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QUALITY ASSURANCE OF PAEDIATRIC LATERAL CHEST RADIOGRAPHS

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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in partial fulfilment of the requirements for the degree of Master of Medicine in Diagnostic Radiology

Johannesburg, October 2017

Declaration

I, Leisha Rajkumar, declare that this research report is my own work. It is being submitted for the degree of MMed (Diagnostic Radiology) at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

Dr Leisha Rajkumar

On this 04th day of October 2017.

To Nischal.

My best friend, my biggest fan.

With you, nothing is impossible. I love you.

Publications and presentations

This work has never been published.

Provisional results were presented by means of a poster at the ESPR congress in Graz, Austria, 2-6 June 2015.

Abstract

INTRODUCTION:

Lateral chest radiographs are widely used, particularly in low and middle income countries, for diagnosing pulmonary tuberculous lymphadenopathy. The World Health Organisation recommends that "**good-quality** chest radiographs (**including lateral view**, if and where possible) are essential for proper evaluation" of paediatric pulmonary tuberculosis. However, the quality of such radiographs has received little attention and there is no currently available quality assurance tool for evaluating these in children (or adults).

AIM:

To develop a quality assurance tick-sheet for paediatric lateral chest radiographs and to test it for quantifying radiographic errors.

METHOD:

A quantitative retrospective cross-sectional study, using a sample of 300 chest radiographs of paediatric patients being investigated for pulmonary tuberculosis for the period February 2008 to January 2013. A quality assurance tick-sheet and scoring system was created, using existing guidelines and reasonable radiological principles. Three readers applied the tick-sheet to the database of radiographs, to establish common errors affecting radiograph quality (radiographer-related and patient-related) and to determine the reliability of each criterion. A majority decision for the presence of each error and an average of the score was reported. Reliability of each quality assurance criterion was evaluated using raw agreement and the kappa statistic.

RESULTS:

Of the 300 radiographs, 67 (22.3%) were considered optimal using the tick-sheet's scoring system i.e. had an average score of less than 1, and 182 (60.7%) demonstrated an average score of 1-2. Patient-related errors were present in 208 (69.3%) of lateral radiographs, the most prevalent being left-to-right rotation in 153 (51%), under-inspired lungs in 82 (27.3%) and the presence of motion artefact in 27 (9%). Radiographer-related errors were present in 110 (36.7%), the most common of which were under-collimation 59 (19.7%) and over-exposure i.e. too dark 40 (13.3%). For 6 of the 11 criteria there was moderate, fair or substantial agreement (based on raw agreement or kappa): No side marker, Static artifact, Over-exposure i.e. too dark, Under-exposure i.e. too light, Under-collimation and Rotation:left-to-right. For the remaining 5 criteria there was slight agreement or less than chance agreement (based on raw agreement or kappa): Over-collimation, Rotation:side-to-side, Under-inspiration (described for the first time in this paper), Position and Motion artifact.

CONCLUSIONS:

Where the lateral chest radiograph is often key in diagnosing TB in children and diagnostic doubt resulting from the quality of the radiograph must be minimised, availability and use of the proposed quality assurance tick-sheet will foster more precise radiographic technique and also improve the radiological service offered. 5 of the 11 criteria with poor inter-rater agreement require improvement of the definition of the criterion to increase reliability.

Acknowledgements

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- My supervisor, Professor Savvas Andronikou, for your infectious passion for this study, and for the incredible support through all the setbacks.

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- Professor Heather Zar, for providing the database for this study, and for your insights.

- Petra Gaylard, for your timeous and thorough efforts in helping me to suss out the statistical component of this study.

- My parents, for affording me the understanding and constant encouragement to work through this incessant undertaking

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1. Rationale

Lateral chest X-rays are still a widely used diagnostic imaging tool in paediatric clinical practice, particularly in those countries where it is believed that they assist in the diagnosis of pulmonary tuberculosis (PTB). The identification of lymphadenopathy around the bronchus intermedius on the lateral radiograph, giving the described 'doughnut sign' is often considered diagnostic of PTB (1; 2) TB is paucibacillary in young children and because the frontal radiograph is often inconclusive (3; 4). However, lateral radiographs in trials have not been shown to add value to frontal radiographs alone, as they did not significantly increase the diagnostic accuracy (2; 5). This may reflect poor training of radiologists and clinicians in radiographic anatomy and diagnosis on lateral radiographs but may also be contributed to by poor radiographic technical quality.

The World Health Organisation (WHO) has recommended that "**good-quality** chest radiographs (**including lateral view**, if and where possible) are essential for proper evaluation" of paediatric PTB (4). However, quality of paediatric lateral chest radiographs has received little attention in the literature. Coulter recognises the poor quality of chest radiographs overall, as a major problem in low and middle income countries in his article regarding the diagnosis paediatric PTB (5). There are also no standardised criteria for lateral chest X-ray quality outside of radiographic texts, which focus on ideal patient positioning and technical factors. Without evaluating the quality of lateral radiographs, those papers, which claim that these add no value to the diagnosis of TB, are making unsubstantiated claims.

The aim of this study was to create a tick-sheet of relevant quality assurance criteria for lateral chest X-rays, and to test this in children with suspected PTB so as to investigate the frequency of poor quality radiographs and indicate where improvements need to be made. Quality improvements, arising form use of this tool, will facilitate adequate interpretation of lateral radiographs, as an essential component in the investigation and diagnosis of PTB in children in South Africa and other low and middle income countries.

2. Introduction

2.1. What is quality assurance?

"Quality imaging is a means of achieving quality radiology and hence quality diagnosis" (6). It is important to differentiate quality control, which deals with the monitoring of equipment and comparison of resultant image quality with regulations, from quality assurance. The latter encompasses the management of quality, which involves the collection and scrutiny of data, followed by the organisation of the outcomes (7). This practice allows improvement of central processes, thereby resulting in improved performance. Simply put, in this setting, the better the quality of the radiograph, the easier it is to interpret, resulting in a more confident diagnosis.

2.2. Benefits of quality assurance in radiologic imaging

Implementing quality assurance measures, limits the effects of poor image quality. These effects are observed from many perspectives, namely radiologists, referring doctors, radiographers, patients, and society (8). Optimising radiograph quality ensures that

adequate information is demonstrated on the radiograph, allowing for a suitable interpretation. Consequently, fewer repeat radiographs are performed, resulting in less unnecessary radiation exposure to both staff and patients. In addition, there are cost-saving benefits, including saving on equipment repairs and on consumables like film (which is still used in developing countries). The precious time of all staff involved (porters, nursing staff, radiographers, radiologists, clinicians), and of the patients and their accompanying families, is better utilised. Appropriate management of patients is also implemented relatively sooner. Further enhanced communication and cooperation among staff results from an efficiently functioning process. These effects are invaluable in the South African medical public health system, where patient turnover is very high and the ratio of available equipment or staff to patients in departments is unbalanced.

2.3. The value of quality assurance in paediatric imaging

Two basic principles need to be adhered to in diagnostic imaging, as recommended by the International Commission on Radiological Protection, namely *justification* of the imaging procedure, and *optimisation* of imaging techniques (9). Quality assurance affects the optimisation limb, since the goal of optimisation is to obtain a prime quality image while keeping the radiation dose to a minimum, by employing methods of radiation protection and modifying imaging technical factors. This is especially important with regard to the varying patient sizes in paediatric imaging (10).

Potential long term effects of diagnostic radiation remain a concern amongst paediatric radiologists (10; 11). As a result, optimising radiation protective measures and limiting the number of repeat radiographs required due to quality factors is a high priority in children.

2.4. Achieving a high level of quality assurance

Because there are many aspects involved in the imaging process, achieving the benefits of quality assurance may not be easy. According to the American College of Radiology (ACR) chest imaging guidelines, QA measures should include having images reviewed by trained staff (12). Suboptimal images should be repeated (12).

While children who are old enough can understand the implications of limiting motion during the imaging process, young children may require assistance in the form of immobilisation devices (13). The large equipment and uncomfortably forced positioning entailed in the imaging process can be a frightening experience for a child. In such cases, the accompanying parent or caregiver must be educated about the benefits of encouraging a calm and safe feeling for the child in an effort to maintain the appropriate position, limit motion and reduce repeat imaging (13). When this cannot be achieved, it may be necessary to restrain or sedate the child (13).

2.5. Radiographic factors affecting images of paediatric lateral chest radiographs

Figure 2.1 below demonstrates an ideal paediatric lateral chest radiograph.

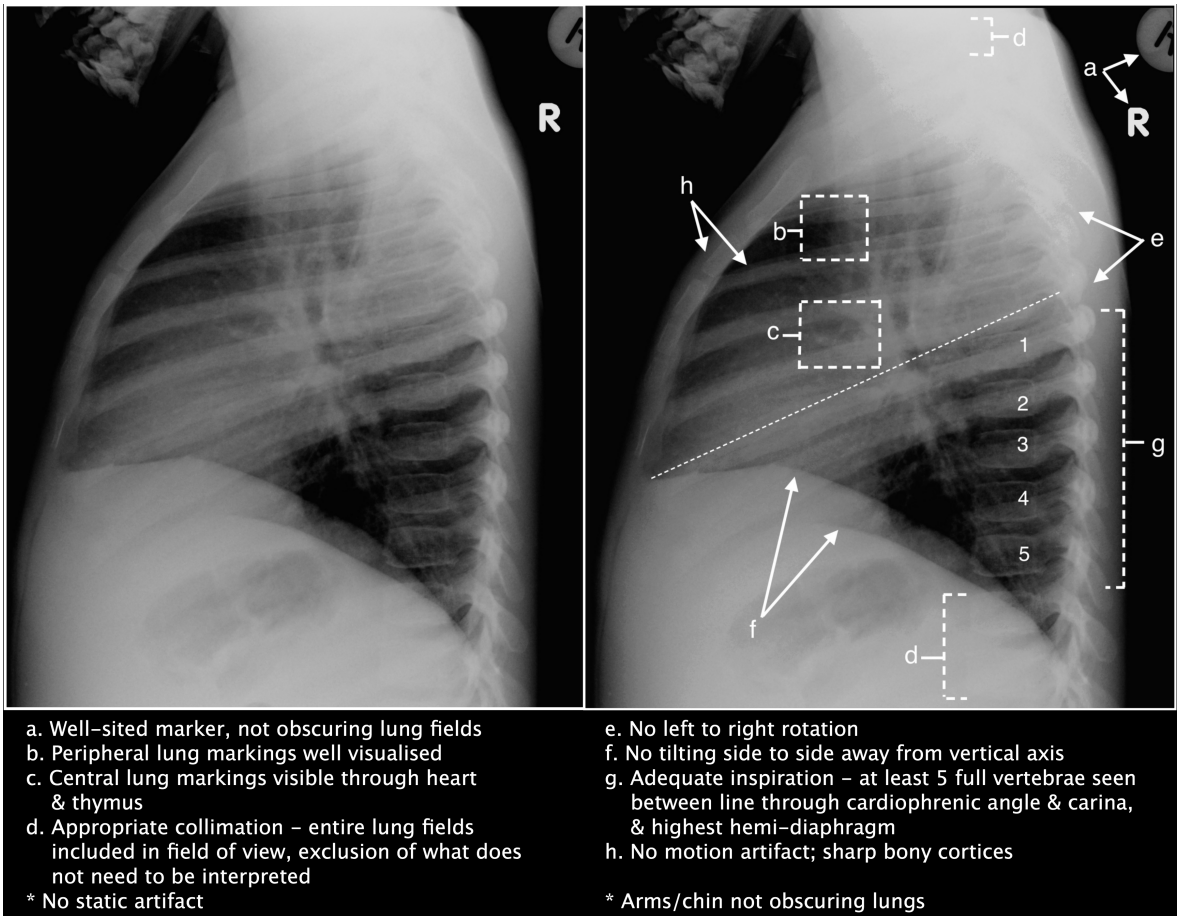


Figure 2.1 Ideal paediatric lateral chest radiograph with annotations a - h

This image encompasses the various quality factors, which can be assessed on the lateral chest radiograph. These factors are categorised and discussed below and are accompanied by pictorial comparisons to the ideal radiograph, where necessary. Our proposed method of measuring inspiration (factor “g”) and under-collimation (factor “d”) are detailed in the Methods section (3.3) of this paper.

2.5.1. Radiographer-related factors

2.5.1.1. Annotation

The ACR recommends that images must be labelled with patient details (name and identification number), institution identification, patient position and side markers, as well as examination date and time (12). These details should be clearly printed so that they are not mistaken for that of another patient, and must not obscure the lung fields in order to avoid misinterpretation of the radiograph (13; 14). In Gallet et al's study, it was found that incorrect/absent markers were the most common radiographic error (6). In order to maintain anonymity of the patients in our study, the patient details as described above were replaced with a radiograph study number.

2.5.1.2 Static artefact

The lung fields must not be obscured by objects on the patient e.g. clothing, jewellery (14). As a result, patients are usually pre-emptively advised to only wear a hospital gown.

2.5.1.3. Exposure

The penetration, contrast and density of a radiograph are affected by the duration of power and beam exposure (15). An under- or over-penetrated film can result in a short scale of contrast with the film appearing diffusely too white or dark respectively (15). Some structures may then be obscured, reducing the diagnostic accuracy of the film.

The above factors must be adequate to demonstrate the vascular markings both centrally and in the periphery of the lung field, as demonstrated in Figure 2.2 below (15). In addition, the soft tissue outlines of the cardiac shadow, the airways and hilar regions must be visualised (15). Cortical outlines of the ribs, sternum and thoracic vertebrae must be well defined (13; 15). Limiting patient motion when obtaining the image, improves the characterisation of these structures (13).

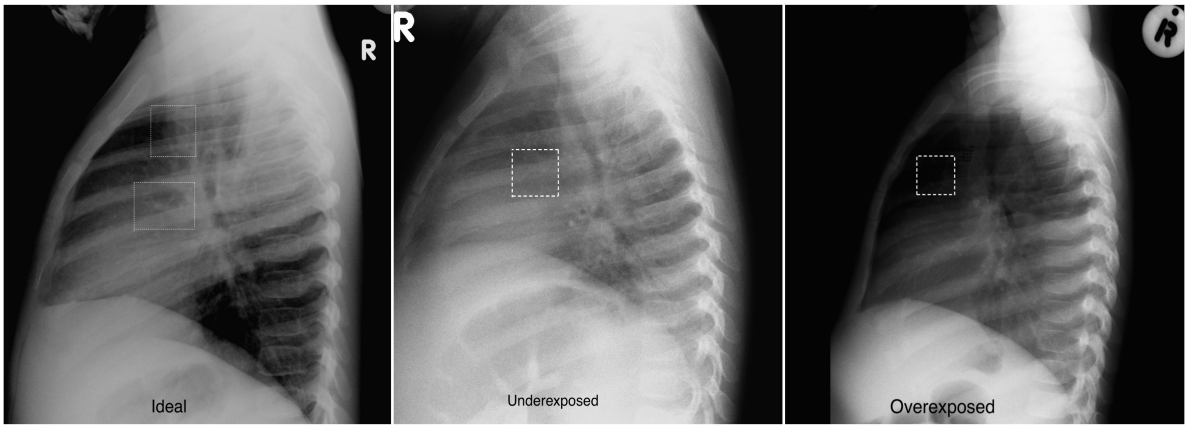


Figure 2.2 Ideal radiograph vs. poor exposure – too light (underexposed) and too dark (overexposed)

2.5.1.4. Field of view

The entire lung fields must be visualised at the peak of inspiration, from the lung apices to the costophrenic angles craniocaudally, and from the sternum to the posterior ribs in the anteroposterior dimension, as depicted in Figure 2.3 below (14).

Precise patient positioning is necessary for proper collimation. This can be very difficult to achieve in a child who is crying or moving around, and as a result, poor collimation has been found to be a common radiographic error in imaging children (6; 13;17). Gallet found overexposure and incorrect (along with absent) markers to be the most common

errors in general paediatric radiography, with improper positioning being the next most common error, while Loovere found under-collimation to be the most common error in chest and abdominal radiographs in a neonatal setting (6; 17). Collimation refers to the restriction of the X-ray beam, such that scattered radiation is reduced. As a result, accurate collimation limits the radiation exposure of radiosensitive organs, which are closer together in children (10). Conversely, over-collimation can exclude structures that are essential to the diagnostic accuracy of the film, as in Figure 2.3.

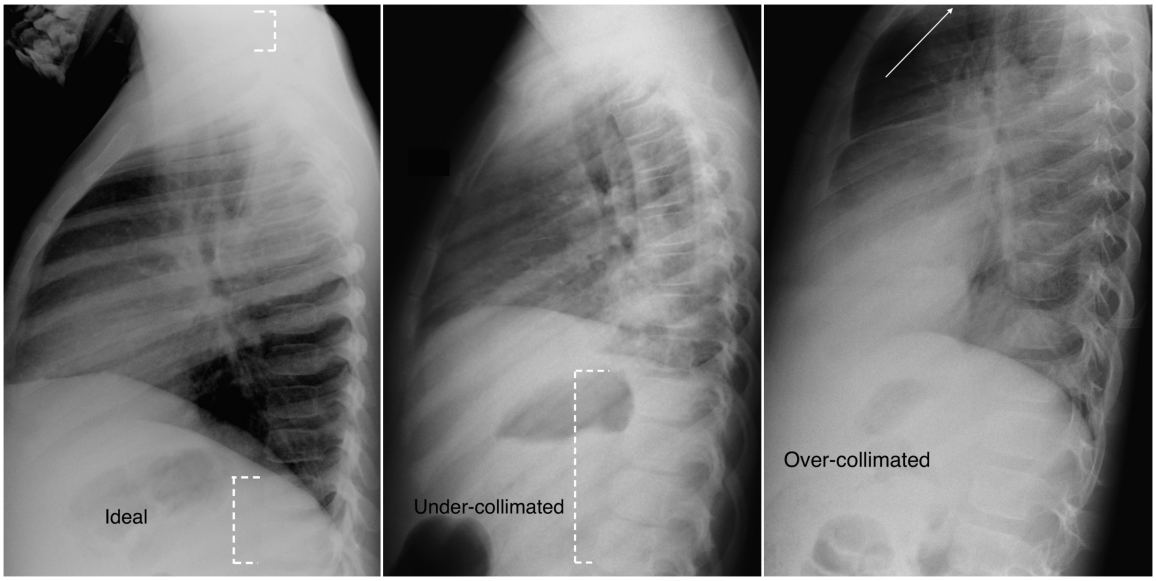


Figure 2.3 Ideal radiograph vs. poor collimation - under-collimated inferiorly and over-collimated superiorly

2.5.2. Patient-related factors

2.5.2.1 Lung Volumes

It is advised that the radiograph be obtained on the patient's second inspiration in order to produce adequate lung volumes, however, this may not be achieved in a patient who is crying or tachypnoeic (14). Under-inspired lungs may hinder detection of volume loss and

may also simulate pathology (15). There is currently no documented method of assessing adequacy of lung volumes in a paediatric lateral chest radiograph.

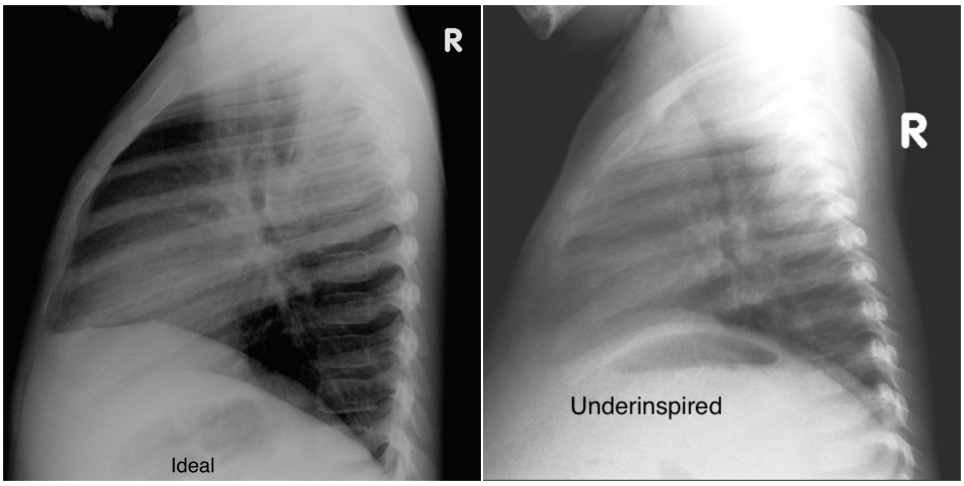


Figure 2.4 Ideal radiograph vs. under-inspiration

2.5.2.2. Rotation and tilting

There should be no chest rotation or tilting (unintentional kyphotic / lordotic and/or side-to-side deviation), since inappropriate positioning obscures areas of the lung field and distorts the cardiac and hilar shadows (15). Tilting results in foreshortening or lengthening of the lung fields (15). Side-to-side tilting away from the vertical axis manifests as the right hemidiaphragm projecting inferior to the left if tilted to the right side, as depicted in Figure 2.5 below (15). To achieve an absence of rotation, the left and right posterior ribs must be superimposed as closely as possible (in adults, the distance between them must not exceed 1 cm), and both hemidiaphragms and costophrenic angles must also be superimposed, demonstrated in Figure 2.5 (14; 15).

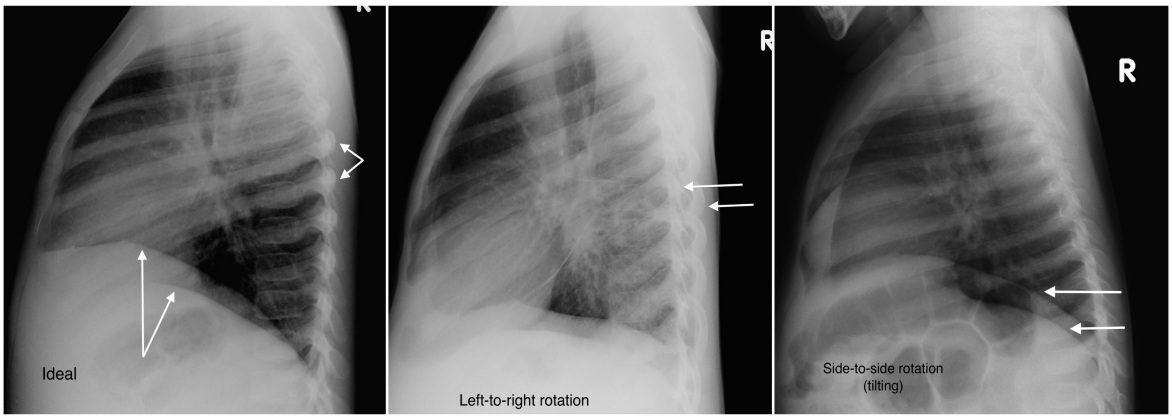


Figure 2.5 Ideal radiograph vs. left-to-right and side-to-side (tilting) rotation

2.5.2.3. Positioning and motion

Appropriate positioning will ensure that the upper limbs and the chin do not obscure the lung fields (refer to Figure 2.6 below). Motion artifact disrupts the continuity of structures, which may mask or mimic pathology (15). In the absence of motion artifact, the sternum is produced clearly in profile, and the rib cortices are defined, as in Figure 2.6 below (14; 15). Yet, such parameters are difficult to achieve to in little children who are resistant to remaining still. Patient and caregiver reassurance with or without the use of simple immobilising devices may assist in limiting motion (13).

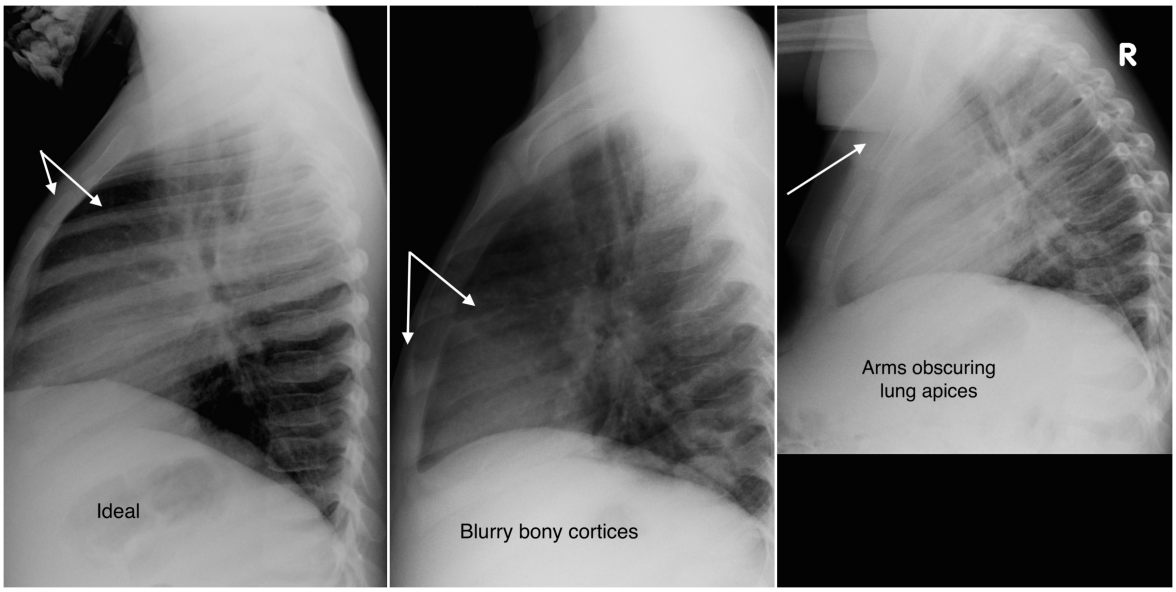


Figure 2.6 Ideal radiograph vs. motion artifact (blurry cortices) and poor positioning (with arms obscuring the lung apices)

Lateral chest radiographs continue to play an important role in the paediatric setting, especially in low and middle income countries where diagnosis of primary pulmonary TB still relies heavily on the chest radiograph. However, there is currently no standardised detailed method of assessing quality of the lateral chest radiograph. Without an adequate quality assessment the accuracy of reported findings in diagnosis of PTB cannot be considered reliable. Development of a standardised quality assurance tick-sheet and demonstration of common radiographic errors in a population in whom the lateral radiographs are considered necessary for making the diagnosis of PTB will greatly improve the value of lateral chest radiograph in such contexts.

2.6. Aim

This study aimed to develop a tick-sheet to evaluate the quality of lateral chest radiographs from a database of paediatric patients with suspected PTB and to apply this tool for determining the reliability of the defined quality criteria and the frequency of specific radiographic errors on lateral radiographs.

2.7. Study Objectives

The objectives of this study were to:

- To develop a user-friendly quality assurance tick-sheet for paediatric lateral chest radiographs based on existing criteria
- To apply the designed tick sheet to children who have undergone chest radiographs for suspected PTB, in order to determine the most reliable quality criteria and to quantify radiographic errors in this context
- Assess inter-observer agreement for each criterion

3. Methods

3.1. Research paradigm

This was a secondary analysis of data collected as part of a prospective study that aimed to improve diagnostic methods for PTB in children. A database of lateral radiographs was evaluated by three readers to establish common errors affecting radiograph quality, via the use of a standardised tick-sheet, which allowed for a quantitative approach.

3.2. Sample

The study sample of 300 children was obtained from an existing database of 2470 paediatric lateral chest radiographs from a study entitled "Diagnosis of TB in children – development of immunological and microbiological strategies". The principal investigator of this study is Professor Heather Zar, who is the Head of Department of Paediatric and Child Health at Red Cross War Memorial Children's Hospital and who had permitted us access to and use of this data. These radiographs were acquired from children up to the age of 15 years, with suspected pulmonary tuberculosis. They were performed as in-patient radiographs at the Red Cross War Memorial Children's Hospital in the Western Cape from February 2008 up until January 2013.

An estimation of sample size is based on the estimation of the percentage of adequate X-rays according to any one criterion. Given an infinite population, 5% precision, a 95% confidence interval, and an estimated level of defects of 15%, the required sample size is 196. Thus, the chosen sample size of 300 is more than adequate.

Sample size for prevalence was determined using the formula:

$$n = \frac{Z^2 P(1-P)}{d^2}$$

where n = sample size,

Z = Z-statistic for the chosen level of confidence,

P = expected prevalence or proportion

d = precision

The database encompassed children being investigated for PTB. As a result, there are radiographs from children with TB disease as well as from those with lower respiratory tract infection from other (non-TB) causes. This reflects the daily findings in our setting, and QA procedures should be applied to all radiographs, irrespective of the cause of lower respiratory tract disease. In many instances, the ill patient is technically more difficult to image, however, it is these patients who require excellent radiographic quality in order to improve diagnostic accuracy.

3.2.1. Inclusion criteria

Since our sample is extracted from an existing database involving a suitable population for our study i.e. children with suspected PTB, all patients were considered but only those with available digital lateral radiographs were included.

3.2.2. Exclusion criteria

All patients with radiographs, which were not obtained digitally, were excluded. This was intended to reduce variations in image quality that can result from transferring an image from hard copy to digital, which does not reflect radiographic quality.

The first sequential 300 images, which satisfied both inclusion and exclusion criteria made up the sample for this study.

3.3. Materials and Methods

During 2014 and 2015, existing criteria and guidelines / tick-sheets regarding the quality assurance of chest radiographs in children were reviewed using the Medline database through PubMed, with the following search phrases: “quality + lateral chest radiograph”, “quality assurance + chest radiograph”, “lateral chest radiograph + guidelines”, “paediatric + lateral cxr + guidelines”, . The following sources were also utilised:

- European Society of Paediatric Radiology (ESPR)
- Society for Paediatric Radiology (SPR) (USA)
- American College of Radiology (ACR)
- World Health Organisation (WHO)
- International Society of Radiographers and Radiological Technologists (ISRRT)
- Recommended texts in radiographer training

The following sources were used to define all of the errors, with the exception of the two which we defined ourselves (under-collimation and under-inspiration – discussed further below):

- Textbooks regarding radiographic technique (14, 15)
- ACR-SPR practice parameters for performing CXR (12)
- European guidelines on quality assurance for diagnostic radiographic images (13)

For some criteria, there was a paucity of existing guidelines. These criteria were thus devised based on reasonable radiological principles, and principles extracted from AP radiograph QA guidelines. This applied to the descriptors of both “under-collimation” and “under-inspiration”.

We propose that “under-collimation” in the cranio-caudal direction be defined as including more than two extra-thoracic vertebral bodies in either direction (cranial or caudal) in the image, as depicted in Figure 3.1. By choosing 2 vertebrae cranially and caudally, we have allowed for radiographer latitude in terms of imaging (to ensure no over-collimation), but also not excluded excessive imaging of extra-thoracic structures.

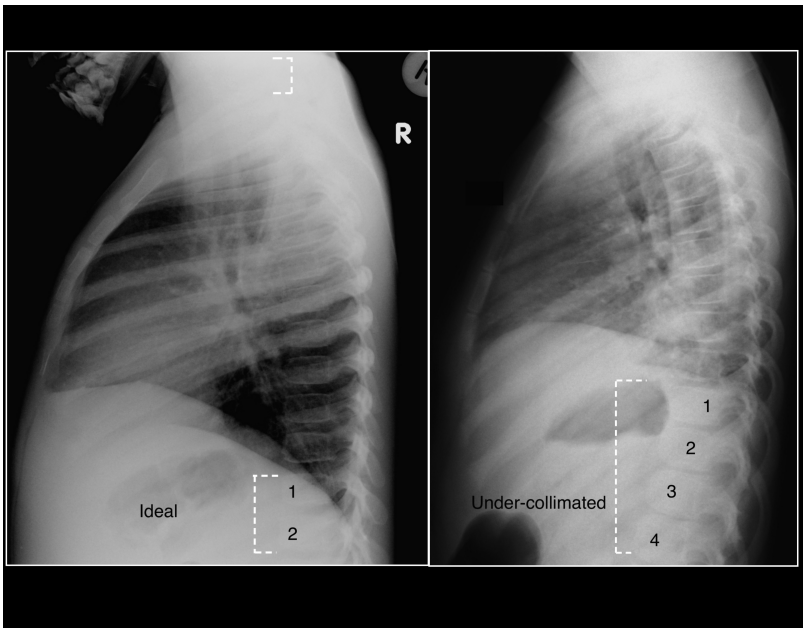


Figure 3.1 Ideal radiograph vs. proposed under-collimation descriptor – square brackets indicate the cranial & caudal number of extra-thoracic vertebral bodies

With regard to “under-inspiration”, we propose a definition of less than 5 vertebral bodies visualised between an extrapolated line from the cardiophrenic angle through the carina and the highest diaphragm. This is demonstrated in Figure 3.2 below. The lateral radiograph should adequately demonstrate the apical and posterior segments of the lower lobes, which are usually obscured by the heart on the frontal radiograph. In the lateral view, the vertebral column is superimposed on this portion of the lung, and offers

a segmented bony landmark that can serve as a metric. The logic stands that the greater the inspiratory effort, the greater the number of vertebrae that are visualised. On pilot review of 20 lateral chest radiographs, those that were considered to be ideal, were seen to have 5 vertebral bodies visible through the lower lobes, whereas radiographs considered to be under-inspired, across the board, had less than 5 vertebral bodies visible through aerated lung above the diaphragm.

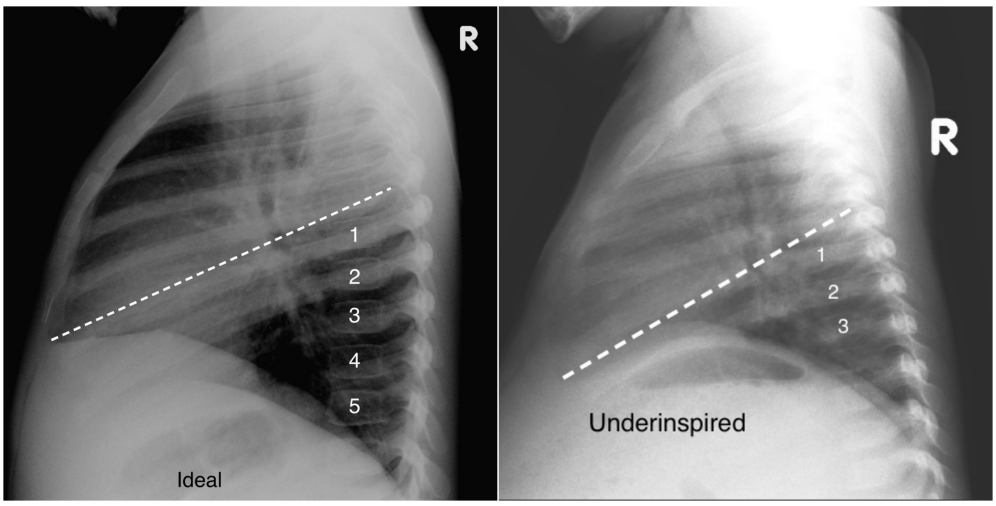


Figure 3.2 Ideal radiograph vs. proposed under-inspiration descriptor demonstrating an extrapolated line extending from the cardio-phrenic angle and passing through carina, below which the number vertebral bodies are counted that are visible above the diaphragm - less than 5 vertebral bodies between the line and the diaphragm indicates under-inspiration

The above criteria were added to existing published criteria which were used to create a quality assurance tick sheet (Appendix 1).

Criteria were categorised according to those that are radiographer-related and those that are patient-related. A clear definition of an optimal outcome for each criterion has been defined, and a score of 0 allocated if observed, and 1 if not observed. An optimal

("perfect") radiograph is defined by an average cumulative score of less than 1 across all three readers. An average cumulative radiograph score greater than or equal to 1 is regarded as suboptimal i.e. not perfect. Failure to meet multiple criteria may result in the inability to interpret the radiograph with respect to the clinical scenario. A binary process of evaluation of whether there are errors or not (i.e. yes or no) on a radiograph is more of clinical interest, as it informs whether the interpretation is reliable or not. However, from a quality improvement perspective, where methods need to be directed at improving specific areas of a film, it's important to know which errors are present as well as the quantity of each individual error. Our tick-sheet additionally allows the individual errors to be summated into an overall QA score for a department, which may be a more useful overall indicator than the binary "error/no error" evaluation i.e. it is insufficient to simply know that the radiograph is not perfect – in order to make it perfect, the details of the errors present needs to be known. For example, a department's performance may have improved with regard to correcting a particular error, yet the binary process of evaluation may not reflect the improvement due to the presence of another error. Refer to Table 3.1 below for list of criteria and optimal outcomes.

Table 3.1 Quality assurance criteria

Radiograph Category	Criterion	Criterion description	Optimal criterion outcome	Optimal criterion score
Radiographer related	Annotation: Patient identifiers	Absence of patient identifiers	Identification details of patient and institution, date and time, in a location which does not obscure the image (these were replaced by a code for this study)	0
	Annotation: Side marker	Absence of side marker (left/right)	Side marker present in a location which does not obscure the image	0
	Annotation: Static Artifact	Presence of static artifact	Lung fields must not be obscured by objects on patient e.g. jewellery, or by the patient's/assistant's body e.g. arm	0
	Exposure: over-exposed	Too dark - vessels in the periphery cannot be visualised	Vascular markings in peripheral lung fields are visualised AND soft tissue outlines of cardiac shadow, airways and hilar regions are visualised. (Fig 2.2)	0
	Exposure: under-exposed	Too light/white - vessels cannot be visualised through the heart or thymus	Central vascular markings are visualised through heart and thymus AND soft tissue outlines of cardiac shadow, airways and hilar regions are visualised. (Fig 2.2)	0
	Field of view: Over-collimation	Over-collimation resulting in exclusion of part of the area of interest	Field of view must include entire lung fields, from lung apices to costophrenic angles (cranio-caudal), and from sternum to the posterior ribs (AP) (Fig 2.3)	0
	Field of view: Under-collimation	Under-collimation resulting in inclusion of anatomy which need not be imaged	Propose that not more than 2 extra-thoracic vertebral bodies be included both below the diaphragm and above the clavicles (Fig 3.1)	0
Patient-Related factors	Left-to-right rotation	Rotation due to patient turning toward left or right	Left & right posterior ribs must be superimposed as closely as possible (not more than a sliver of lucency visualised between them posterior to the vertebral bodies) AND costophrenic angles must be superimposed (Fig 2.5)	0
	Side-to-side rotation	Rotation due to patient tilting	Right hemidiaphragm must always be visualised superior to the left hemidiaphragm. Normal variations in distance between left & right hemidiaphragms prevent use as a measure of tilting (Fig 2.5)	0
	Under-inspiration	Inadequate inflation of lungs due to inspiration	Currently no documented method of assessing lung volume in a paediatric lateral CXR. Propose that at least 5 vertebral bodies should be visualised between an extrapolated line from the cardiophrenic angle through the carina and the highest diaphragm (Fig 3.2)	0
	Patient positioning	Poor positioning of patient's body	Field of view not obscured by body part e.g. arm/chin (Fig 2.6)	0
	Motion artifact	Blurry bone cortices	Cortical outlines of bones must be well-defined (Fig 2.6)	0
			Average cumulative score for Optimal "Perfect" radiograph	**<1**

In the ticksheet, criteria were accompanied by graphic representations and objective measurements where appropriate, to aid the reader. These example images were collected from clinical reporting images that were deemed to demonstrate a radiographic quality error adequately and clearly in the same age group. They were anonymised and placed alongside the descriptor for each criterion.

A pilot review of the tick sheet was performed by the primary investigator and a consultant radiologist not involved in the study, by applying it to a set of 20 lateral chest radiographs from those excluded from the main study. This pilot was carried out after an initial pilot study testing the definitions of the criteria “under-inspired” and “under-collimation”. Once the tick sheet was validated and corrected via the pilot review, it was applied to the study population.

Evaluation of radiographs was performed by three readers: a paediatric radiology consultant (JN), a non-paediatric radiology consultant (LC) and a radiology registrar (the primary investigator, LR). The 2 consultant readers were blinded to each other and to the aims of the study. The radiographs were viewed on Apple computers using Preview software available for image viewing on all Apple computers. This allowed for zooming and density manipulation but not for measurement.

The readers completed the designed QA tick-sheet for each radiograph in the sample. This was performed using REDCap, a web application for creating and managing online databases and surveys (powered by Vanderbilt University in and hosted at multiple partner universities worldwide). Readers were not permitted access to each other’s

results. The readers were given instructions as a group on how to complete the forms prior to distribution of the images for review. The QA tick-sheet provides detailed mechanisms of assessing each aspect of quality, relating to specified anatomical landmarks.

Due to the volume of radiographs, the readings were completed over 4-5 sessions.

3.5. Data collection

The developed quality assurance tick-sheet served as the basis for the data collection sheet, via the REDCap programme. Data was extracted from REDCap into an Excel spreadsheet, and analysed.

Each criterion on the tick-sheet that was not met (i.e. an error) was assigned a score of 1 to quantify errors and yield a cumulative score for each radiograph. In order to determine if a radiograph was optimal vs suboptimal, the average score across the 3 readers was used.

The criteria were divided into categories, as discussed in section 3.3 above.

3.6. Reliability and validity

Reliability of results has been addressed by using 3 readers blinded to each other. The criteria used in the tick-sheet were extracted from existing guidelines/criteria established via the literature search. The entire tick-sheet was validated via a pilot review by testing

its use on 20 paediatric lateral chest radiographs by 2 different readers and amending where necessary, prior to implementation by our readers.

3.7. Data analysis and statistics

The individual points (errors) and total scores were transferred from REDCap to Excel spread sheets for analysis in order to meet our study objectives. Categorical variables were summarised by frequency and percentage tabulation, and illustrated by means of bar charts. Continuous variables were summarised by the mean and standard deviation for normally distributed data, or median and interquartile range for data not normally distributed.

Inter-rater agreement (for the three readers) for each of the individual criteria was determined by Fleiss' kappa for multiple raters and a binary outcome. Inter-rater bias was assessed using Cochran's Q-statistic.

Agreement between different pairs of readers was assessed by the overall agreement, Cohen's kappa and Bowker's test of symmetry. The magnitude of the estimated kappa values was interpreted according to Landis and Koch. Inter-rater reliability for the QA score was determined by the intraclass correlation coefficient (ICC).

Data analysis was carried out using SAS 9.4. The 5% significance level was used throughout. In other words, p-values <0.05 indicated significant results.

3.8. Ethics

This study was a secondary analysis of an existing database of radiographs performed for clinical reasons. Hence, no unnecessary radiation was incurred by any individual. Ethical approval to conduct this study was obtained from the Human Research Ethics Committees (HREC) at the University of Witwatersrand, Ref M140344 (Appendix 2), and the University of Cape Town (Ref 783/2014) (Appendices 3 & 4). Permission to use the existing database of radiographs has been granted by the principal investigator of the respective study, Professor Heather Zar, as well as the CEO of Red Cross War Memorial Hospital (Appendices 5 & 6). Ethics clearance for Professor Zar's study, in which this study is nested, was obtained from the HREC of the University of Cape Town (Ref 045/2008). She has also received permission for use of the data from the CEO of Red Cross War Memorial Children's Hospital. Patients' parents/guardians were consented as part of the larger initial study. All images were reviewed anonymously (no names are present on the radiographs) using a coding system with a secured decipher. Readers consented in writing to participate in the reviewing of radiographs.

3.9. Data safety

All radiographs were anonymised using a numerical code prior to being sent to us from the original study. Data was collected and stored anonymously. Access to this data was only be available to the primary investigator, supervisors and statistician.

3.10. Budget

Expenses were borne by the primary investigator

4. Results

The sample was subjected to two separate sets of data analysis. The first set is based on averages, and the second set is based on majority decision methodology.

4.1 Average data analysis

The analysis below is based on average data. Averages for each criterion were calculated based on number of errors across all 3 readers (3 X 300 radiographs = 900 radiographs) e.g. in Figure 4.1 below, left-to-right rotation errors were the most common and calculated as 54.3% (489 errors out of 900 radiographs). Radiographs can present with more than one error.

The average percentage of radiographs, which demonstrated each error, is reflected in Figure 4.1

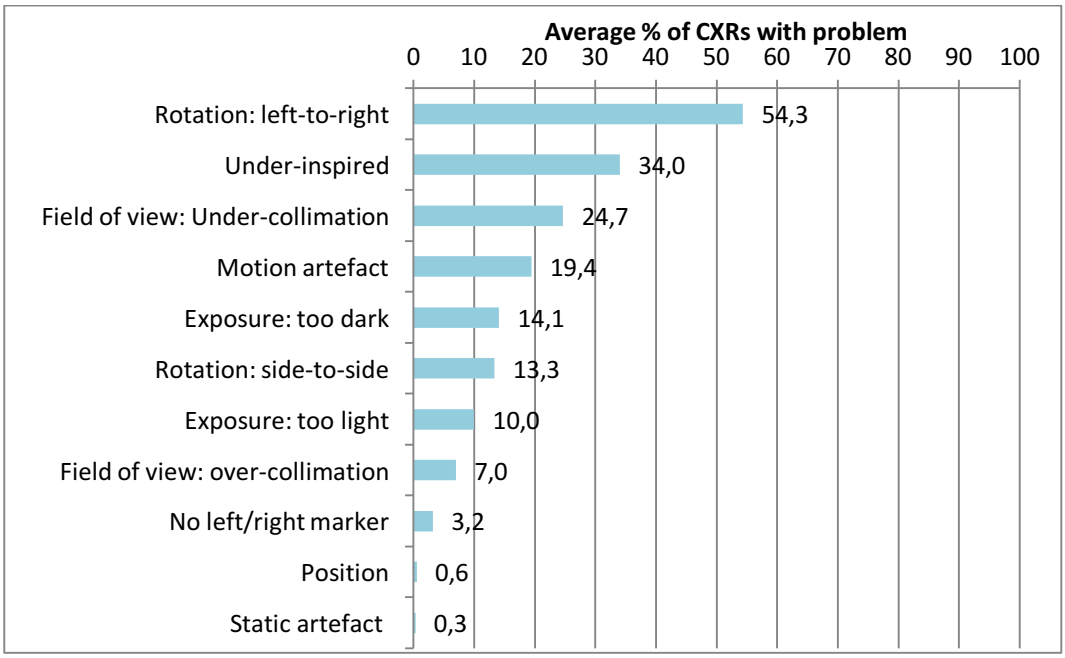


Figure 4.1 Average percentage of radiographs which demonstrated each error

Left-to-right rotation was the most common error (on average, 54.3% of the radiographs demonstrated this error), followed by under-inspiration (34%) and under-collimation (24.7%). The least prevalent error was the presence of static artifact (0.3%), followed by patient position (0.6%). No strong correlation between errors was found.

The percentage or errors due to radiographer-related and patient-related criteria are reflected in Figure 4.2 below, noting that more than one type of error was possible in each radiograph.

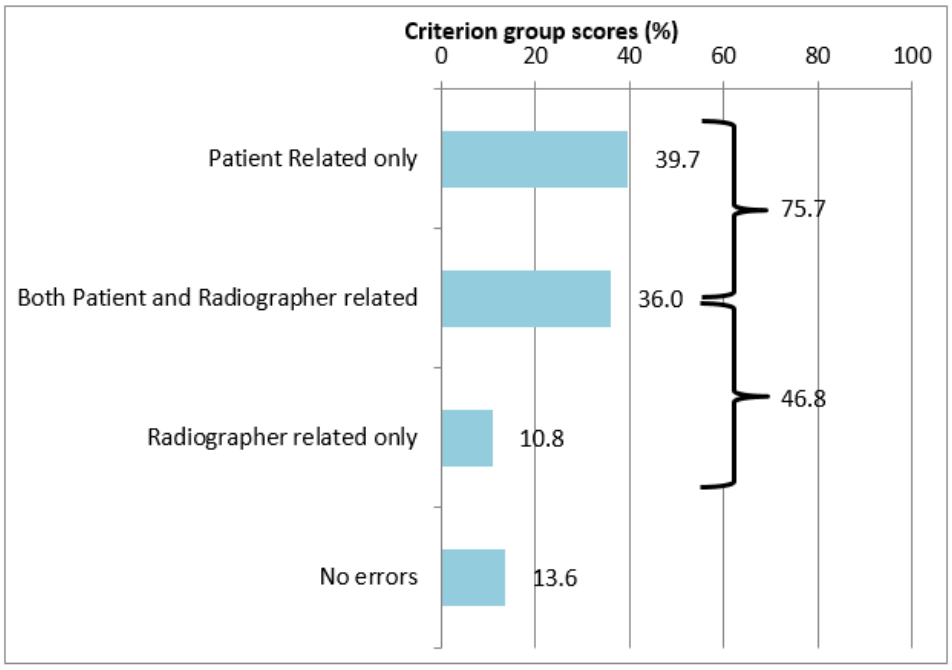


Figure 4.2 Criterion group scores

75.7% of radiographs demonstrated patient-related errors (with 39.7% having only patient-related errors, and 36% having both patient- and radiographer-related errors). 46.8% of the radiographs demonstrated radiographer-related errors (with 10.8% having only radiographer-related errors, and 36% having both radiographer- and patient-related errors). 13.6% demonstrated no errors.

The overall Quality Assurance score for the radiographs was calculated as an average across the 3 readers and is demonstrated in Figure 4.3. An average score of less than 1 is defined as an optimal radiograph. The theoretical range for this score is 0-11.

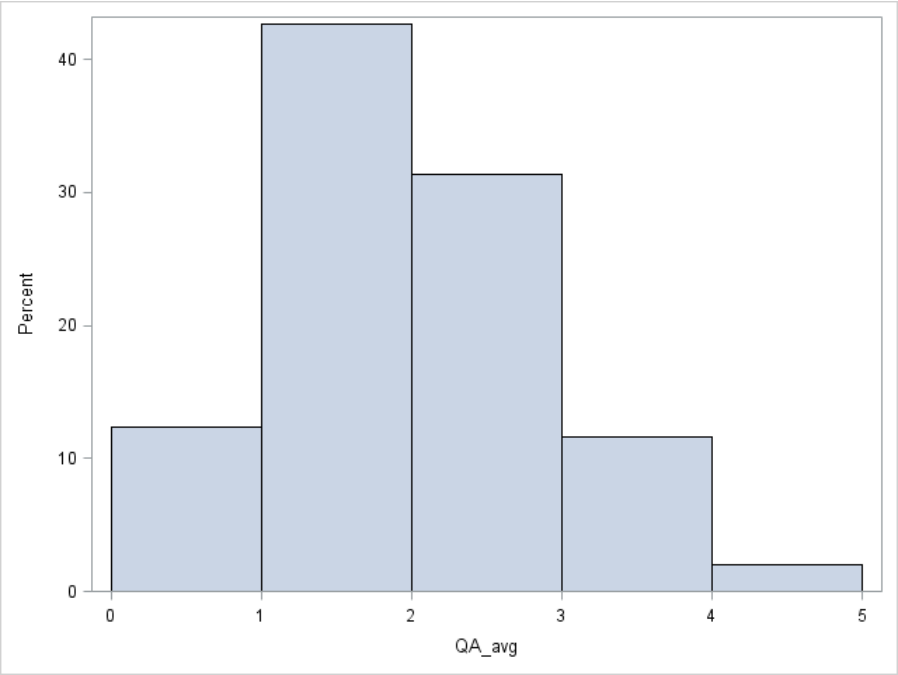


Figure 4.3 Overall average Quality Assurance score

12.3% of the radiographs had an average QA score less than 1. The overall average score was 1,8. The minimum average number of errors for a radiograph was 0,9, while the maximum average number was 4,7 out of a possible 11.

4.2 Majority decision analysis

Figure 4.4 shows the percentage of radiographs which did not meet each criterion (i.e. percentage of errors present), based on the majority decision data. Majority decision measures the prevalence of each error, whereby the error is deemed present if 2 or more out of the 3 readers detect it.

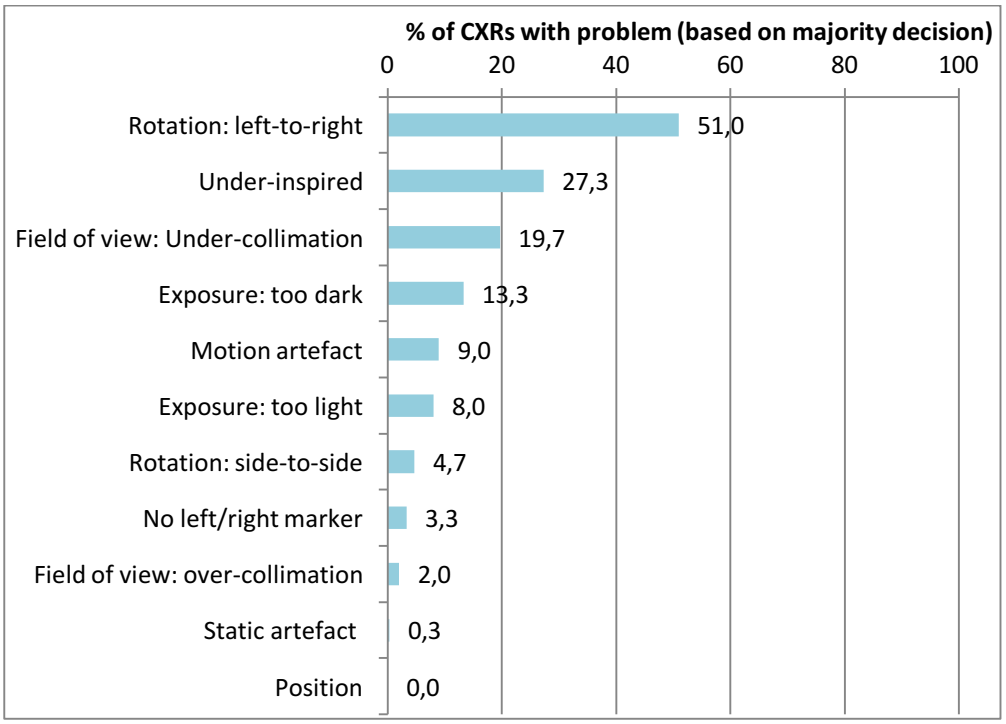


Figure 4.4 Percentage of radiographs which demonstrated each error, for majority decision

The most common error based on majority decision was still left-to-right rotation (51%), followed by under-inspiration (27.3%) and under-collimation (19.7%). The least prevalent errors were position (0%), static artifact (0,3%), and over-collimation (2%).

The percentage of errors due to radiographer-related and patient-related criteria are reflected in Figure 4.5 below, noting that more than one type of error was possible in each radiograph.

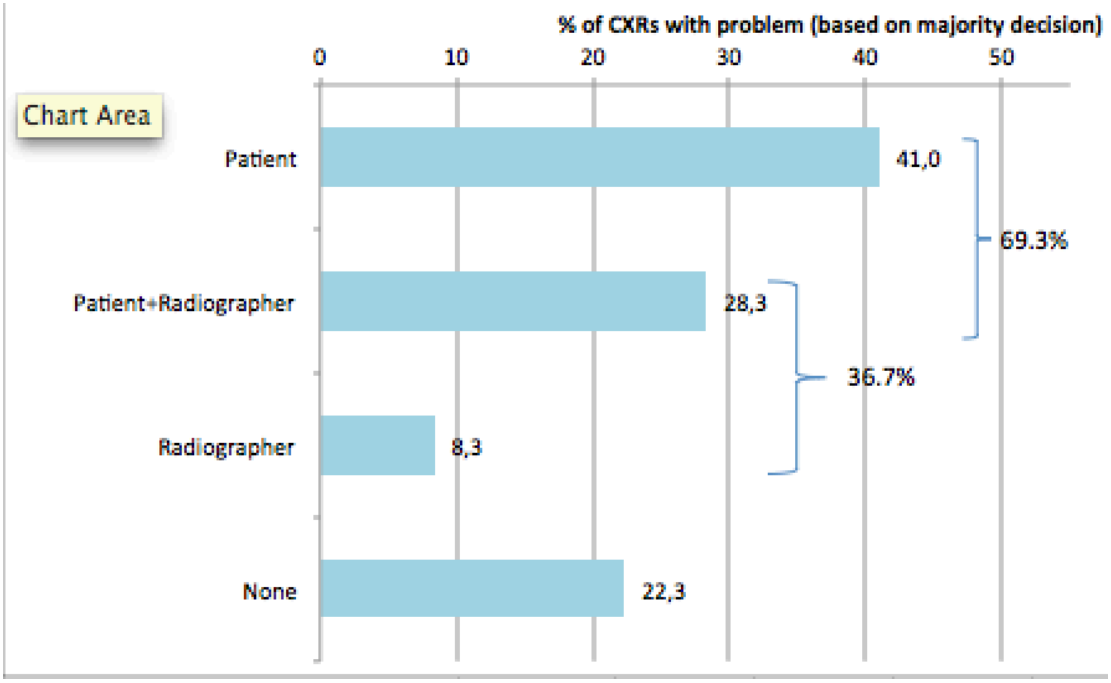


Figure 4.5 Criterion group scores for majority decision

69.3% of radiographs demonstrated patient-related errors (with 41% having only patient-related errors, and 28% having both patient- and radiographer-related errors). 36.7% of the radiographs demonstrated radiographer-related errors (with 8.3% having only radiographer-related errors, and 28% having both radiographer- and patient-related errors). 22.3% demonstrated no errors.

The overall Quality Assurance score for the radiographs was also calculated based on majority decision and is demonstrated in Figure 4.6. An average score of less than 1 remains the definition of an optimal radiograph, with the theoretical range for this score being 0-11.

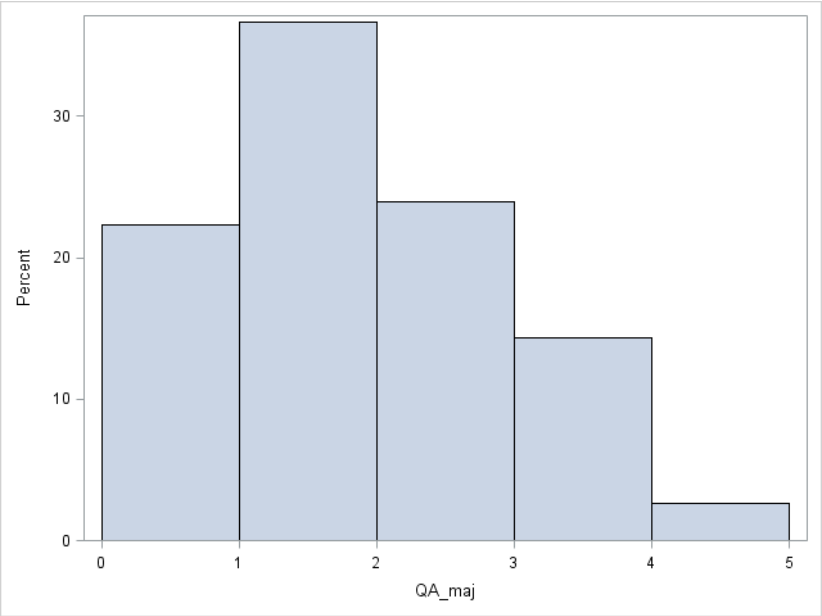


Figure 4.6 Overall average Quality Assurance score for majority decision

22.3% of the radiographs had an average QA score less than 1. The overall average score was 1. The minimum average number of errors for a radiograph was 0, while the maximum average number was 5 out of a possible 11.

Table 4.1 shows for each reader, the percentage of radiographs, which did not meet each criterion, together with the majority decision data.

Table 4.1 Percentage of radiographs which demonstrated each error

Criterion	% of X-rays which did not meet the criterion			prevalence (majority decision) (%)	Inter-rater reliability concern
	Rater 1	Rater 2	Rater 3		
No side marker	3,00	2,67	4,00	3,33	No
Static artifact	0,33	0,00	0,67	0,33	No
Exposure: too dark	20,33	14,00	8,00	13,33	Yes
Exposure: too light	18,33	9,00	2,67	8,00	Yes
Field of view: over-collimation	2,33	0,67	18,00	2,00	Yes
Field of view: Under-collimation	21,33	36,33	16,33	19,67	Yes
Rotation: left-to-right	74,00	43,00	46,00	51,00	Yes
Rotation: side-to-side	30,67	7,33	2,00	4,67	Yes
Under-inspired	64,00	21,00	17,00	27,33	Yes
Position	0,33	0,67	0,67	0,00	No
Motion artifact	15,67	3,00	39,67	9,00	Yes

Five criteria demonstrate a prevalence of <5%: Position (0%), Static artifact (0.3%), Field of view: over-collimation (2%), No side marker (3.3%), and Rotation: side-to-side (4.7%). There was no inter-rater reliability concern with respect to No side marker, Static artifact and Position i.e. good agreement amongst all readers. The criteria marked as inter-rater reliability concern demonstrate poor consistency across the readers' evaluations.

The raw agreement (i.e. all three scored 'yes' or all three scored 'no') for each of the criteria was also evaluated, together with the kappa chance-corrected measure of agreement (and its interpretation), and the p-value for the Cochran's Q-statistic (which measures inter-rater bias) are reflected in Table 4.2

Table 4.2 Inter-rater agreement statistics

Criterion	prevalence (majority decision) (%)	raw agreement (%)	kappa	interpretation of kappa	p-value for Cochrane's Q
No side marker	3.33	97.7	0.751	substantial agreement	0.16
Static artifact	0.33	99.3	0.331	fair agreement	0.22
Exposure: too dark	13.33	82.3	0.514	moderate agreement	**<0.0001**
Exposure: too light	8.00	80.0	0.259	fair agreement	**<0.0001**
Field of view: over-collimation	2.00	81.7	0.061	slight agreement	**<0.0001**
Field of view: Under-collimation	19.67	65.0	0.372	fair agreement	**<0.0001**
Rotation: left-to-right	51.00	56.0	0.409	moderate agreement	**<0.0001**
Rotation: side-to-side	4.67	64.7	-0.019	less than chance agreement	**<0.0001**
Under-inspired	27.33	38.7	0.089	slight agreement	**<0.0001**
Position	0.00	98.3	-0.0006	less than chance agreement	0.82
Motion artifact	9.00	53.3	0.007	slight agreement	**<0.0001**

The side marker, static artefact and patient position criteria are rare, have good raw agreement and no significant inter-rater bias, but low values for kappa. These low values for kappa result from the low prevalence of the criterion, and are not a cause for concern (kappa does not perform well at low prevalence).

The remaining 8 criteria have poor raw agreement, low kappa, and significant inter-rater bias.

4.3 Inter-rater reliability

In order to investigate the findings for the eight problematic criteria, agreement and bias between each pair of raters is assessed, to determine if there are reasons for the low kappa and significant bias between the three raters. The comparisons are presented below, in tables 4.3 to 4.10, for each of the problematic criteria.

Table 4.3 Inter-rater agreement regarding Exposure: too dark

Exposure: too dark	raw agreement (%)	kappa	interpretation of kappa	p-value for Bowker's test of symmetry
Rater 1 vs. 3	90,3	0,663	substantial agreement	0,0004
Rater 1 vs. 2	84,3	0,375	fair agreement	<0.0001
Rater 3 vs. 2	90,0	0,494	moderate agreement	0,0010

Table 4.4 Inter-rater agreement regarding Exposure: too light

Exposure: too light	raw agreement (%)	kappa	interpretation of kappa	p-value for Bowker's test of symmetry
Rater 1 vs. 3	86,7	0,445	moderate agreement	<0.0001
Rater 1 vs. 2	81,7	0,084	slight agreement	<0.0001
Rater 3 vs. 2	91,7	0,255	fair agreement	0,0001

Table 4.5 Inter-rater agreement regarding Field of view: over-collimation

Field of view: over-collimation	raw agreement (%)	kappa	interpretation of kappa	p-value for Bowker's test of symmetry
Rater 1 vs. 3	97,7	0,214	fair agreement	0,16
Rater 1 vs. 2	83,0	0,128	slight agreement	<0.0001
Rater 3 vs. 2	82,7	0,059	slight agreement	<0.0001

Table 4.6 Inter-rater agreement regarding Field of view: under-collimation

Field of view: under-collimation	raw agreement (%)	kappa	interpretation of kappa	p-value for Bowker's test of symmetry
Rater 1 vs. 3	72,3	0,344	fair agreement	<0.0001
Rater 1 vs. 2	83,0	0,446	fair agreement	0,036
Rater 3 vs. 2	74,7	0,379	fair agreement	<0.0001

Table 4.7 Inter-rater agreement regarding Rotation: left-to-right

Rotation: left-to-right	raw agreement (%)	kappa	interpretation of kappa	p-value for Bowker's test of symmetry
Rater 1 vs. 3	63,0	0,307	fair agreement	<0.0001
Rater 1 vs. 2	66,7	0,358	fair agreement	<0.0001
Rater 3 vs. 2	82,3	0,643	substantial agreement	0,22

Table 4.8 Inter-rater agreement regarding Rotation: side-to-side

Rotation: side-to-side	raw agreement (%)	kappa	interpretation of kappa	p-value for Bowker's test of symmetry
Rater 1 vs. 3	70,0	0,105	slight agreement	<0.0001
Rater 1 vs. 2	68,7	0,003	slight agreement	<0.0001
Rater 3 vs. 2	90,7	-0,032	less than chance agreement	0,0025

Table 4.9 Inter-rater agreement regarding Under-inspired

Under-inspired	raw agreement (%)	kappa	interpretation of kappa	p-value for Bowker's test of symmetry
Rater 1 vs. 3	52,3	0,180	slight agreement	<0.0001
Rater 1 vs. 2	48,3	0,128	slight agreement	<0.0001
Rater 3 vs. 2	76,7	0,244	fair agreement	0,15

Table 4.10 Inter-rater agreement regarding Motion artifact

Motion artifact	raw agreement (%)	kappa	interpretation of kappa	p-value for Bowker's test of symmetry
Rater 1 vs. 3	86,7	0,248	slight agreement	<0.0001
Rater 1 vs. 2	60,0	0,068	slight agreement	<0.0001
Rater 3 vs. 2	60,0	0,007	slight agreement	<0.0001

With regard to Exposure: too dark, Exposure: too light, Field of view: under-collimation and Motion artifact (Tables 4.3, 4.4, 4.6 and 4.10), it was found that no two raters agree well. No two raters agree well regarding Rotation: side-to-side Table 4.8), however, this error is rare. Regarding Field of view: over-collimation (Table 4.5), rater 2 is the outlier, whereas in Rotation: left-to-right and Under-inspired (Tables 4.4.7 and 4.9), rater 1 is the outlier.

The inter-rater reliability for the overall quality assurance score data are summarised below in Table 4.11:

Table 4.11 Overall quality assurance score

Criterion	Quality score: median (IQR) (range)			
	Reader 1	Reader 2	Reader 3	Majority decision
Quality score	2 (2-3) (0-6)	1 (1-2) (0-5)	1 (1-2) (0-5)	1 (1-2) (0-5)

Based on the data above, Reader 1's radiograph evaluations appear marginally different to the rest.

The overall intraclass correlation coefficient (ICC) was 0.394. The ICC's for each pair of readers is tabulated below in Table 4.12:

Table 4.12 Inter-rater chance corrected kappa

Quality score	**ICC**
Rater 1 vs. 3	0.469
Rater 1 vs. 2	0.232
Rater 3 vs. 2	0.504

This data demonstrates that no two raters have a sufficiently high ICC.

5. Discussion

Since no tool to assess the quality of paediatric lateral chest radiographs existed in the literature, it was seen as an opportunity to create one, in order to assess our own standard. Considering that this comprehensive tool (i.e. tick-sheet) would be the first of its kind, research into texts regarding guidelines on how to actually perform lateral chest radiographs and their acceptable parameters, was necessary. Some parameters which have a crucial influence on quality had not before been defined (under-inspiration, under-collimation), and we needed to formulate this. Thus, rather than just ascertain common radiographic errors, this study evaluates our proposed interpretation of these parameters, as well as the tick-sheet as a complete tool.

There is no doubt that this tool will be of similar benefit elsewhere, as lateral chest radiographs are still recommended and performed in the paediatric setting – the WHO clearly advises that "good-quality chest radiographs (including **lateral** view, if and where possible) are **essential** for proper evaluation" of paediatric PTB (4). The pandemic of PTB is such that the above recommendation necessitates regular use of paediatric lateral chest radiographs. Similar to a frontal radiograph, interpretation of the lateral relies on adequate quality. In fact, one of the basic prinicples taught in radiological practice and even general medical practice, is that we assess quality before interpreting an image. This is not fully possible with regard to lateral chest radiographs if these boundaries have not adequately been delineated.

5.1 Results in context

Of the 300 lateral radiographs evaluated using our newly devised quality assurance tick-sheet, only 67 (22.3%) would be considered optimal i.e. had an average score of less than 1 based on majority decision, and 182 (60.7%) demonstrated an average score of 1-2 (Figure 4.6). The mean average score was 1. The maximum average score was 5 out of a possible 11, with 2,6% having a score of 4 to 5.

Regarding the high percentage of suboptimal radiographs, it is important to determine the most common contributing errors, in order to improve this rate. Figure 4.5 depicts that the majority of errors fell within the patient-related group, accounting for 69.3% (based on majority decision) - these are more difficult to improve in children because they don't follow instructions like adults. However, radiographer-related errors were also significant, accounting for 36.7%, indicating that improvements can be made within the imaging department itself.

The most prevalent errors within the patient-related criteria based on majority decision, were left-to-right rotation (51%), under-inspired lungs (27.3%) and the presence of motion artifact (9%). The left-to-right rotation error was also the most prevalent of all 11 errors. Although these are classified as patient-related criteria, the radiographer can influence the limitation of these errors by using paediatric radiology techniques of distraction, immobilisation and through experience. Left-to-right rotation and the presence of motion artifact may be due to inadequate direction given to assistants when

positioning the patients. However, infants and young children may be anxious or afraid, and are commonly unable to stay still during such studies. This may be a difficult problem to overcome even with the assistance of family members and assistants (with adequate radiation protection), and soothing the patient prior to and during the examination. Getting babies to sleep prior to obtaining the radiograph may also assist. Where under-inspiration is due to underlying respiratory disease, the radiographer should indicate that the best possible inspiratory effort was achieved. Not only will this prevent unnecessary repeat studies, but all also assist the radiologist/clinician in assessing the severity of disease.

The largest contributing radiographer-related errors based on majority decision were under-collimation (19.7%) and exposure: too dark (13.3%). Since both collimation and exposure settings should be adjusted for each individual patient, these errors should rarely occur. Regular adjustment of these parameters is important in paediatric imaging as the size of patient may differ greatly from study to study, and this will affect the quality of the radiograph produced. Thus this tick-sheet will fulfil a purpose of identifying these errors, thus assisting the radiographers to improve their practice.

Table 5.1 compares the common errors elicited in the current study to other studies in the literature. Alt et al used both quantitative and qualitative parameters to assess conventional and digital chest radiographs from both paediatric and non-paediatric specialised radiology units. This study evaluated both frontal and lateral paediatric chest radiographs (16). While a comprehensive study, the qualitative parameters (which were the majority) used to assess the images, employed a subjective score out of 5, as opposed

to our “presence/absence” approach. Results were not presented for frontal and lateral radiographs separately, which did not allow for direct comparison with our study. However, Alt et al found that centering /positioning and collimation errors were most concerning (16).

Gallet et al’s study, which was also carried out in a paediatric hospital radiology department and had a comparable study duration and number of radiographs, found over-exposure and absent/incorrect markers to be the most common errors (6). However, this study was related to general radiography, and not limited to lateral chest radiographs. Loovere et al found that under-collimation was the most common error in a neonatal ICU setting, with regard to both chest and abdominal radiographs (assumed to be mobile studies) (17). Hlabangana and Andronikou evaluated the quality of frontal paediatric chest radiographs before and after implementing an intervention by means of posters and a crash course (18). In this study, the radiographs were also evaluated via a tick-sheet, and poor collimation was found to be the most common error both before and after the intervention (18).

Our study compares well with the above studies. While we found left-to-right rotation to be the most common error overall, the most common radiographer-related errors were also under-collimation and over-exposure. The current study found that under-inspiration was the second most common error, however the comparison studies did not include inspiration as a marker of quality.

Table 5.1 Comparison of three studies regarding common quality assurance errors of paediatric radiographs (6; 7; 17; 18)

	Gallet et al (1998)	Alt et al (2002)	Loovere et al (2008)	Hlabangana, Andronikou (2015)	Current study
Population	Paediatric hospital	Paediatric nephroblasto-ma study (Paediatric & non-paediatric radiology departments)	Neonatal ICU (paediatric radiology dept. not specified)	Hospital (paediatric radiology dept.)	Paediatric hospital
Study duration	5 years	2,5 months	1 month	10 months	5 years
Type of radiographs	General paediatric radiography	Paediatric chest radiographs	Mobile neonatal chest & abdominal radiographs	Paediatric AP chest radiographs	Paediatric lateral chest radiographs
No. of radiographs	491	351 (217 frontal, 134 lateral)	132	438	300
Method of assessment	Comment card	Unknown tool	Unknown tool	Tick-sheet	Tick-sheet
Common errors	1. Over-exposure (24%) 2. Incorrect/ absent markers (22%) 3. Under-exposure (8%) 4. Patient positioning (8%)	1. Centering/ positioning 2. Collimation	1. Under-collimation (98%) 2. Static artifact (39%) 3. Rotation (23%)	1. Poor collimation (16%) 2. Kyphotic/ lordotic views (14.7%) 3. Rotation (12.9%)	1. Left-to-right rotation (54%) 2. Under-inspiration (34%) 3. Under-collimation (25%)

While the principles regarding quality assessment are similar across these studies, there is no comparison study based solely on paediatric lateral chest radiographs. Only two of the four comparison studies included lateral chest radiographs, however a breakdown of the results with regard to type of radiographs assessed, was not provided, and no specific

parameters were set for lateral radiographs (6; 16). This infers that prior to our study, there was no verified method of focussed assessment of the quality of paediatric lateral chest radiographs.

Concerning development of the tick-sheet, the reliability of each criterion requires evaluation. As there is no pre-existing tick-sheet similar to ours, there is no pre-existing standard against which we can make a comparison. As a result, the inter-rater agreement forms the marker of reliability. As depicted in table 4.2, there was good agreement amongst all readers for 3 criteria: Side marker, Static artifact, and Position. This indicates that these criteria are unquestionably well understood, and need no further elaboration.

Section 4.3 indicates that one of the readers is an outlier in terms of agreement for 4 of the criteria (Field of view: over-collimation, Rotation: left-to-right, Under-inspiration and Rotation: side-to-side). However, for these criteria, there are still two readers who agree that the error is present (also recalling that the readers were blinded to each other during the study, removing the bias of influence). That the outliers are different readers for some of the criteria, is of no consequence in terms of our definition of the majority decision (only 2 readers need agree). Thus, these criteria can also be regarded as being fairly well interpreted. This is particularly important, as the parameters for the Under-inspired criterion were defined by us in the creation of the tick-sheet, with no previously documented method of assessing lung volumes on a lateral chest radiograph. This infers sufficient illustration of the criterion in the tick-sheet.

4 criteria were identified in which there was no significant inter-reader agreement (Exposure: too dark, Exposure: too light, Field of view: under-collimation, and Motion artifact). This implies that the comprehension of these criteria via the tick-sheet is poor. The parameters of the Field of view: under-collimation criterion was defined by us. Thus the results indicate that either these parameters have not been clearly defined, that the readers did not receive adequate training regarding this criterion, or that these criteria are just too subjective. The remaining three criteria have been previously defined in the literature (suggesting that their validity has already been proven). The assumption then, is that the training regarding these criteria was not adequate, or that they too, are subjective and will remain subjective. Consequently, it is evident that more comprehensive training is required prior to the implementation of the tick-sheet at an institution or that more objective measures are needed, and may require a group workshop, with examples of what does and does not constitute the error. A user-guide in print or media form may be required for training/refreshing future staff at an institution.

5.2 Current applications

The aim of this study was to design and put into use a tick-sheet for quality assessment of lateral radiographs so as to determine reliability of the quality criteria and the frequency of specific radiographic errors in children. For the most common errors identified in our environment (rotation: left-to-right, under-inspiration and under-collimation), there are improvement measures, which can be implemented to reduce the frequency of these. In addition to improving on radiographic skills for the radiographer dependent errors, the common patient-related errors can be brought to attention of the department so that

radiographers can work together with assistants and family members to achieve a good quality radiograph. The intended result is that of improved identification of both presence and absence of pathology, as well as a reduction in the need for repeat radiographs due to poor technique and thus reduction in radiation exposure to patients. This, in turn, has important time implications, allowing for a more efficient service from both radiographers and radiologists, as well as cost implications for the department and institution.

5.3 Limitations of study

One of the most evident limitations of this study was the element of subjectivity present in evaluation of the radiographs by each reader and resultant poor inter-rater agreement for certain parameters, despite having created definitions for each criterion. Individual factors such as varying levels of expertise and experience, time constraints and degree of focus may have impacted these results. Ideally, the readers should be sub-specialist paediatric-trained radiologists. However, this is a relatively new sub-speciality with few qualified paediatric radiologists in the country and in reality it is general radiologists and non-radiologist clinicians who interpret the majority of radiographs in South Africa. Unfortunately, the scope of this study did not allow for evaluation of which errors/number of errors affected the ability to interpret the radiograph. Although one would like to achieve the optimal ("perfect") radiograph, the ultimate goal is a radiograph which can be accurately interpreted. Factors within our control include improved definition of each criterion and comprehensive group training on use of the tick-sheet prior to implementation at an institution. Radiology is a subjective field, but in order for

this tick-sheet to fulfil its desired purpose in creating a standard, the problematic criteria need further refinement before widespread use.

No analysis of rejected films was done. Including these films would have highlighted an even higher and perhaps more accurate error rate. However, it should not impact the outcomes of this study as the radiographer has deemed the film unusable and has not submitted to the radiologist for reporting.

5.4 Future applications

The results demonstrate that there are areas, which can be improved upon within the imaging department in order to obtain a better quality of paediatric lateral chest radiographs. As a result of this study, interventions aimed at achieving this can form the basis of future studies, with comparison of the quality of the radiographs before and after the interventions. The designed tick-sheet offers a solution for data collections and scoring the findings for such interventions.

The results also show that there areas in the tick-sheet itself which can be improved upon. The poor inter-rater agreement implies that these particular criteria need to be further refined and retested, before the tick-sheet can be rolled out for widespread use. This is somewhat expected for a tool which is only in its infant stages of development. Nonetheless, of the two criteria which were defined by our study, one of them (Under-inspiration) demonstrates fair inter-rater agreement, which is encouraging.

Once the other criterion defined by our study (Field of view: under-collimation) achieves further clarity, these two components will form integral points in a comprehensive tick-sheet.

Once the snags of this tick-sheet have been resolved, employing it continually for paediatric lateral chest radiographs can form a simple, yet integral part of an on-going quality assurance programme within radiology departments, in order to maintain a high standard. Radiographers can be educated about the common errors and their impact on interpretation of the radiograph. Radiographers can also use the tick-sheet as a means of self-evaluation on a regular basis. In teaching institutions where there are student radiographers, this tool will assist in ensuring good technique from the start of their training. It can serve as a springboard from which radiographer-driven quality improvement initiatives are introduced. The tick sheet can also be printed as an educational poster in departments. Furthermore, detection of equipment-specific technical problems may be detected via repeat errors of the same kind from a particular machine.

Use of such a tick-sheet is practical in both South Africa and other low and middle income countries faced with the similar burden of childhood TB. The most common manifestation of paediatric respiratory TB is the presence of peri-hilar and peri-carinal lymphadenopathy (2; 19; 20). Smuts et al observed that a significant number of cases depicted lymphadenopathy on lateral chest radiographs only (not frontal radiographs), and paediatric TB diagnostic guidelines recommend lateral chest radiographs to assist with accurate localisation of lymph nodes (19; 21).

Another potential investigation arising from this study may be to determine which errors most affect the interpretation of paediatric lateral chest radiographs. The result may further streamline repeat studies due to technical errors. This is particularly relevant in a high TB burden environment such as ours, where lateral chest radiographs can provide vital diagnostic information in the paediatric setting.

In this study, a single centre was evaluated. Future research can involve comparison of the quality of paediatric lateral chest radiographs across multiple centres. Peripheral and central institutions, and in-patient vs out-patient radiographs can be compared. Such an undertaking can be replicated in other countries as well.

6. Conclusion

Achieving and maintaining a high standard of quality of radiographs requires active contribution by all parties involved, from the patients and their families, to the radiographers as well as the radiologists, so that both patient-related and radiographer-related errors can be kept to a minimum.

The most common errors identified in this study using the designed tick-sheet involved both patient-related (rotation left-to-right, under-inspiration) and radiographer-related (field of view: under-collimation) errors, similar to findings of other studies highlighted in the literature.

Every imaging department should strive to bring down the number of technical errors in these basic examinations, and our tick-sheet has the potential to represent a concise, cost-effective tool that can be easily applied in varying levels of health care institutions both countrywide and worldwide.

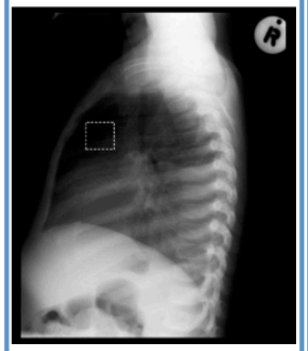
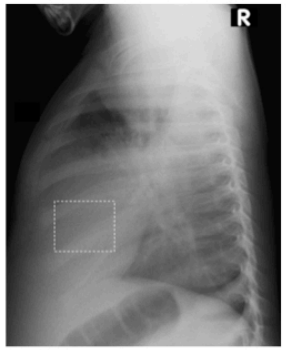
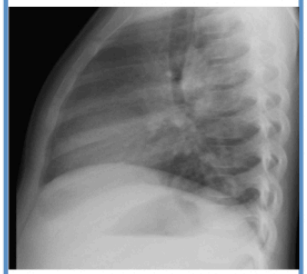
This study demonstrates that standardised criteria to assess the quality of paediatric lateral chest radiographs can be devised and collectively represented, with some criteria being very reliable. Having identified the criteria of the tick-sheet which have poor inter-rater agreement, efforts can now be made to revise them and employ further pre-training of individuals using it. This tool has the potential to foster precision and consistency if utilised to its full capabilities, and can be used as a springboard for further research both within single and across multiple health care institutions, with added benefit if it becomes a universal application. The intention is to reduce unnecessary repetition of radiographs (with radiation dose implications) resulting in the improved efficiency of patient management across all dimensions of safety, time, cost and quality.

Consequently, endeavours to refine the concerning areas of this promising tick-sheet are paramount, in order to raise the bar on overall quality of paediatric lateral chest radiographs.

Appendix 1. Tick-sheet

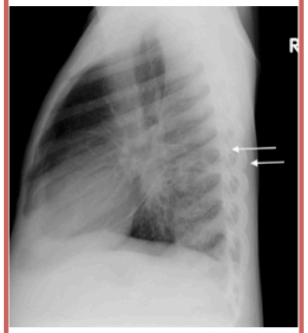
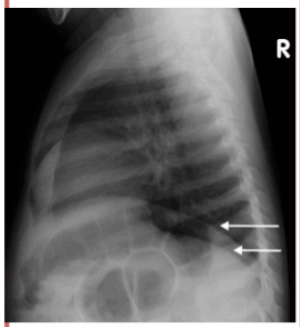
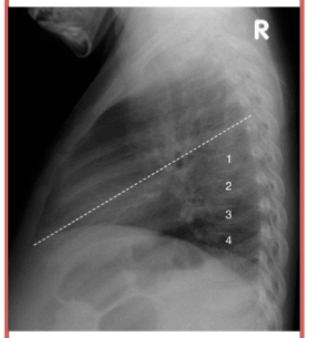
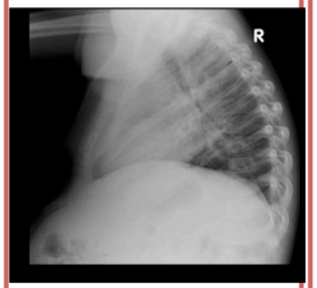
Case number: _____ **Score (total number of errors):**_____/12

Radiographer related

Exposure: Too Dark	Exposure: Too Light	Field of view: Cutoff	Field of view: Poor collimation	Patient identifiers not present
				
Unable to see vessels in the periphery	Unable to see vessels through the heart or thymus	Area of interest not included in image	Unrequired anatomy included in image. Not more than 2 vertebral bodies should be visible below diaphragm or above clavicles	

No left/right marker	Static artifact

Patient related

Rotation left/right	Rotation side to side	Under-inspired	Position	Motion Artifact
				
Posterior ribs not superimposed. Should not be more than a sliver of lucency between left and right posterior ribs, posterior to vertebral bodies.	i.e. tilting of body to left or right. On left lateral CXR, the left diaphragm is normally most inferior.	Less than 5 vertebral bodies between extrapolated line from cardiophrenic angle through carina, and highest hemidiaphragm	Body obscuring area of interest e.g. arms/ chin	Blurry cortices of bones

Appendix 2. Ethics clearance certificate, University of Witwatersrand

R14/49 Dr Leisha Rajkumar et al

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M140344

NAME: (Principal Investigator)	Dr Leisha Rajkumar et al
DEPARTMENT:	Radiology Charlotte Maxeke Johannesburg Academic Hospital
PROJECT TITLE:	Quality Assurance of Paediatric Lateral Chest Radiographs in the Investigation of Pulmonary TB
DATE CONSIDERED:	28/03/2014
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Prof S Andronikou
APPROVED BY:	Professor P Cleaton-Jones, Chairperson, HREC (Medical)
DATE OF APPROVAL:	11/03/2015

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Secretary in Room 10004, 10th floor, Senate House, University.
I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report**.

Principal Investigator Signature _____ Date _____

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix 3. Ethics clearance letter, University of Cape Town (UCT)

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E52-24 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6338 • **Facsimile** [021] 406 6411
Email: shuretta.thomas@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

31 October 2014

HREC REF: 783/2014

Prof S Andronikou
c/o Prof H Zar
Red Cross War Memorial Children's Hospital
ICH Building

Dear Prof Andronikou

PROJECT TITLE: QUALITY ASSURANCE OF PAEDIATRIC LATERAL CHEST RADIOGRAPHS IN THE INVESTIGATION OF PULMONARY TB (Sub-study linked to 045/2008) - Masters Candidate Dr L Rajkumar

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30th November 2015.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

Please quote the HREC REF in all your correspondence.

We acknowledge that the Masters student, Dr Leisha Rajkumar will also be involved in this study.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Yours sincerely

pp T Burgess

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP) and Declaration of Helsinki guidelines.
The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

Appendix 4. Ethics continuation clearance certificate (UCT)

HUMAN RESEARCH ETHICS COMMITTEE
19 AUG 2016
UNIVERSITY OF CAPE TOWN

UNIVERSITY OF CAPE TOWN

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

FHS016: Annual Progress Report / Renewal

HREC office use only (FWA00001637; IRB00001938) This serves as notification of annual approval, including any documentation described below.			
☑ Approved	Annual progress report	Approved until/next renewal date	30.8.2017
☐ Not approved	See attached comments		
Signature Chairperson of the HREC		Date Signed	19/8/16

Comments to PI from the HREC

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	12/08/16		
HREC REF Number	783/2014	Current Ethics Approval was granted until	30/11/2015
Protocol title	Quality assurance of paediatric lateral chest radiographs in the investigation of pulmonary TB		
Protocol number (if applicable)	N/A		
Are there any sub-studies linked to this study?	No		
If yes, could you please provide the HREC Ref's for all sub-studies? **Note:** A separate FHS016 must be submitted for each sub-study.			
Principal Investigator	Professor Savvas Andronikou		
Department / Office Internal Mail Address	docsav@mweb.co.za		

1.1 Does this protocol receive US Federal funding?	☐ Yes	☐ X No
1.2 If the study receives US Federal Funding, does the annual report require full committee approval?	☐ Yes	☐ X No
1.3 Has sponsorship of this study changed? If yes, please attach a revised summary of the budget.	☐ Yes	☐ X No

(Note: Please complete the Closure form (FHS010) if the study is completed within the approval period)

Appendix 5. Permission letter – Professor Zar

UNIVERSITY OF CAPE TOWN
DEPARTMENT OF PAEDIATRICS AND CHILD HEALTH
RED CROSS WAR MEMORIAL CHILDREN'S HOSPITAL
KLIPFONTEIN ROAD
RONDEBOSCH
7700

TEL: +27 21 658 5324
FAX: +27 21 689 1287

Professor V Mngomezulu
Head of Diagnostic Radiology Faculty of Health Sciences
University of Witwatersrand
Braamfontein

Dear Professor Mngomezulu

This is to confirm that I will be collaborating with and co-supervising (with Dr Savvas Andronikou) Dr Leisha Rajkumar on a clinical research project entitled "Quality Assurance of Lateral Chest Radiographs in Children (TB Imaging)".

The student will have full access to the radiological data and limited access to the clinical data from the study entitled "Diagnosis of TB in children – development of immunological and microbiological strategies" on which I am the Principal Investigator. I give this student permission to use the data for degree purposes. Provided the student undertakes all the necessary analysis and writing, the student will be the first author on the paper emanating from this analysis and the supervisor s will be the co-authors.

Yours sincerely,

Professor Heather Zar
Head of Department of Paediatrics and Child Health
Director of Paediatric Pulmonology
Director of the School of Child and Adolescent Health

19 August 2013



Appendix 6. Permission letter – CEO of Red Cross War Memorial Children's Hospital

Western Cape Government
Health

Dr R Mistry
Manager: Medical Services
Email: Roshni.Mistry@westerncape.gov.za
Tel: +27 21 658 5788 fax: +27 21 658 5166

Dr L Rajkumar
Red Cross War Memorial Children's Hospital

Dear Dr L Rajkumar

APPROVAL OF RESEARCH

PROJECT TITLE: QUALITY ASSURANCE OF PAEDIATRIC LATERAL CHEST RADIOGRAPHS IN THE INVESTIGATION OF PULMONARY TUBERCULOSIS.

We have the pleasure of informing you that approval is hereby granted to conduct the above-mentioned study at Red Cross War Memorial Children's Hospital.

Yours sincerely,

DR ROSHNI MISTRY
MANAGER: MEDICAL SERVICES
DATE: 03 MARCH 2015

7. References

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