

This presentation is dedicated to the patients
who participated  in this trial

Tuberculous meningitis is a devastating form of tuberculosis, killing or disabling over half of its sufferers

This is a randomised clinical trial looking at enhancing antimycobacterial treatment for tuberculous meningitis

The trial has been running in 2 hospitals in Southern Vietnam since April 2011

817 patients participated in the trial

These images represent a typical day in the life of
our clinical trial



Receiving patients at the Hospital for Tropical Diseases, Ho Chi Minh City

On the way to ward rounds



The Vietnam-UK research ward



CHẤM DỪNG
KHÔNG ĐƯỢC ĐƯỢC

CHỖ ĐÓNG CHẤM DỪNG KHÔNG ĐƯỢC ĐƯỢC

VIỆT - ANH
KHOA NHIỄM VIẾT - ANH

KHOA NHIỄM VIẾT - ANH
25/11/99

HỘ THU GÓP Ý

KHOA NHIỄM VIẾT - ANH

GIỜ LÀM VIỆC
XIN MIỄN VÀO KHOA
TỪ 6^h30 - 16^h00



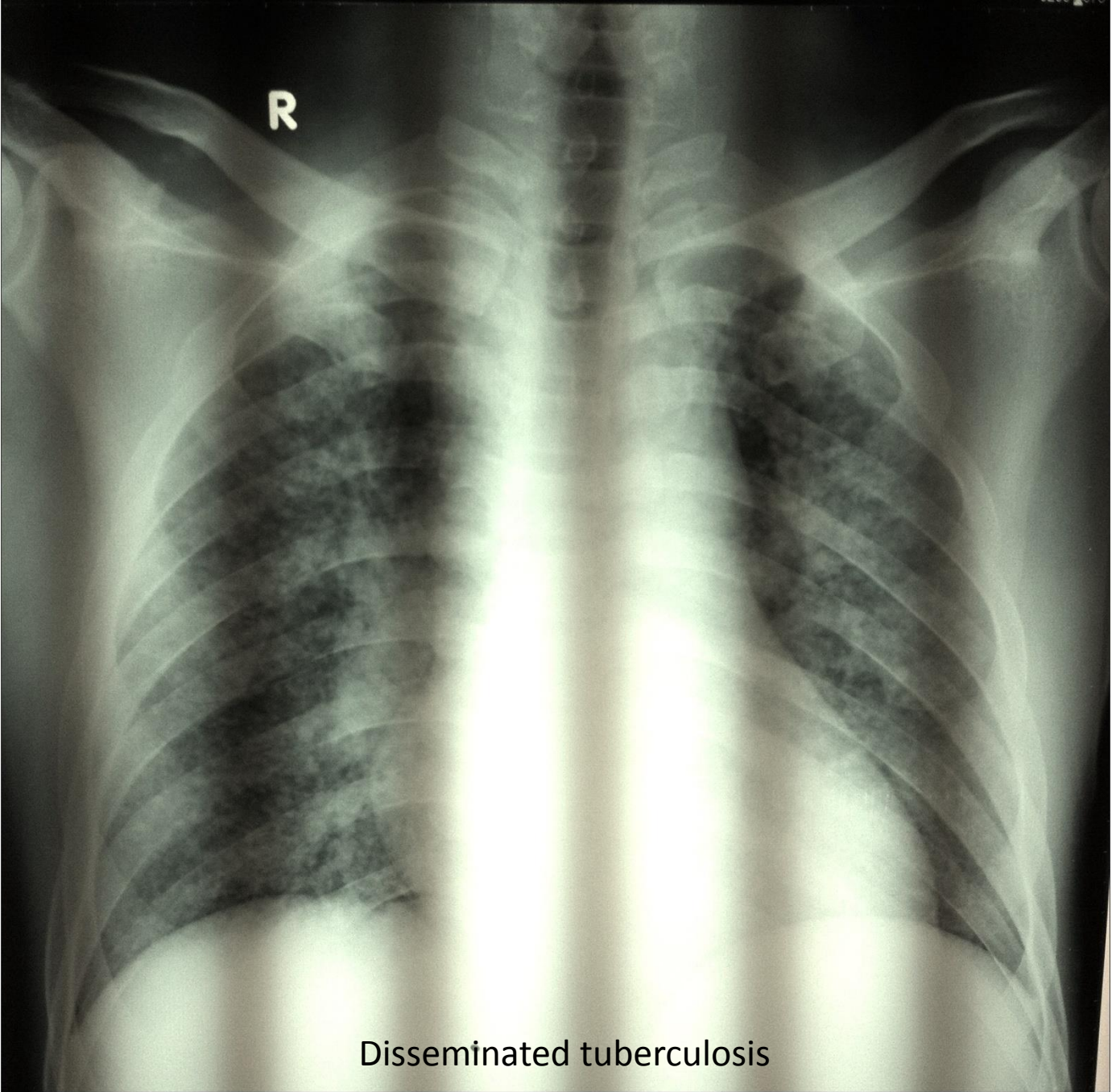




Diagnosing patients

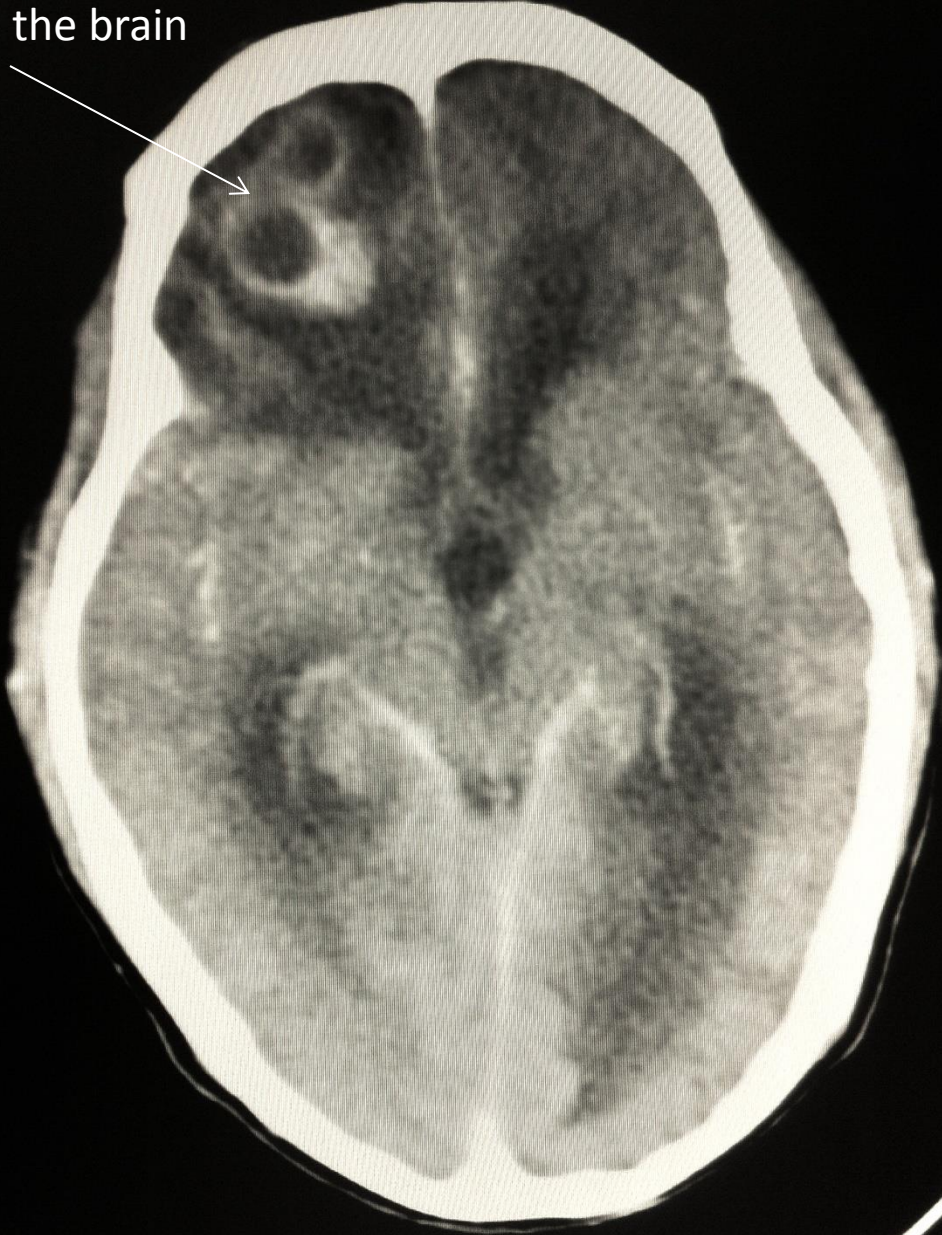
In the absence of sensitive and specific tests diagnosis is often presumptive





Disseminated tuberculosis

Large tuberculoma in the brain





Lumbar puncture

Recording clinical data





Treatment

All patients receive standard anti -
tuberculous treatment

and are randomised to additional
levofloxacin and rifampicin
or
placebo





On the way to the other study site; a 7 minute motor-bike ride

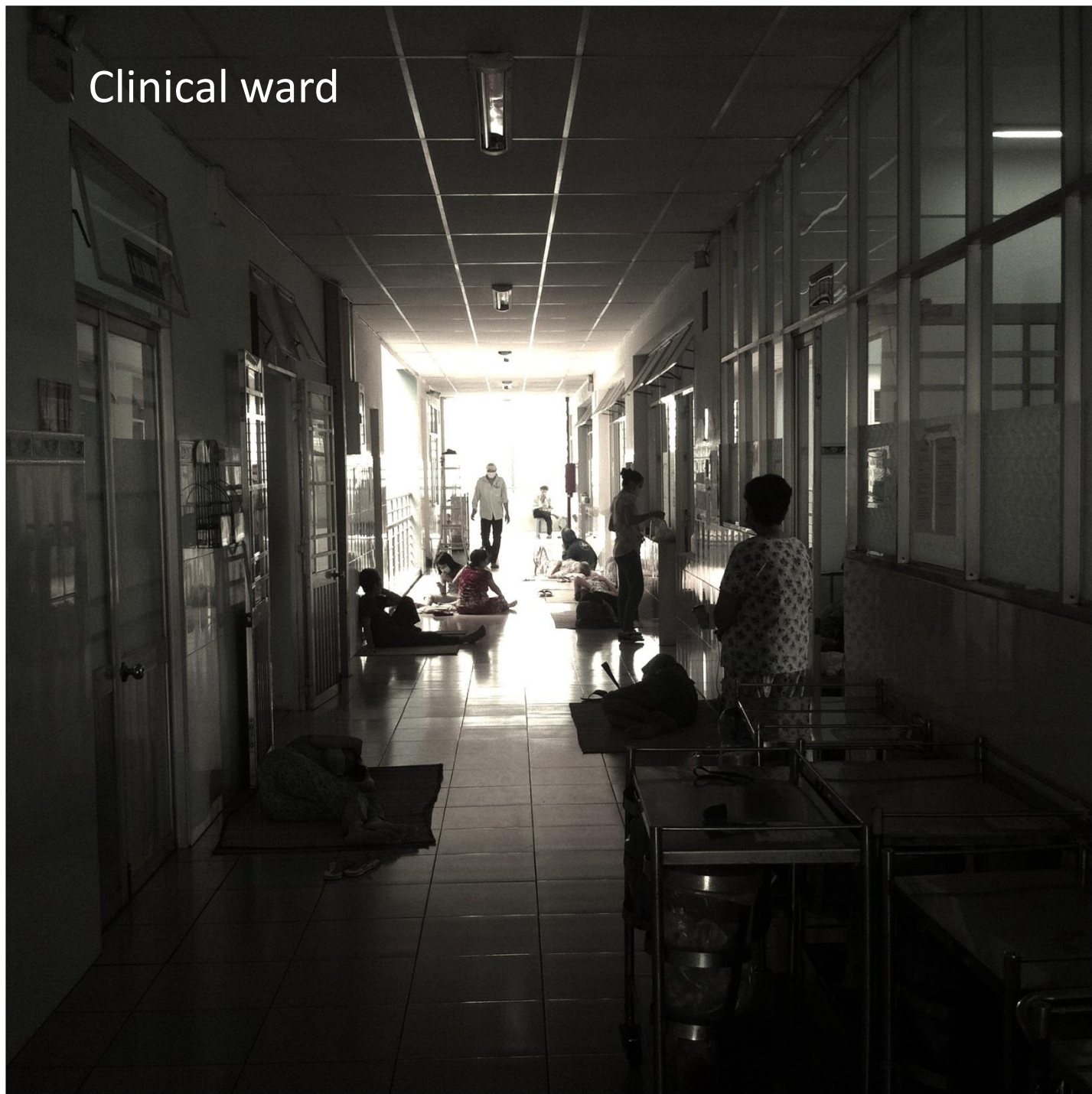


Pham Ngoc Thach National Hospital for Tuberculosis and Lung Diseases



Patients waiting

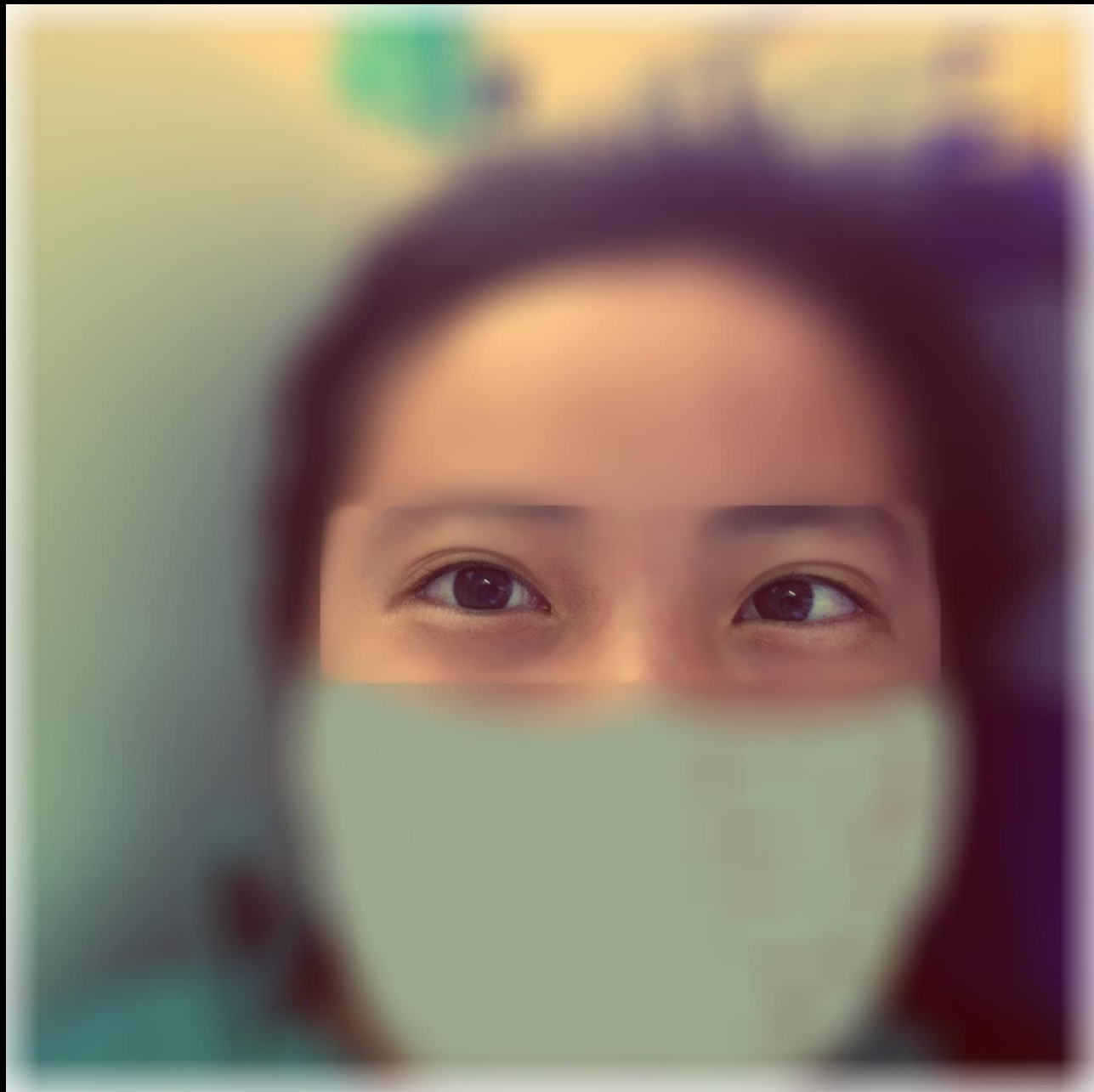
Clinical ward





Diagnosis

6th nerve palsy;
typical for
TB meningitis





Treatment





Recording data

Phụ lục 1.0 Chẩn đoán và phân độ Lao màng não

1.1 Tiêu chuẩn chẩn đoán Lao màng não

Phân loại	Tiêu chuẩn chẩn đoán
Khoảng LMN	Đầu tiên làm sáng Viêm màng não và tìm thấy acid-fast bacilli trong DNT hoặc cấy DNT tìm vi trùng <i>M. tuberculosis</i>
Rất có khả năng LMN	Đầu tiên làm sáng Viêm màng não và có một trong các tiêu chuẩn sau: <ul style="list-style-type: none">Có bằng chứng lao phổi trên hình chụp X-quang phổiTìm thấy Acid-fast bacilli trong mẫu đàm và dịch dệ dàyCó bằng chứng lao ngoài phổi
Có thể LMN	Có một trong các tiêu chuẩn sau: <ul style="list-style-type: none">Có bằng chứng lao ngoài phổiCó bằng chứng lao ngoài phổiCó bằng chứng lao ngoài phổi



An adverse event



Intensive care ward



DANH SÁCH BỆNH NHÂN - HSCC.C

SG	HỌ VÀ TÊN	SG	HỌ VÀ TÊN	SG	HỌ VÀ TÊN
65	...	69	...	83	...
66	...	70	...	84	...
67	...	71	...	85	...
68	...	72	...	86	...
69	...	73	...	87	...
70	...	74	...	88	...
71	...	75	...	89	...
72	...	76	...	90	...
73	...	77	...	91	...
74	...	78	...	92	...
75	...	79	...	93	...
76	...	80	...	94	...
77	...	81	...		
78	...	82	...		



Discussing patient management



Obtaining
informed consent



After ward rounds back to the office



PHAM NGOC THACH HOSPITAL – OUCRU
Research Office

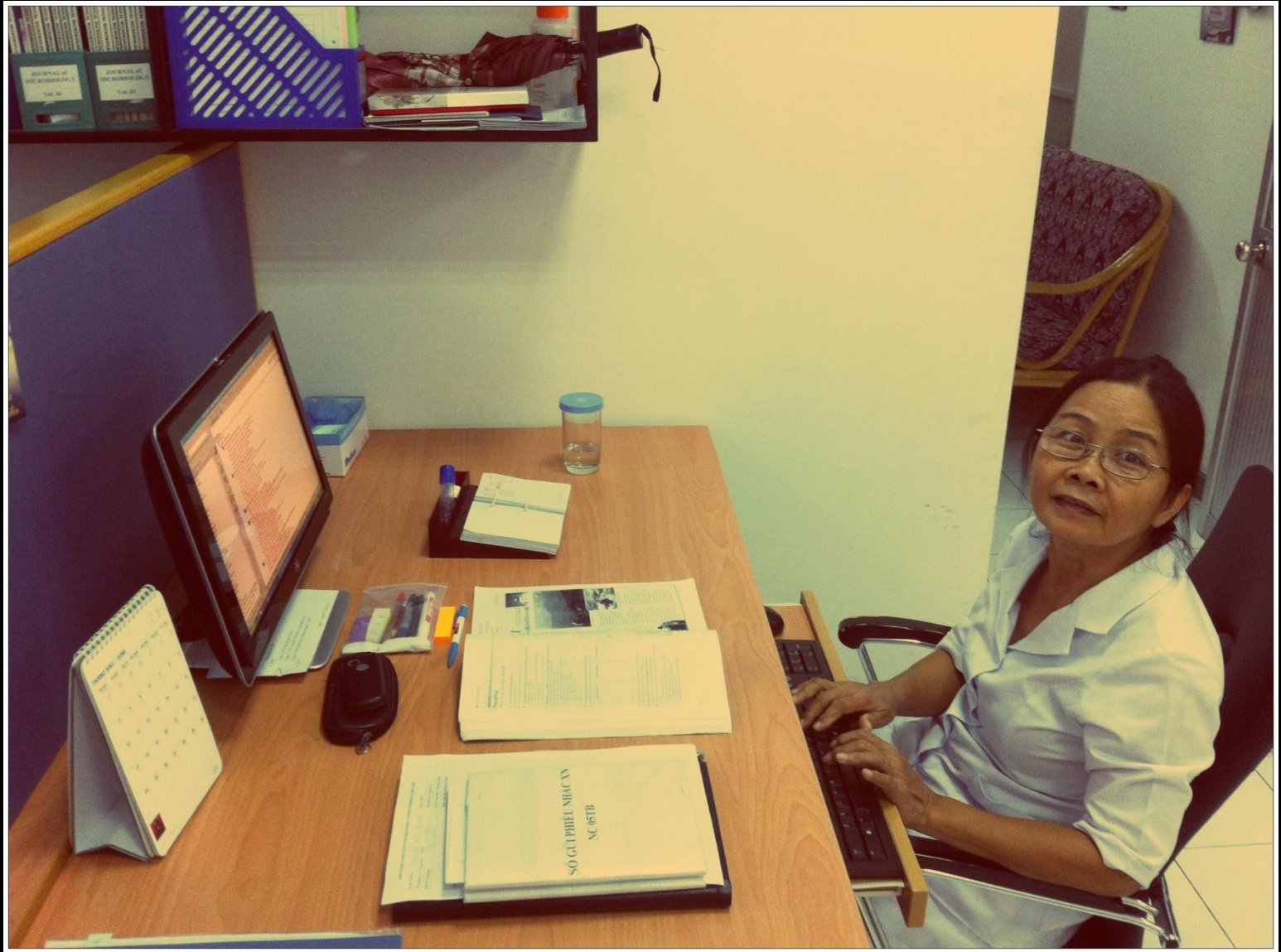


wellcometrust



Room 100





B	C	D	E	F	G	H	I
PATIENT ID	INITIALS	MỤC	ĐÃ NHẬP	SỬA LẠI			
33031	TTM	GCS	W4- N4	XÓA			
31040	HMT	GCS	W7 - N7	XÓA			
42065	LVT	GCS	W7 - N7	XÓA			
41029	NVV	CLINEVE	SỐ 12	XÓA			
41033	TVD	CLINEVE	SỐ 12	XÓA			
43028	HHS	TBDR	SỐ 18	XÓA			
32038	NTPC	S.HÓA	171213-0500	181213-0500			
31029	NĐK	ECG	2/5/2013	30/04/13			
33029	TTHA	H.HỌC	21/04/13	XÓA			
		DNT-H.HỌC	21/04/13	XÓA			

Real-time data entry



CRFs



We send reports regularly to the Ministry of Health and ethical review boards



An independent monitor checks data collection and data-entry processes regularly

Archive housing source documents



Office lunch







Hospital staff relaxes after lunch



HỆM

CHOLON MUI





Our Clinical Trials Unit supports us in many ways.



During 9 months
patients return
monthly for follow-up

This patient is
hemiplegic

This patient was diagnosed with multi-drug resistant TB meningitis and was comatose for 3 months.

After 9 months of 2nd line treatment only slight residual paraplegia remained.



Sample transport



File transport



Patient transport

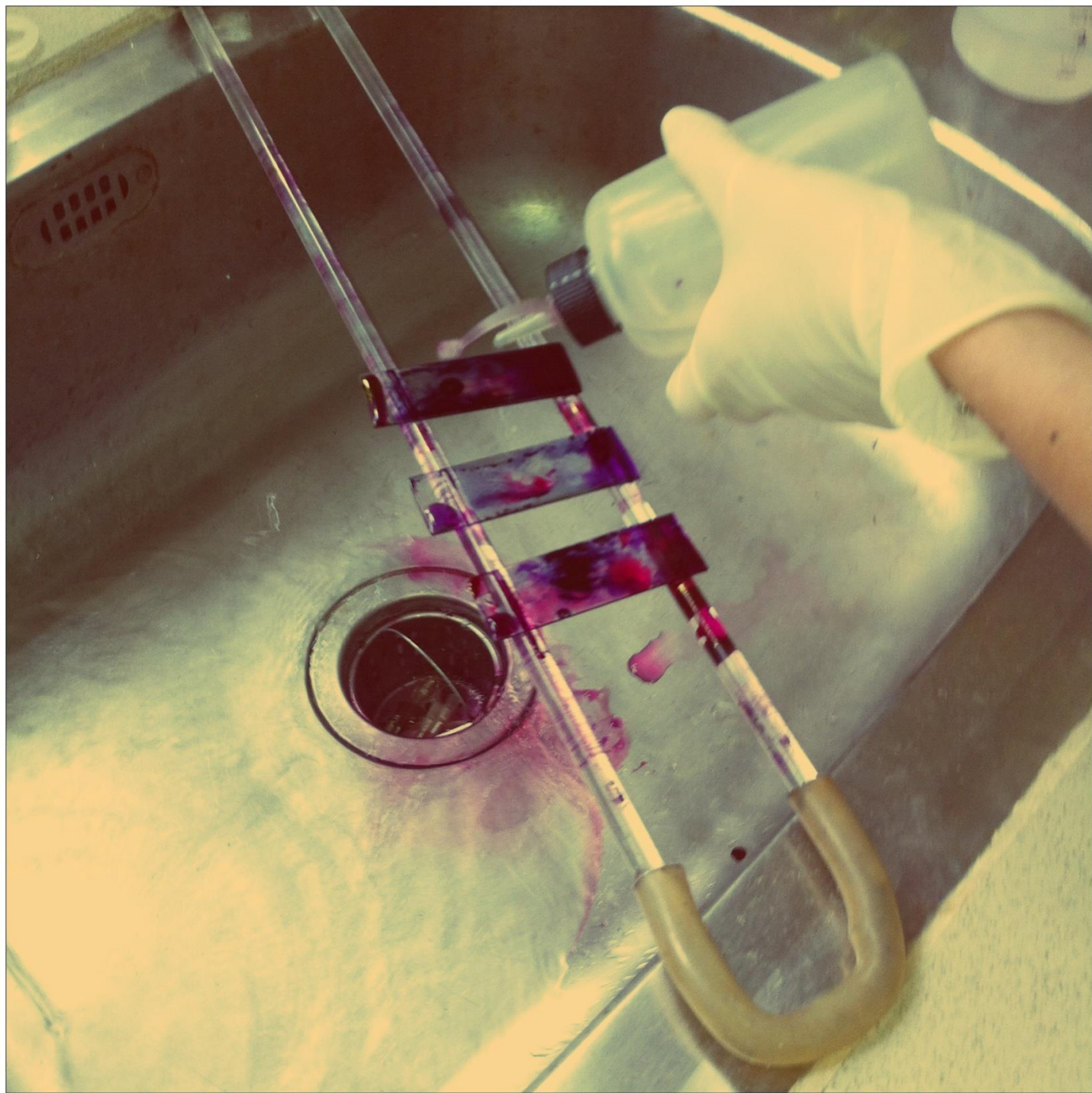


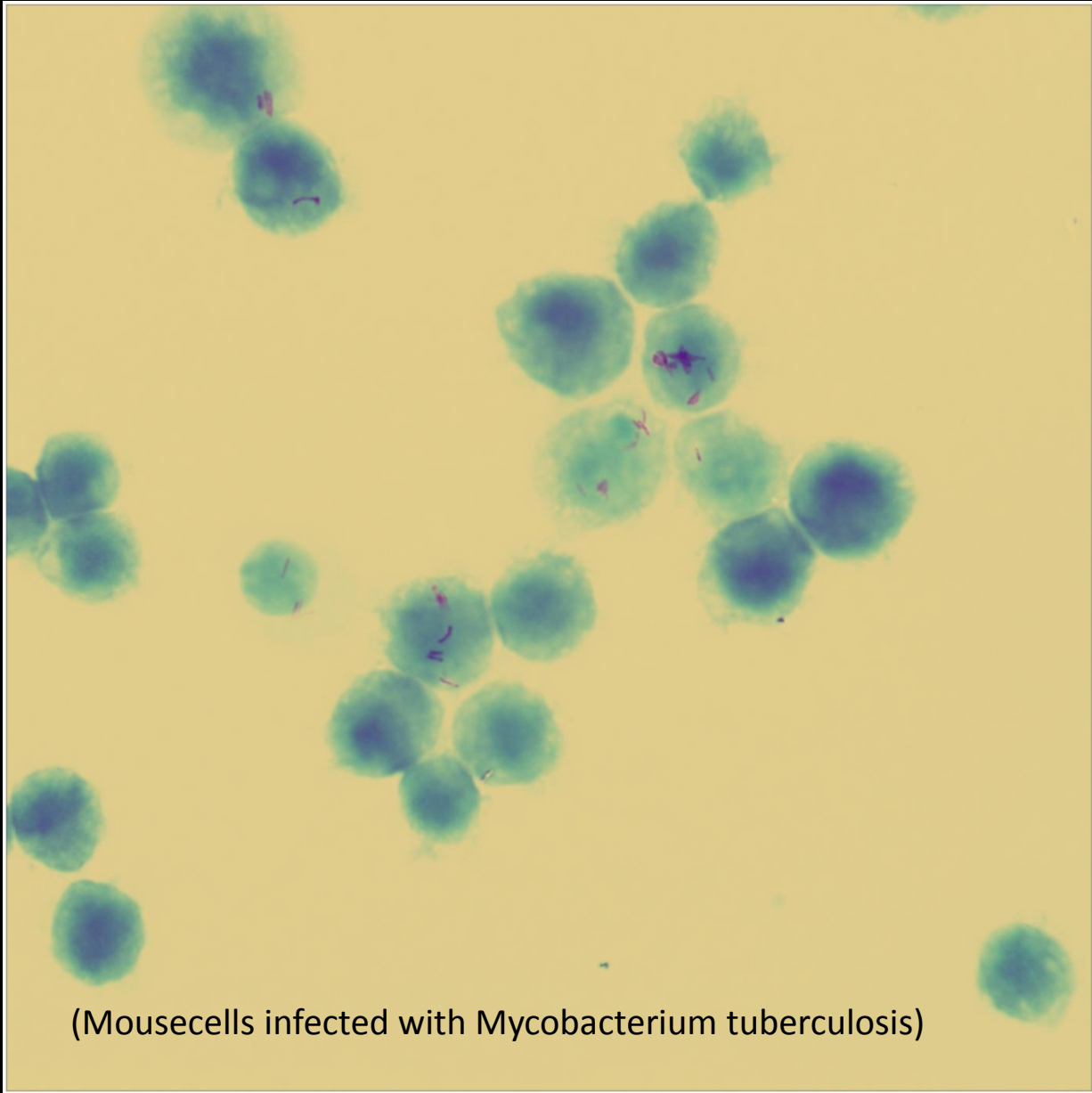
The (new) TB lab



Classical Ziehl-Neelsen staining to detect Acid Fast Bacilli.

It is very insensitive on cerebrospinal fluid





(Mouse cells infected with *Mycobacterium tuberculosis*)

We are looking into novel staining techniques
to improve diagnosis

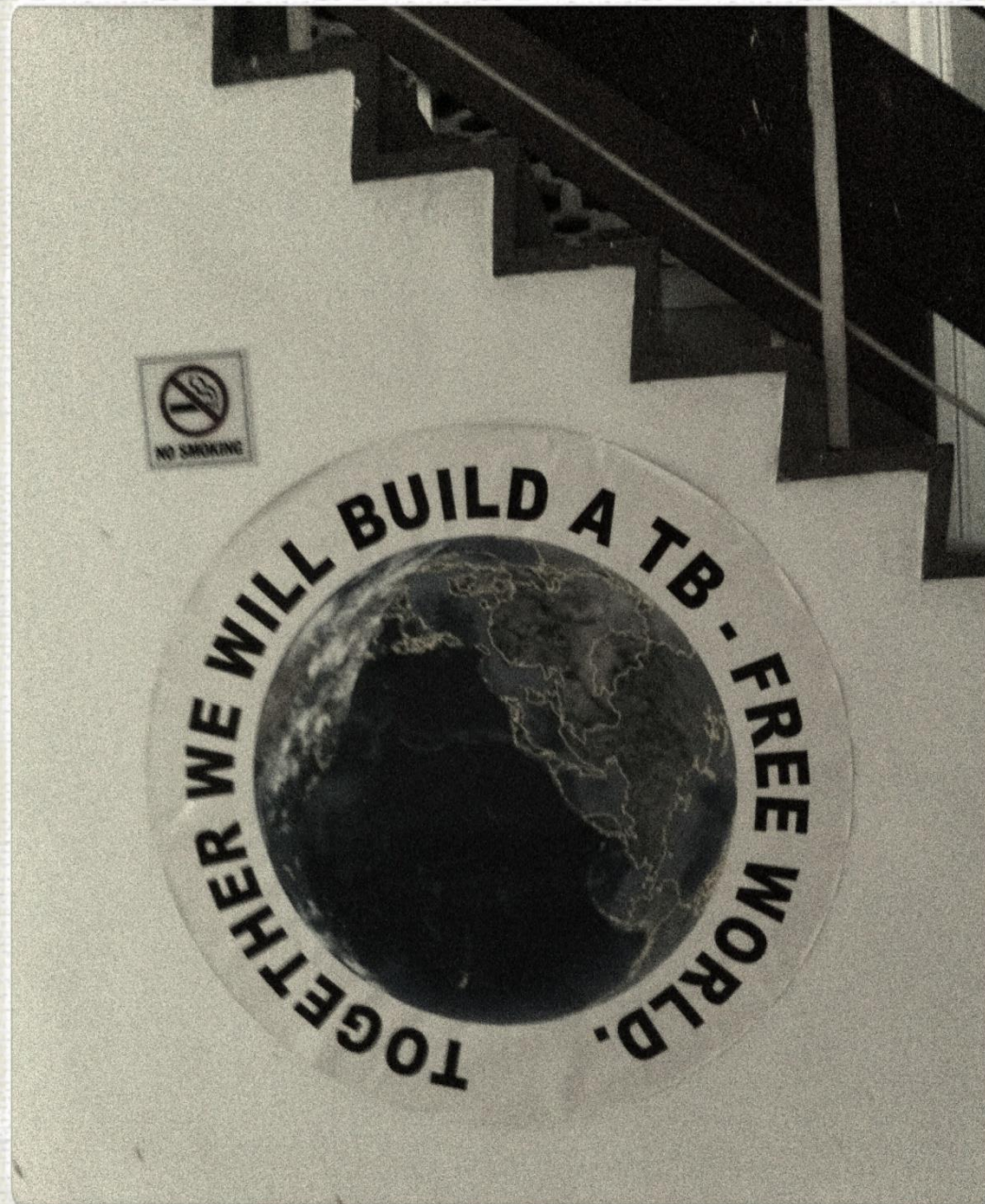


The overall blinded mortality in this trial is 25%.

We will unblind the data in March 2015, after the last patient has finished follow up.

We hope to be able to show a benefit of intensified treatment to have an impact on global mortality of this disease.

**Vietnam ranks 12th
of 22 high burden
tuberculosis
countries in the
world**



This trial is run by:

The Oxford University Clinical Research Unit 's '05TB' study team
Hospital staff of the Hospital for Tropical Disease and Pham Ngoc Thach hospital

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Jeremy Farrar

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Slideshow and images:

Doortje Heemskerk

Music:

Thanh Tuyen 'Mua Rung'

Trial registration:

ISRCTN61649292