
**EVALUATION OF THE EFFECTIVENESS OF IMPLEMENTATION OF THE PRACTICAL
APPROACH TO LUNG HEALTH (PALSA) IN THE FREE STATE
PROTOCOL**

Revised draft compiled by Bosielo Majara and on behalf of the PALSA group

EVALUATION OF THE EFFECTIVENESS OF IMPLEMENTATION OF PALSA IN THE FREE STATE PRIMARY CARE

Revised draft October 2002 – compiled by Bosielo Majara

1. BACKGROUND

Respiratory diseases constitute a large fraction of the main health problems in the world. Every year some 4.3 million people die of lower respiratory infections, 2.2 million die of chronic obstructive airway disease (COAD), and 1.9 million die of tuberculosis. Lower respiratory disease, COAD and TB together are responsible for 11% of all disability adjusted life years (DALYs) in the world.

Future projections of the global burden of disease predict that in developing countries respiratory diseases will occupy three of the top ten places by the year 2020¹. COPD will be ranked fourth, tuberculosis sixth, lower respiratory tract infections seventh and HIV tenth. In these countries, in particular sub-Saharan Africa, additional problems such as the rise of HIV/AIDS, tuberculosis, tobacco use and indoor air pollution have significant social and economic implications. Add to this the contribution made by acute respiratory infections, and opportunistic infections in retroviral positive individuals, it becomes evident that developing countries face a crisis of great magnitude. In South Africa, 28% of all patients who present to Primary Health Care facilities have respiratory complaints².

These and many other diseases place a considerable strain on already suffering healthcare systems in countries in the Sub-Saharan Africa, especially at primary health care level. Health practitioners are expected to fulfil a multipurpose function. They are expected to appropriately diagnose, treat and manage all patients who present to these first-level facilities with all kinds of illnesses. This is compounded by the lack of, or limited availability of standard operating procedures, resources and poor infrastructure.

Despite the enormity of the above-mentioned problems, few effective and cost-effective interventions exist that aim to manage respiratory diseases in a syndromic manner. Numerous intervention strategies have been developed that aim to improve the detection and treatment of various respiratory diseases, but these have been applicable mainly to developed countries. The absence of effective respiratory interventions has numerous consequences, such as the over-diagnosis of smear-negative tuberculosis especially in settings of high HIV prevalence, under-recognition of obstructive lung diseases and unnecessary prescription of antibiotics for viral respiratory tract diseases.

South African national and provincial departments of health have for some time attempted to implement a national tuberculosis programme in collaboration with the World Health Organisation. However, there are no equivalent programmes for obstructive lung disease or pneumonia, which are at least as common and important. Most importantly, from the point of view of clinicians, respiratory diseases present with a variety of signs and symptoms and must still be sorted into diagnostic categories before disease specific protocols can be followed. The current challenge is to apply past lessons to strategies that promote co-ordination and where appropriate, greater integration of activities in order to improve the prevention and management of adult lung disease. One example of such an integrated approach is the Integrated Management of Childhood Illnesses (IMCI).

The World Health Organisation (WHO)'s Communicable Disease Programme with the Non-Communicable Disease Programme and other relevant programmes have taken up this challenge by developing the Adult Lung Health Initiative (ALHI), now renamed the Practical Approach to Lung Health (PAL). This initiative aims to improve the effectiveness and quality of respiratory disease management in low-to-middle income countries. It was also designed to be a low-cost, low technology intervention aimed at reducing the burden of respiratory diseases. The PAL objective is to use the global tuberculosis control programme as the nucleus on which to build a syndromic, or integrated, case management approach. This will result in: increasing tuberculosis case detection; improving the quality and treatment of chronic respiratory diseases; decreasing inappropriate drug prescription and increasing the cost-effectiveness and delivery of health systems. In order to achieve its aim, the PAL researchers developed a core set of interventions with the main tool being a clinical practice guideline. They used the Integrated Management of Childhood illnesses (IMCI) case management strategy as a model as it was developed to integrate the management of some of the most important causes of

childhood illnesses and addressed other activities such as training, supervision, communication and monitoring of different child healthcare management programmes.

The Practical Approach to Lung Health in South Africa (PALSA) came into being as a response to local requests to prioritise disease problems and to develop cost-effective interventions in South Africa. PALSA has undertaken to break new ground by borrowing from the TB programme and thus aims to develop an intervention strategy to improve the management of lung diseases in South Africa. A symptom-based clinical practice guideline aimed at nurses who work in primary health care clinics was designed. It is an evidence-based but locally adapted guideline that draws heavily from the existing South African respiratory and primary care guidelines including the national tuberculosis guideline. Simplified diagnostic and treatment algorithms were designed to a form that will be implemented in respect of the profile of diseases encountered in South Africa, the level of staffing of the health care facilities and the availability of diagnostic equipment and drugs.

PALSA has, however, taken into account that although clinical practice guidelines improve health outcomes and quality of healthcare, they have very little impact if merely disseminated and not actively implemented, and also if they do not address barriers to change. This has formed the basis for the formulation of a new approach to changing poor professional practices. This approach will be tested in this trial.

PALSA has determined to address poor professional practices by developing an intervention strategy that consists of the clinical practice guideline and support materials such as patient and nurse information leaflets and a set of key messages. These materials, once validated, will be tested by means of a pragmatic randomised control trial. We also aim to test the implementation strategy of the PALSA project, thereby, proving that passive dissemination of guidelines are not effective and that multifaceted interventions, including educational outreach, are vital to the success of guideline implementation. We also aim to develop a single local utility outcome measure. This forms part of health-related quality of life research. The EUROQOL 5D will be translated to a local language, Sesotho and adapted and each question in the 5 domains of well-being will be combined to form a single utility outcome measure. Finally, a health economic analysis of the pragmatic randomised control trial will be performed.

AIM:

The aim of the proposed study is to estimate the effects of implementation of the Practical Approach to Lung Health in South Africa (PALSA) on the processes and outcomes of respiratory care in Free State Government primary health care clinics.

2. STUDY OBJECTIVES

2.1 PRIMARY OBJECTIVES

Process

- 2.1.1 To reduce the rate of antibiotic prescription among patients with upper respiratory tract infection (URTI).
- 2.1.2 To increase the rate of appropriate prescriptions for patients with asthma (inhaled steroids).
- 2.1.3 To increase the rate of sending sputa for TB testing.
- 2.1.4 To increase the number of positive sputa TB cases which are 1+.
- 2.1.5 To reduce time in delay to diagnose TB.
- 2.1.6 To increase appropriate referral of patients with LRTI.
- 2.1.7 To increase appropriate referral of patients with severe respiratory disease (i.e. RR > 30/min, breathless on talking or at rest, use of accessory muscles, confusion, temperature > 38 degrees Celsius).
- 2.1.8 To increase VCCT/HIV counselling practices.

- 2.1.9 To increase counselling practices for smoking cessation.
- 2.1.10 To increase appropriate use of cotrimoxazole prophylaxis in HIV positive patients.
- 2.1.11 To increase the rate of readiness to quit smoking.

2.2 SECONDARY OBJECTIVES

Health outcomes

- 2.2.1 To increase TB case detection rate.
- 2.2.2 To reduce the rate of mortality due to TB.
- 2.2.3 To improve on the rate of appropriate urgent and non-urgent referral of patients with severe respiratory conditions.
- 2.2.4 To increase the rate of sending of sputa for laboratory testing in TB suspects.
- 2.2.5 To decrease frequency of difficulty sleeping due to chest symptoms.
- 2.2.6 To decrease frequency of chest symptoms during daytime.
- 2.2.7 To decrease frequency of problems of usual activities due to chest problems.
- 2.2.8 To decrease frequency of problems with mobility due to chest problems.
- 2.2.9 To decrease frequency of problems with self-care.
- 2.2.10 To decrease frequency of pain/discomfort.
- 2.2.11 To decrease frequency of problems of anxiety/depression.
- 2.2.12 To decrease frequency of pain/discomfort.
- 2.2.13 To decrease all domains of the Euroqol-5D and combined score.

Health Care utilisation

- 2.2.14 To reduce the rate of unplanned visits to clinics among patients with respiratory conditions.
- 2.2.15 To increase appropriate admissions to hospitals due to respiratory conditions.
- 2.2.16 To increase the rate of utilisation of lay counsellors in VCCT services.
- 2.2.17 To increase the rate of smoking cessation among current smokers.
- 2.2.18 To decrease each dimension of the Euroqol-5D and combined score.

3. DESIGN OF THE STUDY

The study will be a cluster randomised controlled trial.

3.1 STUDY POPULATION

Clinics:

The study will take place in the 40 largest clinics of the Free State Government excluding the three pilot clinics as well as Bloemfontein clinics due to nature of services rendered e.g many patients are seen by doctors or at hospitals. Nursing staff in Bloemfontein clinics circulate between clinics quite often and this would result in high contamination of data. A purposive sample of 40 largest clinics has been selected for logistical and recruitment purposes of eligible patients.

Patients:

A total of 50 patients per clinic will be recruited for the study. In total 2000 patients will be recruited, 1000 per arm.

3.1.1 Inclusion Criteria

- All patients 15 years and older.
- All patients who present to a primary health care clinic with a problem of difficulty breathing on the day of attendance or in the last 6 months.
- All patients who present to a primary health care clinic with a problem of cough for more than a week or recurrent cough in the last 6 months.
- All patients with a history of cough for less than 1 week but a marker of severe disease (RR > 30 min breaths/min and/or > 38 degrees Celsius).
- All symptomatic patients attending repeat visits to TB, COPD and asthma clinics.

3.1.2 Selection Record

A screening form will be used for screening eligible patients for the study. All eligible patients will be recorded in a logbook for proper recording purposes. Patient initials, age, sex, presenting complaint and duration will be recorded.

3.2 SAMPLE SIZE ASSUMPTION AND ESTIMATES

Results of the pilot reveal the following points:

- 70% of patients interviewed had antibiotic prescriptions
 - 17% of patients interviewed had inhaled steroids prescriptions
 - 50% of patients interviewed had problems with their usual activities
- To decrease antibiotic prescription by 10% - from 70% to 60% with 90% power, we will require 500 patients per arm. Because of cluster randomisation, we need to double the number and therefore end up with 1000 per arm.
 - To increase inhaled steroids prescription by 10% - from 17% to 26% with 90% power, we will require 458 patients per arm. Because of cluster randomisation, we need to double the number and therefore end up with 916 per arm.
 - To decrease the frequency of problems usual activities by 10% - from 50% to 40% with 90% power, we will require 538 patients per arm. Because of cluster randomisation, we need to double the number and therefore end up with 1076 per arm.

From the above assumptions and estimates, it is evident that for the trial, an ideal sample size should be approximately 1000 per arm i.e intervention and control.

3.3 RANDOMISATION

Randomisation of the 40 largest clinics was done in blocks of 4 and by district. All the 5 districts of the province are represented and the list of the clinics is attached as Annex 4.

3.3 ENROLLMENT OF PARTICIPANTS

3.3.1 Informed Consent

Eligible patients will be asked to complete a consent form that will briefly explain the background, purpose and methods of the trial. It will be clearly stated that: participation is voluntary; the patient may withdraw at any time and will not be discriminated against by the trial or clinic staff; he/she will be interviewed by a research assistant and will be requested to come back for a follow up visit after three month of the initial visit. All participating patients will be entitled to a food voucher/parcel worth Sixty Rand (R60) which they will receive on the day of the follow up visit to the clinic. Participating patients will also be reimbursed transport expenses in a form of a standard fee. Should the patient not turn up for the follow-up visit at the clinic, he/she will be followed up at home and reasons for not coming to the clinic noted.

3.3.2 Assessment of Eligibility and Enrolment

Upon arrival at a health facility, patients will be screened for eligibility to participate in the study by using a screening question of " do you have cough and/ or difficulty breathing today or in the last 6 months?" in all patients that are 15 years and above. All patients whose response is "yes" to the screening question will be given a tag before seeing nurse/doctor. In the event of an interviewer being overloaded with eligible patients, a systematic sampling procedure will be applied to avoid eligible patients having to queue for interviews.

After being seen by a clinic nurse/doctor, patients with tags will be interviewed using the inclusion form to establish the severity and duration of the presenting respiratory problem prior to being send to the exit interview corner. Informed consent will be sought from these eligible patients for enrolment to the study after a thorough explanation of what the study is all about. All patients who give verbal and/or written consent for enrolment to the study will be interviewed using an exit interview questionnaire. Information obtained will be recorded and safely filed by the research assistant. The enrolled patients will then be requested to return to the clinic for a follow up three months after this initial interview. A total of 2000 patients will be recruited for both arms, that is, in the intervention and control, 1000 per arm.

3.3.3 Blindness

To avoid contamination of data to be collected both the patient and the interviewer will be blinded.

The intention is to finally interview the interviewers to establish if they were able to differentiate between the intervention and control clinics during interview sessions that they conducted.

3.4 INTERVENTION

3.4.1 Description and schedule

The intervention package is designed and meant to reduce the burden and costs of priority lung disease, and to also provide conclusive evidence to support rational decision-making regarding implementation.

The intervention essentially comprises the following:

- 4 training sessions delivered on-site by district TB co-ordinators over 9 weeks

- Clinical Practice Guideline and support materials (desk blotter, pens, penholders, butterfly fridge magnets)
- Changes in prescribing provisions for PCNPs (cotrimoxazole prophylaxis for symptomatic HIV infected persons, initiate and step-up or step-down inhaled steroids for asthma, short course oral steroids for exacerbations of asthma and COPD).
- Doctor sensitization about PALSAs (personally addressed letters).

3.4.2 Pilot

The training will follow pilot testing of the intervention which was recently undertaken in three primary care clinics within Thaba-Nchu district namely Gaongalelwe, Thaba Nchu and Tiger River. These will be excluded from the randomised trial. The pilot exercise concentrated on the academic detailing method of training and data collection tools. Information obtained from the pilot was used to modify the training to local conditions, make an assessment of the number of eligible patients per day per clinic, feasibility of data collection, especially patient interviews in terms of time taken for an interview, and assessment of follow up of patients. The pilot has served as a final check of clinic staff knowledge and skills needs.

3.4.3 Measures of compliance

PALSA researchers and provincial TB Co-ordinators will undertake periodic support visits to the intervention clinics to ensure compliance and utilisation of the intervention package by the clinic staff. A maximum of two visits per clinic will be conducted in a period of five months.

TIME FRAME JANUARY 2003 TO DECEMBER 2003

Year by Quarter	Jan - March	April - June	July - Sept	Oct - Dec	Jan - March	April - June	July - Sept	Oct - Dec.
Revise Protocol	→							
Finalize DCT	→							
Conduct TDI	→							
Quality Assurance Training	→							
Training of Professional Nurse intervention arm	→	→						
Recruitment of PALSAs Patients		→						
Follow-up of PALSAs patients			→					
Data Cleaning and coding				→				
Data analysis								
Literature review								→
Report writing								→

3.5 FOLLOW-UP

Three months after collection of the base line information, each patient will return for a follow up interview. This will be conducted using a similar questionnaire to the exit interview except that it will have utilisation questions added.

Patients who fail to turn up at the clinic on the date of the interview will be followed up at home.

3.6 ASCERTAINMENT OF RESPONSE VARIABLES

3.6.1 Training

A total of 18-20 research assistants will be recruited specifically for data collection purposes. They will be assigned in teams of three and will as a team conduct interviews at each primary care clinic.

The research assistants will first of all be trained on data collection techniques, basic respiratory clinical signs and symptoms and qualitative data collection techniques. They will also be trained and familiarised with the data collection tools as well as essential primary and secondary outcome measures expected. Each research assistant will interview patients and fill the questionnaire appropriately.

3.6.2 Data collection tools

3.6.2.1 The Exit interview questionnaire (Annex 5)

The exit interview questionnaire has been developed with technical input of lung disease experts from the UCT Lung Institute. It comprises of questions about the presence of a cough and or difficulty breathing, in terms of severity and duration. It goes on to establish presence of other symptoms related to either the upper or lower respiratory tract infections and their severities during the day and night.

The questionnaire also includes the international three dimension Euroqol-5 questionnaire. Smoking habits and counselling on cessation questions also form part of the questionnaire. An abbreviated form of a questionnaire devised by Prochaska and DiClemente which classifies patients according to their readiness to quit smoking will be used for collecting smoking information.

Also included are questions on details of consultation of patients by nurse practitioners, further tests recommended, emergency treatments given, prescriptions for the day, regular/on-going medication taken by patients and referrals.

Last are questions on health care utilisation and their financial implications on the patient.

Because of the diversity of languages in the Free State, the questionnaire will be translated into four local languages that are commonly spoken in the province. These are Sesotho, Afrikaans, Xhosa and Tswana.

3.6.3 Data collection process

Following training on data collection tools and quantitative data collection techniques, the research assistants will be assigned in teams of three per clinic and will conduct interviews at each clinic until a target of 50 patients per clinic is attained. Each team is expected to spend at least 3-5 days at a clinic to recruit 50 PALSA patients. The team will then move on to the next clinic and recruit another 50 patients and so on. The team will initially collect base-line information on the health status of eligible PALSA patients during their first visit to the trial clinic through an exit interview. Data will be collected using an exit interview questionnaire.

Patients will then be requested to return to their respective clinics for follow-up purposes three months after the initial visit. Patients who do not turn-up for follow-up visits will be visited at home. Information on why they did not return to the clinic will be chaptered for analysis purposes. The follow-up visits will be meant for establishing whether or not there has been any change on the respiratory health conditions of the PALSA patients as a result of the intervention on the clinic nurses' care delivery. Data will be collected using a follow-up questionnaire.

Research assistants will be responsible for ensuring safe storage of daily collected data collection tools and making them available to the researchers as and when required to do so. The study researchers from UFS and UCT LI will ensure timely and efficient collection of the appropriately filled questionnaires from the field to a central point in UFS Centre for Health Systems Research and Development.

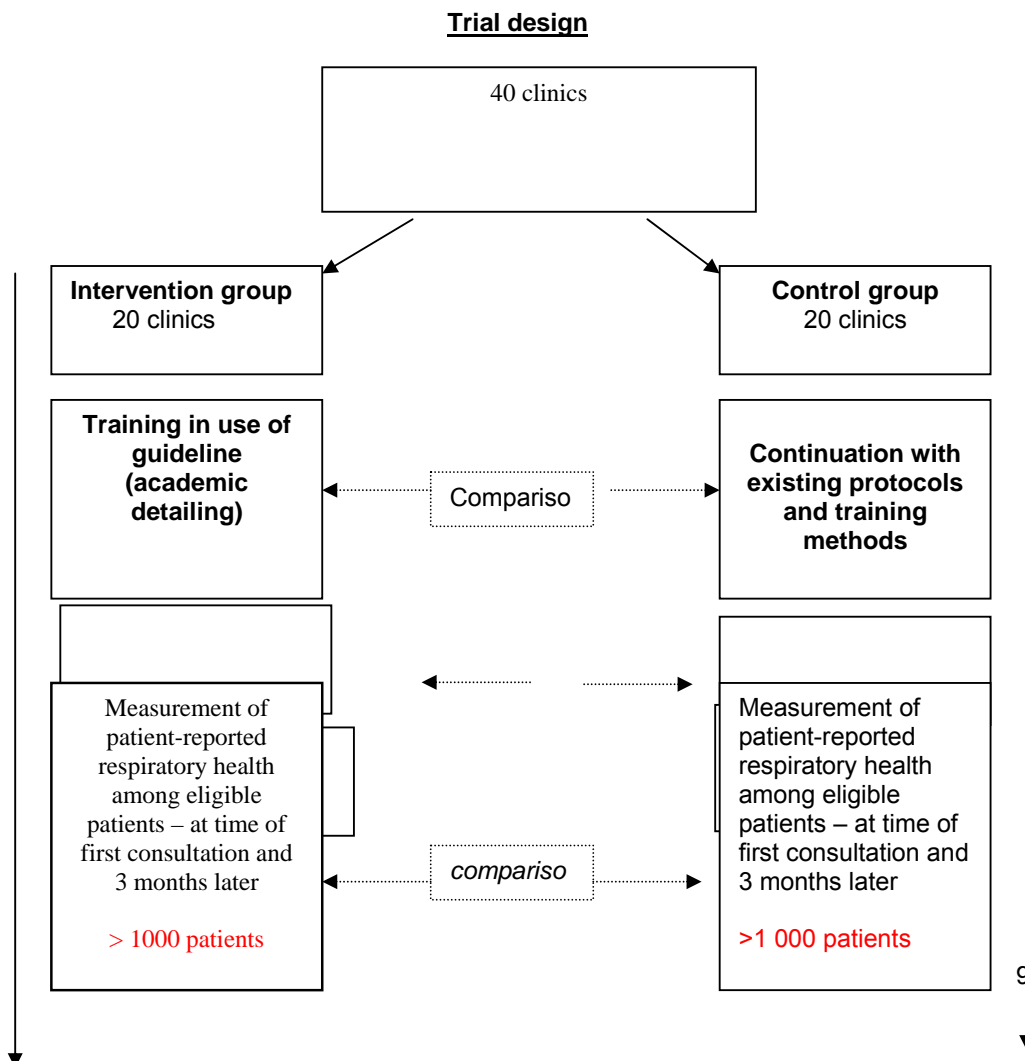
3.6.4 Quality control

During the data collection process, PALSA researchers will monitor and spot check research assistants to verify that all questions are answered in each questionnaire as well as to ensure that they are correctly filled. Failure to fulfil this requirement will result in the questionnaire being returned to the research assistant to follow the right procedure and or suspension from the exercise.

All data collection documents and recorded tapes will safely stored at the UFS Centre for Health Systems Research and Development. Data will regularly backed-up by CD, hard drive and stiffer discs

3.7 DATA ANALYSIS

Prevalence of outcomes will be compared adjusting for cluster randomisation effect.



DATA TO BE COLLECTED

The following variables will be assessed and measured in all patients and recorded by the research assistant on the Data Collection sheet:

a. Patient contact details

- Name and surname
- Date of birth
- Sex
- Name of clinic
- Clinic folder number
- Home address
- Work address
- Details of next of kin

b. History variables

- Presenting complaint:
 - cough only
 - duration of current cough
 - sputum colour
 - hemoptysis
 - night cough
 - chest pains
 - difficulty breathing only
 - duration of difficulty breathing
 - tight chest, wheeze
 - fever
 - runny nose/blocked nose
 - itchy nose/sneezing
 - sore throat
 - ear problem
 - weight lose
 - presence of TB
- Symptom severity
 - Difficulty sleeping due to chest symptoms
 - Chest symptoms during daytime
 - Interference with usual activities
- Euroqol-5
 - Mobility
 - Self-care
 - Usual activities
 - Pain/discomfort
 - Anxiety/depression
- Smoking history
- Details of consultation
- Health care utilisation
- Income and changes due to current illness
- Expenditure on health care utilisation

4.0 ORGANISATION

1. Participating investigators

Participating institutions in the trial are:

- a) UFS's Community Health Department
- b) UFS's Bio-statistics Department
- c) UCT's Lung Institute
- d) Medical Research Council- Cape Town
- e) University of the Western Cape, Pharmacy Department
- f) Erasmus University, Rotterdam
- g) The Free State Provincial Health Department
- h) World Health Organisation
- i) Provincial primary care clinics that provide respiratory care services

2. Study Administration

- a) Steering Committee

A PALSA Board/Committee comprising representatives from UFS, UCT, Free State provincial health department, the National TB programme, the National Chronic Disease directorate, the South African Nursing Council and WHO is in the process of being established. The mandate of the board/committee will be to monitor and oversee implementation of the entire PALSA project and advise accordingly. The committee will meet at least once a year during which progress reports will be compiled and distributed to stake holders.

- b) Funding Organisation

The PALSA project, which is currently being implemented on a trial basis in South Africa's Free State province is a multifaceted intervention. It enjoys technical and financial support of several local and international organisations. Among these are the Government of South Africa, MRC, WHO, WOTRO, IDRC and Lesotho Highlands Development Authority.

4.0 ETHICS REVIEW

The intervention has minimal capacity to cause harm, since it is mainly a training strategy that is meant to build on existing methods. On the other hand, there is still no evidence to suggest that it will improve patients' health. The main ethical issues are therefore confidentiality and consent.

Patients and clinic identities will remain confidential. Managers and staff will be informed of the trial, be invited to participate, and will have a right to refuse to take part. Because this is a training intervention conducted as part of a broader training programme, it will not be necessary to obtain patients consent for their local clinics to be included in the trial. However, for all patients who agree to be interviewed, their informed consent will be sought prior to being interviewed.

The final study protocol will be re-submitted the Ethics Committee, School of Medicine, University of the Free State for approval.

SCREENING LOG

SCREENING NUMBER	NAME	AGE	PRESENTING COMPLAIN
S1			
S2			
S3			
S4			
S5			
S6			
S7			
S8			
S9			
S10			
S11			
S12			
S13			
S14			
S15			
S16			
S17			
S18			
S19			
S20			
S21			
S22			
S23			
S24			
S25			
S26			
S27			
S28			
S29			
S30			

PRACTICAL APPROACH TO LUNG HEALTH

PROPOSED STANDARD OPERATING PROCEDURE FOR SCREENING

IN WAITING ROOM (BEFORE CONSULTATION)

Section 1

24 Hour Clinic:

1. Arrive at clinic at 8am (? 7am).
2. Ask clerk to identify first booked patient to arrive at the clinic that day.
3. Starting with first booked patient, ask each patient individually and in the sequence that they are standing or sitting in the waiting area, the screening questions in Section 2.

8am – 5pm clinic:

1. Arrive before the clinic opens at 8am (? 7am).
2. As patients enter the door ask each patient individually and in sequence of entering the clinic the screening questions in Section 2.

Section 2

Ask patient the following (repeat word for word):

1. *How old are you?*
If patient is 15 years or older ask:
2. *Do you have a cough and/or difficult breathing / tight chest / shortness of breath today or have you had any of these problems in the last 6 months?*

If patient answers yes, select patients for further screening according to the guide that follows.

3. Guide for selecting patients for further screening:

Monday:	1 in 6 patients who answer “yes” from the general queue
	1 in 12 patients who answer “yes” from the TB queue
	1 in 2 patients who answer “yes” from the emergency queue
Tuesday:	1 in 5 patients who answer “yes” from the general queue.
	1 in 16 patients who answer “yes” from the TB queue.
	1 in 3 patients who answer “yes” from the emergency queue.
4. Exclude those patients who are too ill to participate and require immediate emergency treatment:
 - * unconscious patients
 - * patients who are not breathing
 - * patients who are unable to talk
 - * patients who are psychotic (clearly hallucinating, manic and unable to sit still, aggressive)

Note these patients on the screening log.

1. For patients identified for further screening (15 years or older, “yes” to cough and/or difficult breathing, not too ill to participate).

Distribute coupon to patient, explain that we are conducting a lung health study and would appreciate their help. Ask them to meet an interviewer at the

interviewing station after their consultation today and to bring their folder with them (coupon to reflect this information).

AT INTERVIEWING STATION (POST CONSULTATION)

1. Ask:
Were you seen by a doctor or nurse / nursing sister today?

Doctor	ن		If doctor, patient doesn't qualify → do not continue
Nurse	ن		If nurse → go to the next question

2. Ask:
Do you have difficult breathing / shortness of breath / tight chest today or have you had any of these problems in the last 6 months?

YES	ن		patient qualifies → complete this form & consent
NO	ن		go to the next question

3. Ask:
Do you have a cough?

YES	ن	→	go to the next question
NO	ن	→	patient does not qualify → do not continue

4. Ask:
For how long have you been coughing?

One week or longer	ن	→	patient qualifies → complete this form & consent
Less than one week	ن	→	go to next question

5. Ask:
Have you had a cough like this in the last 6 months?

YES	ن	→	patient qualifies → complete this form & consent
NO	ن	→	go to the next question

6. *What is the respiratory rate?*
Instructions to interviewer: count respiratory rate over 1 minute

Respiratory rate:..... breaths/min

30 breaths per minute or more	ن	→	patient qualifies
			→ complete this form & consent
29 breaths per minute or less	ن	→	go to the next question

7. *What is the temperature?*
Take the temperature with strip thermometer

Temperature:.....degrees Celsius

38 or more	ن	→	patient qualifies
			→ complete this form and consent
37.9 or less	ن	→	go to the next question

7. Did the patient qualify?

YES	ن	→	Consent patient
			→ If consent given, complete baseline interview
			→ If consent not given, complete screening log
NO	ن	→	Thank patient for their time
			→ Return patient's folder to records
			→ Patient leaves clinic

PATIENT INFORMATION AND WRITTEN CONSENT FORM – PALSA - RCT

Study Number: _____

Patient's Initials: _____

You are invited to participate in a Randomised Control Trial. Before you agree to take part you need to understand what it involves.

Purpose of study

Researchers from the UFS community Health Department are studying patient's who present to primary health care clinics with a complaint of difficult breathing and/or cough.

The reason for doing this study is to test better ways to diagnose and treat lung disorders. We will compare nurse diagnoses of respiratory diseases using PALSA intervention compared to a nurse without PALSA intervention.

What are the possible benefits of participating in this study?

The information that we obtain from the study will help us improve the diagnosis and treatment of respiratory disease by nurses at primary health care level. You will be entitled to a R60 worth of food upon your return to the clinic for a follow up visit 3 months from today.

What are the possible drawbacks or discomforts in participating in this study?

None since this is only a training intervention.

Do I have to participate in this study?

Your participation in this study is voluntary. Should you agree to participate, you are to sign this form. You are free to withdraw from the study at any stage and this will in no way affect your management. Likewise, should we feel that further participation in the study would not be in your best interest we will withdraw you from the study.

What will happen to me if I participate?

After being seen by a clinic nurse who will record information about your medical history and your current condition, you will be screened for whether you qualify for inclusion to the study and questionnaire. Thereafter, you will be escorted to another cubicle where you will be interviewed by a research assistant using an exit interview questionnaire. Information regarding your medical history and current condition will also be recorded. You will then be requested to return to the clinic 3 months from today for a follow up visit.

Will the information remain confidential?

Should you agree to participate in the study all your records will be viewed by the researchers only. Your information will not be viewed by any other persons or parties not involved in this study. All the information will be safely stored on a computer and at the study site. At no time will anyone be able to link the information stored on the computer to your name.

Contact details of the study staff

Should you have any questions relating to this study, please contact any of the following members of our researchers.

Name _____

Phone Number _____

Name _____

Phone Number _____

District	Clinic
Lejwel	Khotalong
Lejwel	AM Kruger
Lejwel	Hoopstad
Lejwel	Bothaville
Lejwel	Bophelong (Odend)
Lejwel	Thabong
Motheo	Wepener Clinic
Motheo	Botshabelo J
Northern	Thusanong (Sasol)
Northern	Osizweni
Northern	Koppies CHC
Northern	Bophelong (Kroon)
Northern	Hill Street
Xhariep	Matlakeng
ThabaMof	Petsana
ThabaMof	Paballong
ThabaMof	Ma-haig
ThabaMof	Marakong
ThabaMof	Phuthaditjhaba
ThabaMof	Bohlokong
Lejwel	Tshepong (Welkom)
Lejwel	K-Maile
Lejwel	Albert Luthuli Mem
Lejwel	Phomolong (Henn)
Lejwel	Welkom
Lejwel	Boithusong
Motheo	Botshabelo B
Motheo	Botshabelo U and S
Northern	Phahameng (Frank)
Northern	Tumahole
Northern	Thusanong (Kroon)
Northern	PAX
Northern	Seeisoville
Xhariep	Petrusburg
ThabaMof	Riverside
ThabaMof	Tseki
ThabaMof	Mphohadi
ThabaMof	Bethlehem Clinic
ThabaMof	Tebang
ThabaMof	Namahali