OPTIMIZED SMEAR MICROSCOPY

Same-day smear microscopy

LED-FM

Luis E. Cuevas
WHO-TDR

- TB is a disease of poverty
- Each year
  - > 9 m cases
  - 1.8 m deaths

Smear microscopy: most commonly used diagnostic test

Smear microscopy

- Available in most laboratories
- Staff familiar with the technique
- Good specificity

but

- Low sensitivity
- Requires several visits to health facilities
- Patients often fail to complete diagnosis

Access to diagnosis is a major barrier to access treatment

Several studies suggested that collection of specimens could be optimised

INT J TUBERC LUNG DIS 7(7):678–683

Efficacy and safety of short-term bleach digestion of sputum in case-finding for pulmonary tuberculosis in Ethiopia

Tropical Medicine and International Health doi:10.1111/j.1365-3156.2007.01952.x

VOLUME 12 NO 12 PP 1459–1463 DECEMBER 2007

Same-day smears in the diagnosis of tuberculosis

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A one-day method for the diagnosis of pulmonary tuberculosis in rural Ethiopia

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WHO guidelines

- 2 sputum samples

WHO recommends the number of specimens to be examined for screening of TB cases can be reduced from three to two, in places where a well-functioning external quality assurance (EQA) system exists, where the workload is very high and human resources are limited.

- New smear-positive case

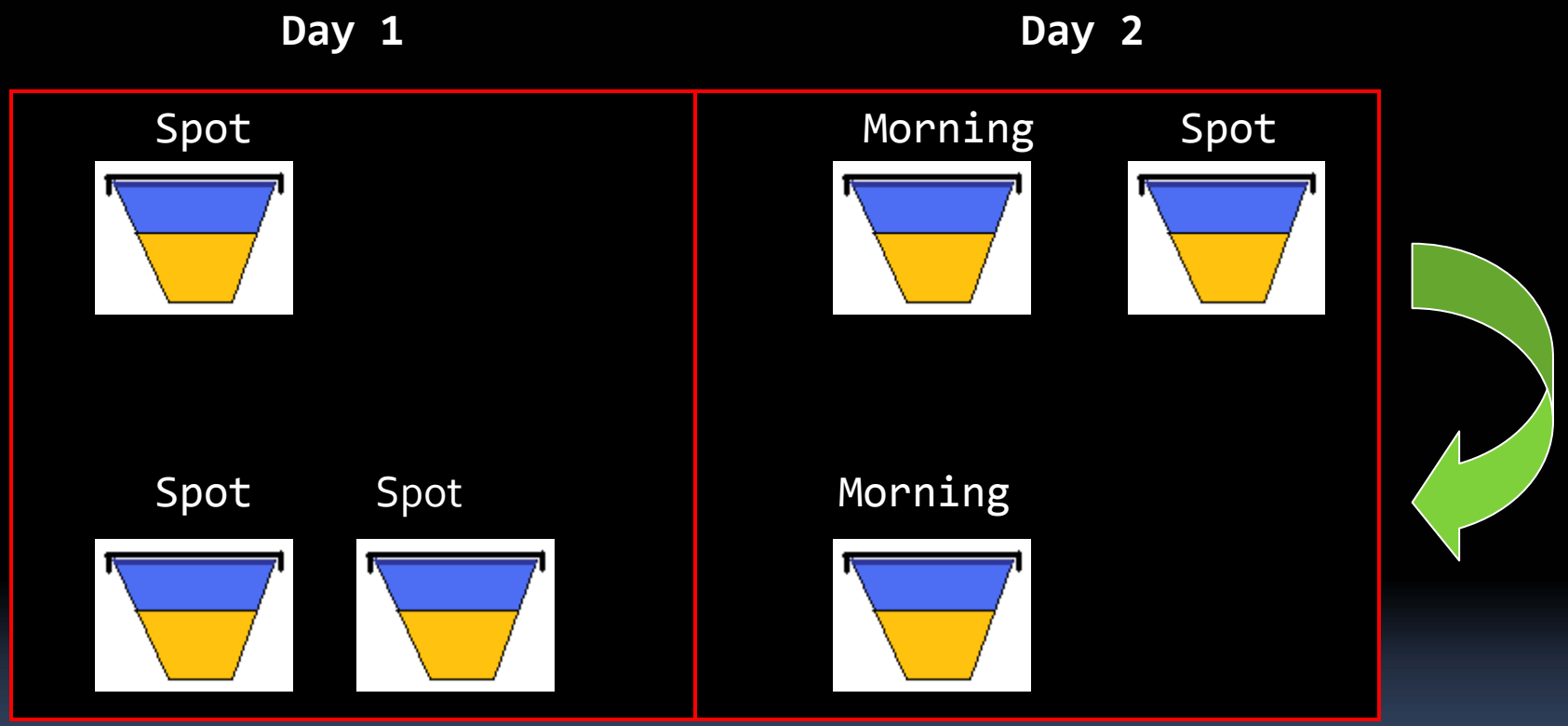
Revised definition of a new sputum smear-positive pulmonary TB case:

the presence of at least one AFB in at least one sputum sample in countries with a well functioning external quality assurance (EQA) system

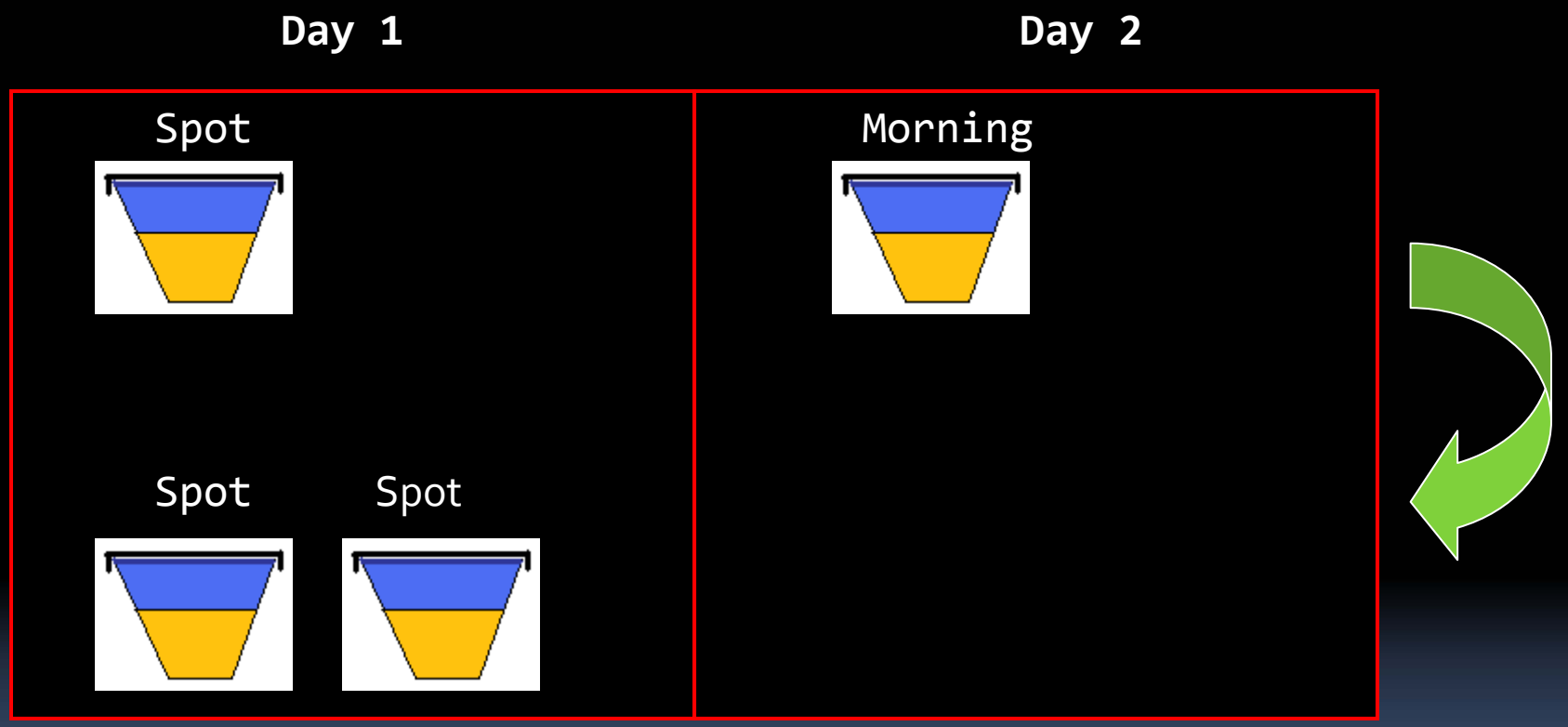
Two samples

- Spot-morning: reduced lab workload
- Same number of visits by the patient
- Could this be improved?

Frontloading smear microscopy



Frontloading smear microscopy



2006

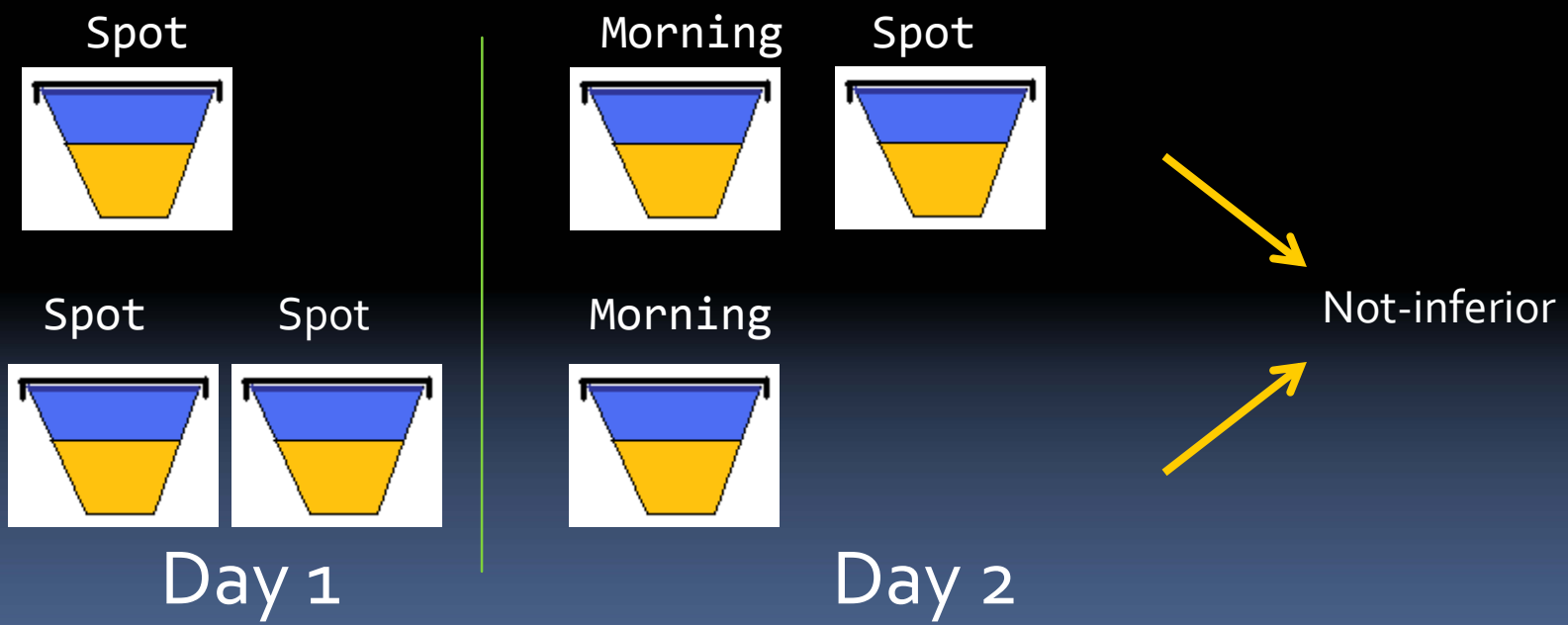
- Report that LED could be used to develop cheaper and long lasting LED-FM
- FM is faster
- Larger volume of samples

- Requires a dark room
- Short half life of light bulb
- Safety concerns

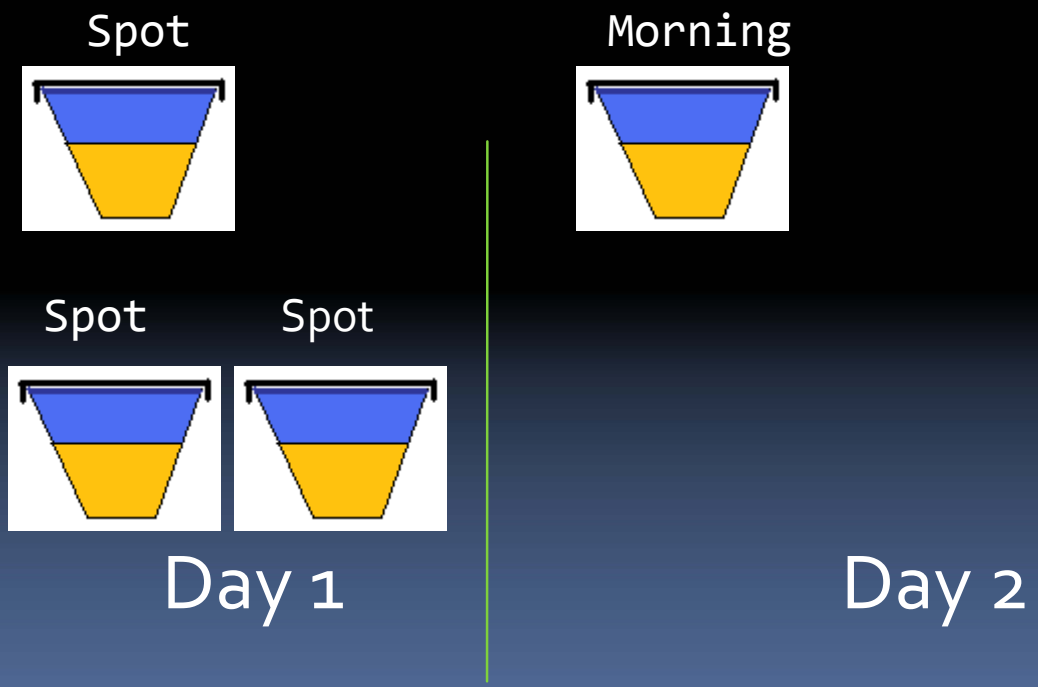
- Performance of LED-FM versus FM?

Same-day ZN

- Non-inferiority trial
- Adults with cough > 2 weeks
- Schemes randomised by week



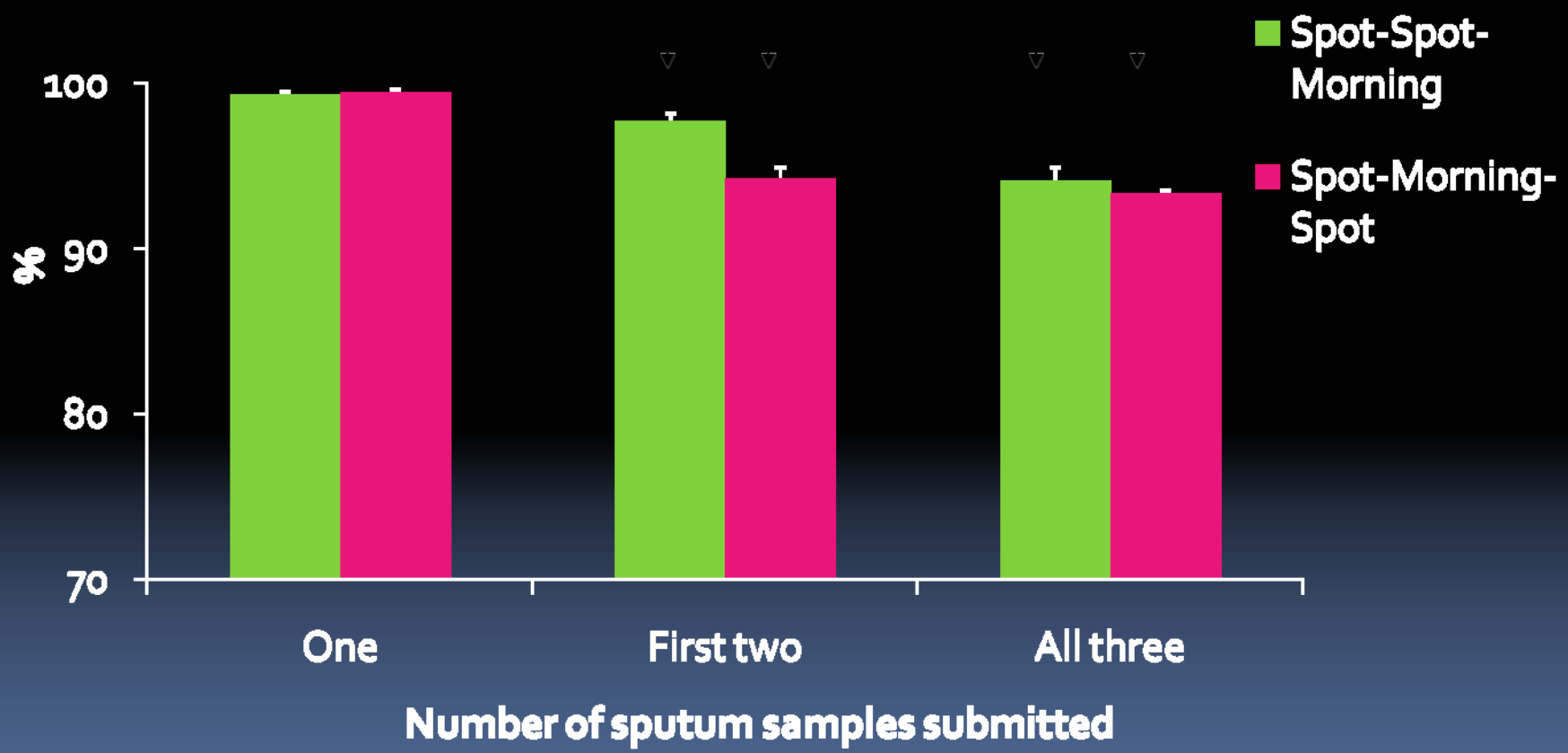
- Clinical trial
- Adults with cough > 2 weeks
- Schemes randomised by week



- Ethiopia
- Nigeria
- Yemen
- Nepal

- Reference standard: culture positive
- N = 6466

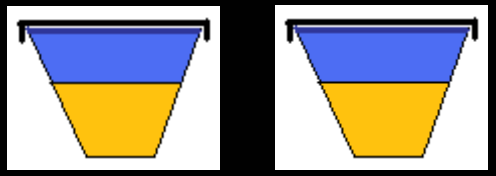
Percentage of patients submitting the first, first two and all three specimens



Analysis

Spot

Morning Spot



sensitivity

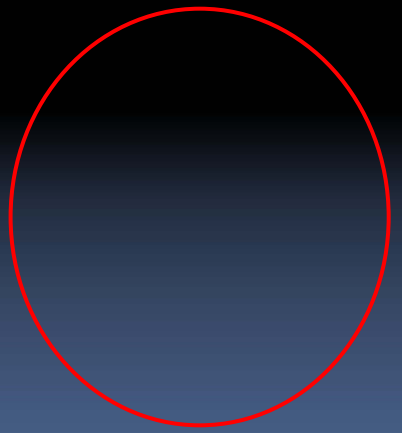
Spot Spot

Morning

SSM not inferior to SMS

Specificity*

- Same specificity



WHO guidelines

SAME-DAY-DIAGNOSIS OF TUBERCULOSIS BY MICROSCOPY

- POLICY STATEMENT -

July 2010

Review evidence

- Systematic reviews
- External expert panel
- Review evidence
- Grade strength of evidence
- Make recommendations
- STAG review/endorsement
- WHO adoption

- Countries that have successfully implemented the current WHO policy for a two-specimen case-finding strategy consider a switch to the same-day-diagnosis approach, especially in settings where patients are likely to default from the diagnostic process;

- Countries that are still using the three-specimen case-finding strategy consider a gradual change to the same-day-diagnosis approach, once WHO-recommended external microscopy quality assurance systems are in place and good quality microscopy results have been documented;

Considerations

- Changes to a same-day-diagnosis strategy be preceded by a detailed situation assessment of the programmatic, logistic and operational implications at country level, and supported by a carefully phased implementation plan that considers the following programmatic issues:

- Service providers should be able to initiate or refer patients for treatment on the same day of consultation. This will require training of health staff responsible for requesting sputum smear microscopy, instructing patients on sputum collection, and those responsible for registering patients and initiating treatment;

- Laboratory operations and procedures should be realigned with sputum collection and reporting of results on the same day, within existing human resource and laboratory workload constraints. Particular attention must be given to internal quality control and external quality assurance of microscopy procedures;

- Contact time between infectious patients and other vulnerable groups attending the same facility should be minimized, especially in settings with high HIV prevalence and/or drug-resistant TB burden. Separation and rapid triage of coughing patients is especially important to reduce the risk of TB transmission in health care settings;

- Monitoring of patient drop-out between laboratory- and patient registers, and of trends in case detection and treatment outcomes are therefore essential.

LED-FM

FLUORESCENT LIGHT EMITTING DIODE (LED) MICROSCOPY FOR DIAGNOSIS OF TUBERCULOSIS

Same process

- Larger studies
  - FIND
  - Liverpool

Accuracy of LED compared to ZN Systematic review

- 6% increase in sensitivity (95CI 0.1% - 13%),
- no appreciable loss in specificity,

LED-FM versus FM Systematic review

LED

- 5% (95CI 0% - 11%) more sensitive
- 1% (95CI -0.7% - 3%) more specific than FM

LED

- Similar gains in efficiency as FM
- Half the time than ZN for smear examination
- Improved cost-effectiveness of LED compared to ZN

Recommendations

- *Conventional FM be replaced by LED-FM in settings where FM is currently used*
- *LED-FM be phased in as an alternative for conventional ZN light microscopy in high- and low-volume laboratories*

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- Jailson Barros Correia
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- John Jolly


CAMPUS

- Questions?