic surgery
❑ Explorative abdominal surgery
❑ Orthopaedic intervention
❑ Transfer of patient to another facility
❑ Other, specify_____</td><td>Comments:</td></tr>
<tr><td>Planned prescription 1
(before X-ray & teleradiology)
(only fill if treatment plan is drug based)
Name of drug:_____
Dose per day:_____
Duration: _____</td><td>Planned prescription 2
(before X-ray & teleradiology)
(only fill if treatment plan is drug based)
Name of drug:_____
Dose per day:_____
Duration: _____</td></tr>
<tr><td>Planned prescription 3
(before X-ray & teleradiology)
(only fill if treatment plan is drug based)
Name of drug:_____
Dose per day:_____
Duration: _____</td><td>Planned prescription 4
(before X-ray & teleradiology)
(only fill if treatment plan is drug based)
Name of drug:_____
Dose per day:_____
Duration: _____</td></tr>
</table>

6.4 Final diagnosis and treatment plan AFTER X-ray and teleradiology

Clinical Dx and treatment plan AFTER X-ray & teleradiology	
Date: ……..	**N° Identification du patient: ……..**
Radio #:……..	**Study number:……..** **(given by study coordinator – ONLY if telerad is requested)**
Final Dx - after X-ray & teleradiology **(considering X-ray and teleradiology report)** ❑ Respiratory illness – bacterial (excl. TB) ❑ Respiratory illness - pulmonary TB ❑ Respiratory illness – viral ❑ Respiratory illness – non infectious ❑ Pleural effusion ❑ Foreign body – thorax ❑ Foreign body – abdomen ❑ Bowel obstruction ❑ Fracture upper extremity ❑ Fracture lower extremity ❑ Fracture spine ❑ Fracture pelvis ❑ Other, specify_____	**Final treatment plan after X-ray & teleradiology:** ❑ Conservative (no medication/treatment) ❑ Antibiotic (excl. TB) ❑ TB treatment ❑ Explorative thoracic surgery ❑ Explorative abdominal surgery ❑ Orthopaedic intervention ❑ Transfer of patient to another facility ❑ Other, specify_____
Final prescription 1 (after X-ray & teleradiology) (only fill if treatment plan is drug based) Name of drug:_____ Dose per day:_____ Duration: _____	**Final prescription 2** (before X-ray & teleradiology) (only fill if treatment plan is drug based) Name of drug:_____ Dose per day:_____ Duration: _____
Final prescription 3 (before X-ray & teleradiology) (only fill if treatment plan is drug based) Name of drug:_____ Dose per day:_____ Duration: _____	**Final prescription 4** (before X-ray & teleradiology) (only fill if treatment plan is drug based) Name of drug:_____ Dose per day:_____ Duration: _____
Comments	

6.5 Referral guidelines

Provide relevant clinical details on the request form, as well as a suspected working diagnosis.

Purpose of x-ray: Either a diagnosis is to be confirmed or ruled out. Most imaging investigations that do not specify an anticipated result turn out to be of little additional value. It often helps to try to formulate on the request form the purpose of the x-ray and how the result may impact or change the management. This step focuses on the decision making process whether or not to carry out the x-ray. It also helps the person interpreting the image to answer the question.

Clinical details should include a brief summary of current symptoms and physical findings as well as pertinent past medical history such previous surgery or previous diagnosis of cancer or immune system compromise. Only request an x-ray if the result will actually have an impact on the management of the patient. For example, if pulmonary tuberculosis is suspected and proven by sputum tests, a chest x-ray is generally not necessary for diagnosis. However, a chest x-ray can use useful to exclude concurrent pathology or demonstrate complications of TB such as collapse, consolidation, pneumothorax, cavities etc. and serve as a baseline for follow-up and monitoring the evolution of disease. This can be particularly useful for paediatric patients.

Similarly, if an abdominal perforation is suspected and the patient will go for a laparotomy, an x-ray is not indicated as it will not change management. An x-ray of the nasal bone is also unnecessary if you have clinical findings that the patient's nose is broken and there is no immediate treatment that needs to be done for which you require an image.

If a diagnosis is suspected for which there is no treatment available, it is not necessary to prove the diagnosis with an x-ray. For example, in a patient with a head injury a skull x-ray to prove presence of a fracture is usually not indicated if there is no way to treat the related intra-cranial injury. The presence or absence of a fracture will not change management of that patient. (It may be necessary, however, to confirm a fracture where documentation of injury is required or to prompt observation or referral of a child). Similarly, if there is no treatment for spinal diseases such as stenosis, spinal x-rays are not indicated to confirm the diagnosis.

However, if there is a differential diagnosis, then an x-ray may be helpful.

When sending a patient for an x-ray, please indicate clearly:

- The anatomy you would like to be x-rayed.
- The 'Left' or 'Right' side when requesting a limb x-ray.
- The standard views for that part of anatomy.
- Any optional extra views that you would like.
- Relevant clinical information and suspected diagnosis.

Standard and optional extra x-ray views

Anatomy Requested	Standard Views	Optional Extra Views
Chest	PA[1] if patient can stand AP[2] if adult patient is lying and for all children	Lateral
Abdomen	AP supine	AP erect or lateral decubitus
Pelvis	AP	lateral Hip 'Frog leg' view for pediatrics
Upper Limb		
Shoulder	AP	Axial, lateral, trans-scapular *(when querying dislocation)*
Humerus	AP & lateral	
Elbow	AP & lateral	
Forearm	AP & lateral	
Wrist	AP & lateral	
Hand	AP & oblique	Lateral *(for foreign body)*
Lower Limb		
Femur	AP & lateral	
Knee	AP & lateral	
Tibia/Fibula	AP & lateral	
Ankle	AP & lateral	
Foot	AP & oblique	Lateral *(for foreign body)*
Spine		
Cervical	AP & lateral Lateral only for pediatrics	Odontoid *(for visualizing C1/2),* Swimmer's view *(when C6/7 is not visualized on lateral)*
Thoracic	AP & lateral	
Lumbar	AP & lateral	
Skull / Facial	AP & lateral	Water's view *(to assess facial trauma)*

[1] PA: Posterior-Anterior. I.e. back of patient facing the x-ray beam.
[2] AP: Anterior-Posterior. I.e. front of patient facing the x-ray beam.

Standard x-ray indications

Chest (AP or PA view)	An erect **PA view** on full inspiration (demonstrating 10 posterior ribs) is the standard view. A supine **AP view** is indicated in paediatric patients and patients who are unable to stand for a PA view. A **lateral view** is helpful in determining if a mediastinal lesion is in the anterior/middle/posterior compartment or if a lesion is arising from the pleura, bone or muscular layer rather than in the lungs. It is also recommended in children suspected of TB and should be routine if available.
	Pneumonia in adults ▪ In the absence of clinical improvement, it is advised to repeat CXRs 4-6 weeks after commencement of antibiotic therapy. If consolidation persists after that time it may be due to an atypical infection for which conventional antibiotics are not going to be effective, e.g. TB, or may be secondary to a centrally obstructing mass lesion.
	Pneumonia in children ▪ Not routinely indicated.[1] ▪ Indications for a follow-up CXR a) persistent symptoms despite treatment; causes for this would include an atypical infection such as TB or an endobronchial lesion such as an aspirated foreign body; b) round pneumonias when these can't be differentiated from a mass lesion ▪ Severely ill child ▪ Fever of unknown origin (sometimes children have pneumonia without showing clinical signs)
	Pleural effusion
	Haemoptysis
	Chest trauma ▪ Not routinely indicated in minor trauma (e.g. proof of a rib fracture does not change management).
	Chest pain ▪ Myocardial infarction: evaluate heart size and presence/absence of pulmonary oedema
	Pericardial effusion
	Clinical cardiomegaly or heart failure

Abdomen	**Acute abdomen pain: suspicion of perforation or obstruction** ▪ Supine abdominal x-ray (for gas pattern)

	▪ Erect abdominal x-ray (or left lateral decubitus view when a patient cannot stand) if supine abdominal x-ray is normal but clinically there is a strong suspicion of perforation. An erect abdominal or erect chest x-ray may be helpful in confirming a pneumoperitoneum in clinically equivocal cases. However, a) a normal x-ray does not exclude the presence of a pneumoperitoneum (20-60% of cases can be missed on plain film)[2]; b) if a pneumoperitoneum is suspected clinically, an x-ray is not necessary for confirmation of diagnosis since radiological signs may not always be present in this clinical scenario. However, an erect abdominal x-ray may be useful for demonstrating associated pathologies or possible causes. ▪ A plain abdomen x-ray will demonstrate some obstructions (air-filled loops). Note: sometimes, obstructed, dilated bowel loops are fluid filled and therefore an obstruction may not be evident on an x-ray, hence clinical suspicion over-rules an x-ray which is negative for obstruction. Plain film detection for small bowel obstruction has an accuracy of 67%[3]
	Abdominal trauma (see below: Trauma)
	Not routinely indicated for: ▪ Vague central abdominal pain or back pain ▪ Gastroenteritis ▪ Haematemesis ▪ Pyloric stenosis ▪ Uncomplicated appendicitis ▪ Chronic constipation, encopresis or enuresis The preferred diagnostic tool for abdominal pathologies is ultrasound. Where no ultrasound service is available, an x-ray may be indicated to confirm calculus or obstruction in the case of pyloric stenosis in children.

Trauma	**Limb fractures** X-ray of the suspected fracture site as well as the joints above and below. Follow up films after reduction of a displaced fracture should be done to assess position.
	Major trauma: general screen in unconscious or confused patients ▪ Cervical spine x-ray ▪ Chest x-ray ▪ Abdominal x-ray (will also demonstrate pelvis and spine) All views above can be obtained in the supine AP position.
	Major trauma: abdomen / pelvis ▪ Chest x-ray: to exclude a pneumothorax large enough to necessitate chest drain insertion. ▪ Pelvis x-ray: to exclude pelvic fractures.

	▪ Abdomen x-ray: in case of blunt or penetrating injury.
	Major trauma: chest ▪ Chest x-ray: to exclude a pneumothorax large enough to necessitate chest drain insertion; to exclude haemothorax
	Non-accidental injury in children ▪ If a non-accidental injury in a child is suspected, an x-ray should be taken as formal documentation of injury, even if the x-ray may not impact clinical management.

Musculoskeletal	**Extremities** ▪ Suspected osteomyelitis ▪ Septic arthritis where it is unsure if there is associated osteomyelitis ▪ Suspected fracture (include views of the joint above and the joint below the suspected fracture) ▪ Foreign body
	Spine ▪ Indicated in TB endemic areas where bone destruction related to TB may influence management. ▪ Not routinely indicated for patients presenting with waist/lower back pain with no history of trauma.

Skull	**Blunt or penetrating injury** (only where surgical intervention is available).
	Not routinely indicated for: ▪ Headache ▪ Possible pituitary problems ▪ Possible space-occupying lesion ▪ Epilepsy ▪ Dementia or memory loss ▪ Middle or inner ear problems ▪ Nasal trauma ▪ Sinus disease - mucosal thickening is a common incidental finding and not diagnostic

Recommendations based on European Referral Guidelines for Imaging (in conjunction with UK Royal College of Radiologists) and adapted for settings in which MSF operate.

6.5 Quality assessment criteria

QUADAS item [3]	**How addressed**
1. Was the spectrum of patient's representative of the patients who will receive the test in practice?	The study will be performed over a period of 4-6 months and will include all patients attending Mweso hospital for any condition deemed clinically relevant for X-ray. There may be seasonal variation in presenting conditions which could reduce representativeness of the conditions to the annual Mweso hospital population. The patients may not be representative of other locations where teleradiology could be used.
2. Were selection criteria clearly described? [Were patients recruited consecutively?]	Consecutive patients presenting to the clinic who may benefit from teleradiology will be invited to participate.
3. Is the reference standard likely to correctly classify the target condition? *(Where the after test is not a recognised reference standard for the target disease full delineation of the impact of test errors requires evaluation of all study subjects with a reference standard.)*	X-rays will be read by a radiology consultants, so while not the gold standard, the diagnostic accuracy is expected to be high.
4. Is the time period between reference standard and index test short enough to be reasonably sure that the target condition did not change between the two tests?	Patients will receive X-ray within 24-48 hours of being requested.
5. Did the whole sample or a random selection of the sample, receive verification using a reference standard of diagnosis?	N/A
6. Did patients receive the same reference standard regardless of the index test result?	All patients included in the study will have their X-ray read by vRad.
7. Was the reference standard independent of the index test (the index test did not form part of the reference standard)? *(Before after studies are concerned with evaluating the value of adding a test. Consequently the results of the before test are usually known at the time of interpreting the after test results. This item is therefore redundant for diagnostic before-after studies.)*	N/A
8. Was the execution of the index test described in sufficient detail to permit replication of the test? *(Whether a diagnostic technology has therapeutic impact might depend on the physician using the test.)*	Clinical diagnosis may be somewhat physician dependent. However, all medical staff should be referring to standard MSF clinical guidelines.
9. Was the execution of the reference standard described in sufficient detail to permit replication of the test? [Who performed the clinical evaluation and image analysis?]	All X-rays will be read by radiologists at vRad who have extensive experience with teleradiology, however reading X-rays does not always result in an indisputable diagnosis.

[3] as included in Meads & Davenport [5] *(with additional reference to Guyatt on metholodological issues[6])*

QUADAS item [3]	**How addressed**
10. Were the index test results interpreted without knowledge of the results of the reference standard? [Was the study and/or collection of clinical variables conducted prospectively?]	Clinical diagnosis and treatment plan will be documented before the X-ray has been sent.
11. Were the reference standard results interpreted without knowledge of the results of the index test? *(Before after studies are concerned with evaluating the value of adding a test. Consequently the results of the before test are usually known at the time of interpreting the after test results. However therapeutic plans based on the before test results should not be known at the time of making therapeutic plans based on a combination of the before and after test results. Before-after studies can be strengthened by an independent review of the after test's contribution to therapeutic decisions relative to the before test.)*	In order to minimise the role of individual physician opinion on treatment, the same physician who made the initial diagnosis and treatment plan will receive the X-ray diagnosis and review the treatment plan. It is acknowledged that this may result in some over-estimation of the benefit of the X-ray result.
12. Were the same clinical data available when test results were interpreted as would be available when the test is used in practice? *(The addition of a test may have appeared to have had an impact because of an incomplete pre-test work-up.)*	Physicians in the clinic will be instructed to undertake a complete examination, diagnosis and treatment plan as if no X-ray result would be available. This will need to be monitored to ensure that over time they do not change their diagnostic practice and come to rely on the X-ray diagnosis.
13. Were un-interpretable/intermediate test results reported?	X-rays that are of suboptimal quality will be included in the analysis.
14. Were withdrawals from the study explained? [What was the explanation for patients who did not receive the test?]	All refusals or withdrawal of consent will be documented.
Additional methodological issue raised by Guyatt: • Criteria for establishing therapeutic impact should be formulated a priori • Sufficient clinical information and/or evidence of the effectiveness of available therapies are required to judge whether therapeutic changes will alter patient outcomes	The type of therapeutic change will be documented, but the impact of this on patient outcome will be not established. Determining impact on outcome is not the aim of this study.