Design, Conducting, and Analysing Field Epidemiological Study

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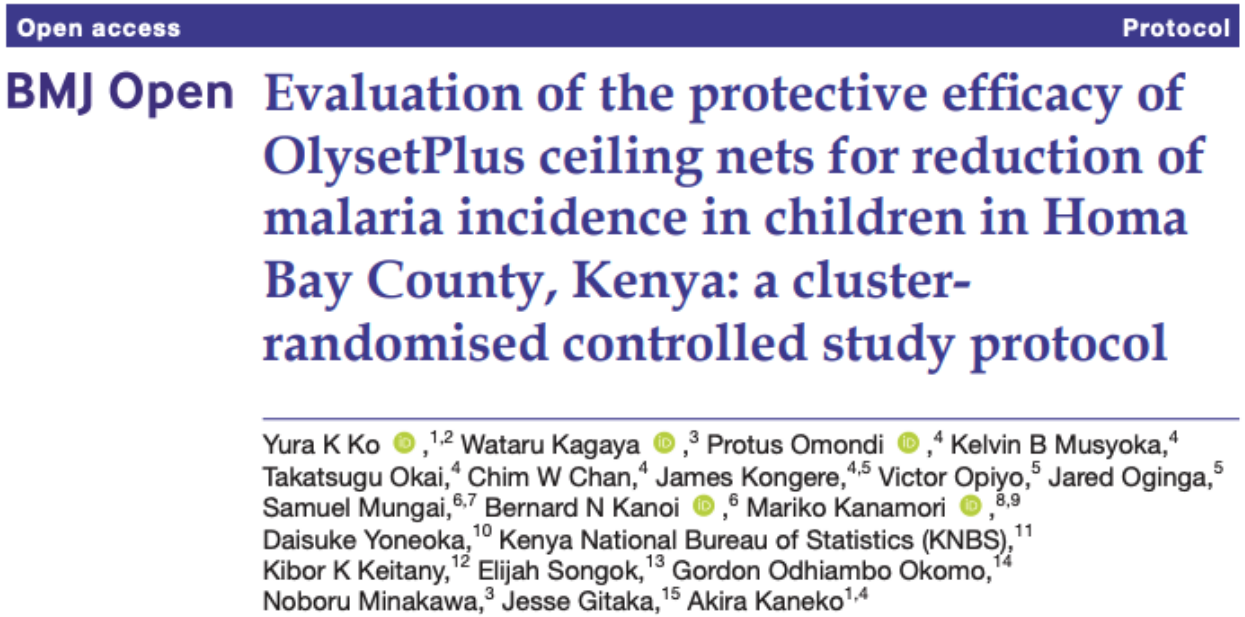
Outline

1. Design an experimental field study (45 min lecture)
2. Data handle and analysis (2 hr workshop)

How to evaluate the ceiling nets?



Open access Protocol

BMJ Open

Evaluation of the protective efficacy of OlysetPlus ceiling nets for reduction of malaria incidence in children in Homa Bay County, Kenya: a cluster-randomised controlled study protocol

Yura K Ko [1,2] Wataru Kagaya [3] Protus Omondi [4] Kelvin B Musyoka,[4] Takatsugu Okai,[4] Chim W Chan,[4] James Kongere,[4,5] Victor Opiyo,[5] Jared Oginga,[5] Samuel Mungai,[6,7] Bernard N Kanoi [6] Mariko Kanamori [8,9] Daisuke Yoneoka,[10] Kenya National Bureau of Statistics (KNBS),[11] Kibor K Keitany,[12] Elijah Songok,[13] Gordon Odhiambo Okomo,[14] Noboru Minakawa,[3] Jesse Gitaka,[15] Akira Kaneko[1,4]

How to evaluate the ceiling nets?

1. Objective

How to evaluate the ceiling nets?

Objective

1. Reduction of malaria infection? Or Clinical malaria?
2. Redution in incidence or prevalence?

...

Previous field studies

ARTICLES · Volume 401, Issue 10375, P435-446, February 11, 2023 · *Open Access* Download Full Issue

Efficacy of pyriproxyfen-pyrethroid long-lasting insecticidal nets (LLINs) and chlorfenapyr-pyrethroid LLINs compared with pyrethroid-only LLINs for malaria control in Benin: a cluster-randomised, superiority trial

Manfred Accrombessi, PhD [a,*] · Jackie Cook, PhD [b,*] · Edouard Dangbenon, MSc [c] · Boulais Yovogan, MSc [c] · Hilaire Akpovi, MD [c] · Arthur Sovi, PhD [a] · Constantin Adoha, MSc [c] · Landry Assongba, MSc [c] · Aboubacar Sidick, MSc [c] · Bruno Akinro, MSc [c] · Razaki Ossè, PhD [c] · Filémon Tokponnon, PhD [c] · Rock Aïkpon, PhD [d] · Aurore Ogouyemi-Hounto, PhD [d] · Germain Gil Padonou, PhD [c] · Immo Kleinschmidt, PhD [b,e,f] · Louisa A Messenger, PhD [a] · Mark Rowland, PhD [a] · Corine Ngufor, PhD [a] · Natacha Protopopoff, PhD [a,†] · Martin C Akogbeto, PhD [c,†] Show less

Variables	Descriptions
Intervention	New LLINs
Outcomes	Malaria case incidence
Test type	RDT only for symptomatic cases
Visit frequency	Every 2 weeks during the transmission season Every 1 month in the dry season
Parasite clearance at baseline	AL administration at enrolment and at 1 year after distribution
Endemicity	Assuming a control group incidence of 1 malaria case per child-year

Previous field studies

The American Journal of Tropical Medicine and Hygiene

Print ISSN: 0002-9637

Online ISSN: 1476-1645

A Longitudinal Cohort to Monitor Malaria Infection Incidence during Mass Drug Administration in Southern Province, Zambia

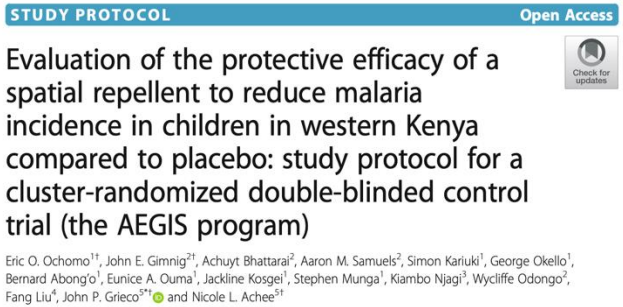
Adam Bennett, Travis R. Porter, Mu... View More +

DOI: https://doi.org/10.4269/ajtmh.19-0657 Page(s): 54–65

Volume/Issue: Volume 103: Issue 2_Suppl

Variables	Descriptions
Intervention	MDA
Outcomes	Infection incidence, time-to-first malaria infection
Test type	RDT and PCR for all
Visit frequency	Monthly
Parasite clearance at baseline	No clearance
Endemicity	High transmission strata: 1.8 infections per person-year Low transmission strata: 0.6 infections per person-year

Previous field studies


STUDY PROTOCOL Open Access

Evaluation of the protective efficacy of a spatial repellent to reduce malaria incidence in children in western Kenya compared to placebo: study protocol for a cluster-randomized double-blinded control trial (the AEGIS program)

Eric O. Ochomo[1†], John E. Gimnig[2†], Achuyt Bhattarai[2], Aaron M. Samuels[2], Simon Kariuki[1], George Okello[1], Bernard Abong'o[1], Eunice A. Ouma[1], Jackline Kosgei[1], Stephen Munga[1], Kiambo Njagi[3], Wycliffe Odongo[2], Fang Liu[4], John P. Grieco[5*†] and Nicole L. Achee[5†]

Variables	Descriptions
Interventino	Spatial repellent
Outcomes	Infection incidence, time-to-first malaria infection
Test type	RDT and microscopy
Visit frequency	Biweekly, monthly blood smear for all but RDT for those with symptoms, other rounds blood sampling only for those with symptoms
Parasite clearance at baseline	AL administration at enrolment
Endemicity	3.0 infections per person-year

How to evaluate the ceiling nets?

2. Study design

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Eg. distribute ceiling nets in the communuity, and assess malaria infection prevalence after one year comapring those who installed the ceiling nets to those who did not.

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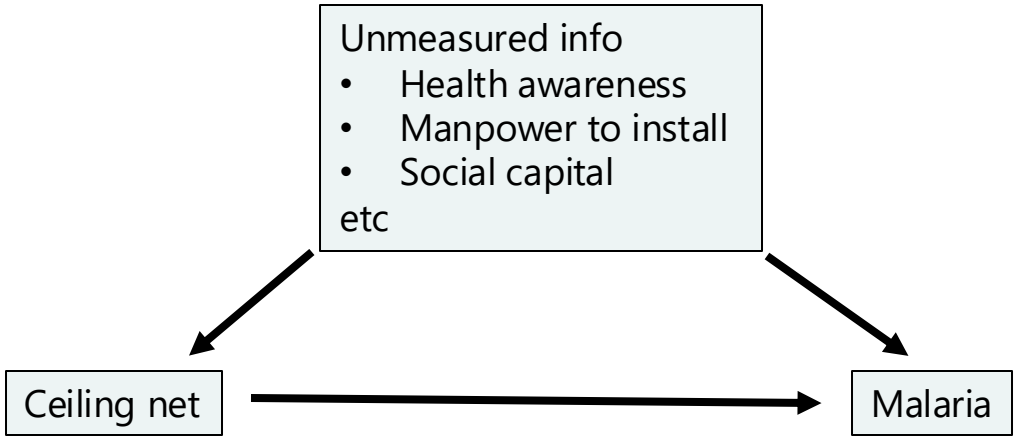
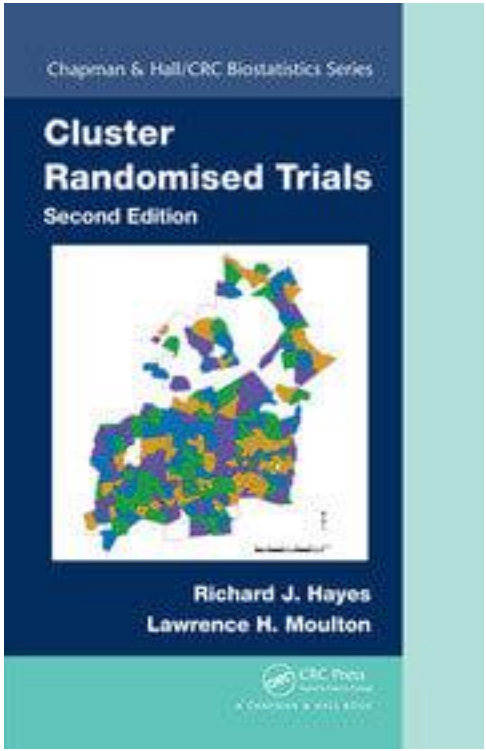
- **Comparing non-exchangeable populations**



How to evaluate the ceiling nets?

Study design

- Cluster Randomized Control Trial



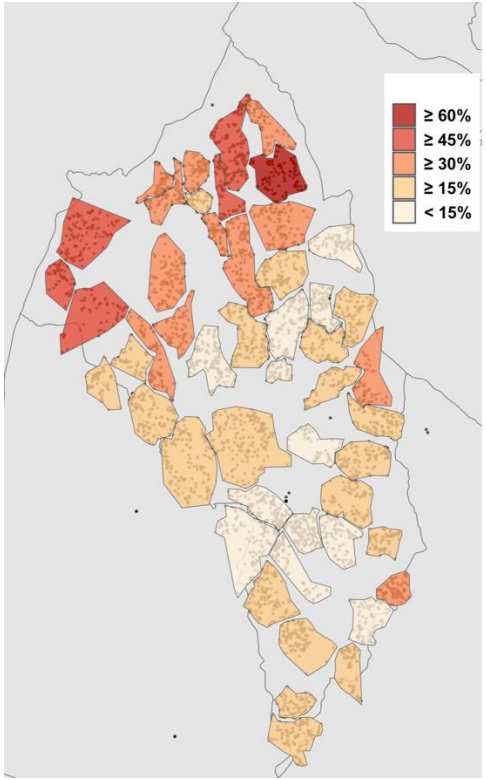
Why Cluster randomized trial?

- The intervention by its nature has to be applied to entire communities or other groupings of individuals; or it is more convenient or acceptable to apply it in this way.
- We wish to avoid the *contamination* that might result if individuals in the same community were to be randomised to different treatment arms.
- We wish to capture the population-level effects of an intervention applied to a large proportion of a population; for example, an intervention designed to reduce the transmission of an infectious agent.

Hayes, Richard J., and Lawrence H. Moulton. Cluster Randomised Trials, CRC Press LLC, 2017. ProQuest Ebook Central,

Cluster randomized trial

- Observations on individuals in the same cluster are correlated



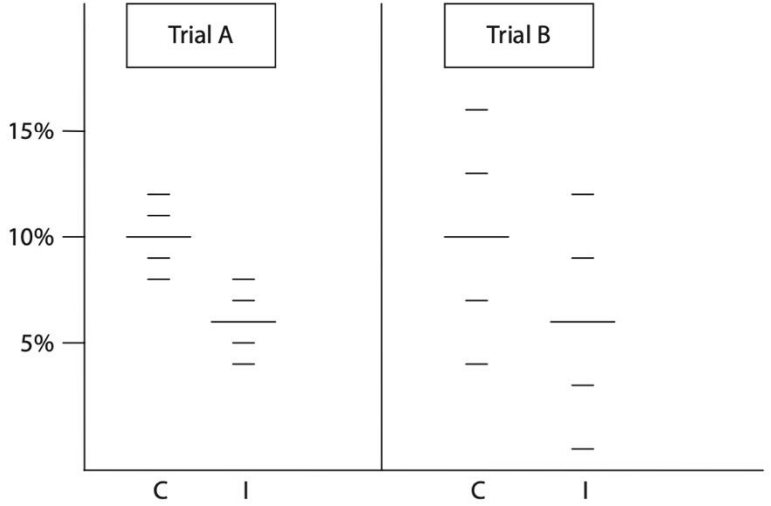


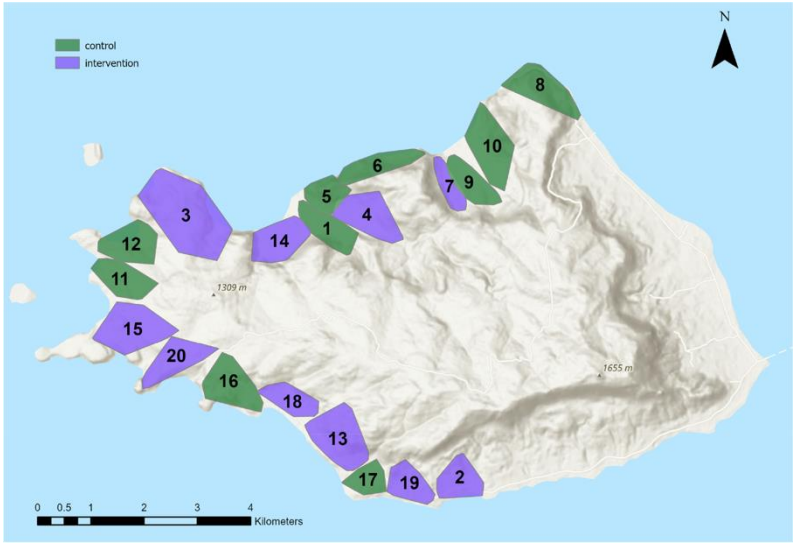
FIGURE 2.1
Prevalence of diarrhoea in children in 10 villages in two hypothetical CRTs (C: Control arm, I: Intervention arm).

Hayes, Richard J., and Lawrence H. Moulton. Cluster Randomised Trials, CRC Press LLC, 2017. ProQuest Ebook Central,

Study design

Cluster randomized trial

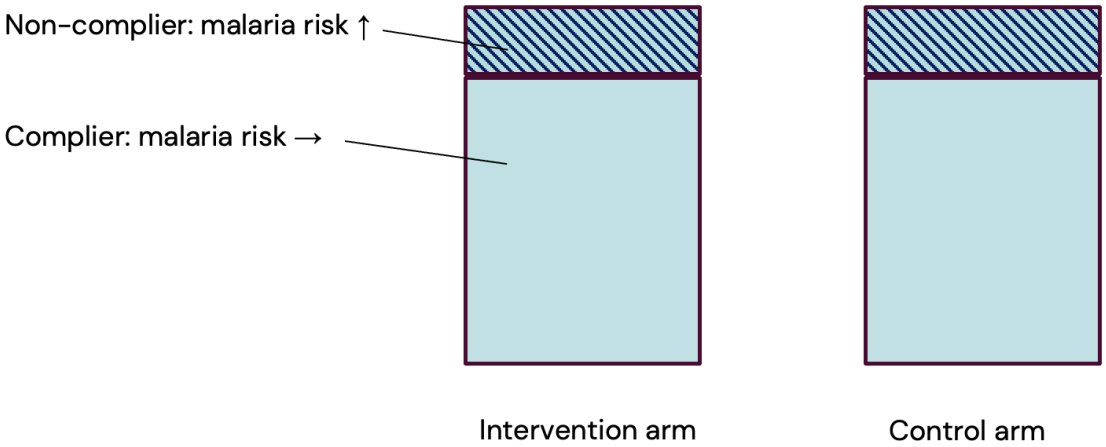
- With 20 clusters (10 intervention, 10 control clusters)
- Primary outcome: Clinical malaria incidence among children aged 0.5–14 y.o
- Monthly visit for malaria tests and questionnaires
- Follow up period: 1 year



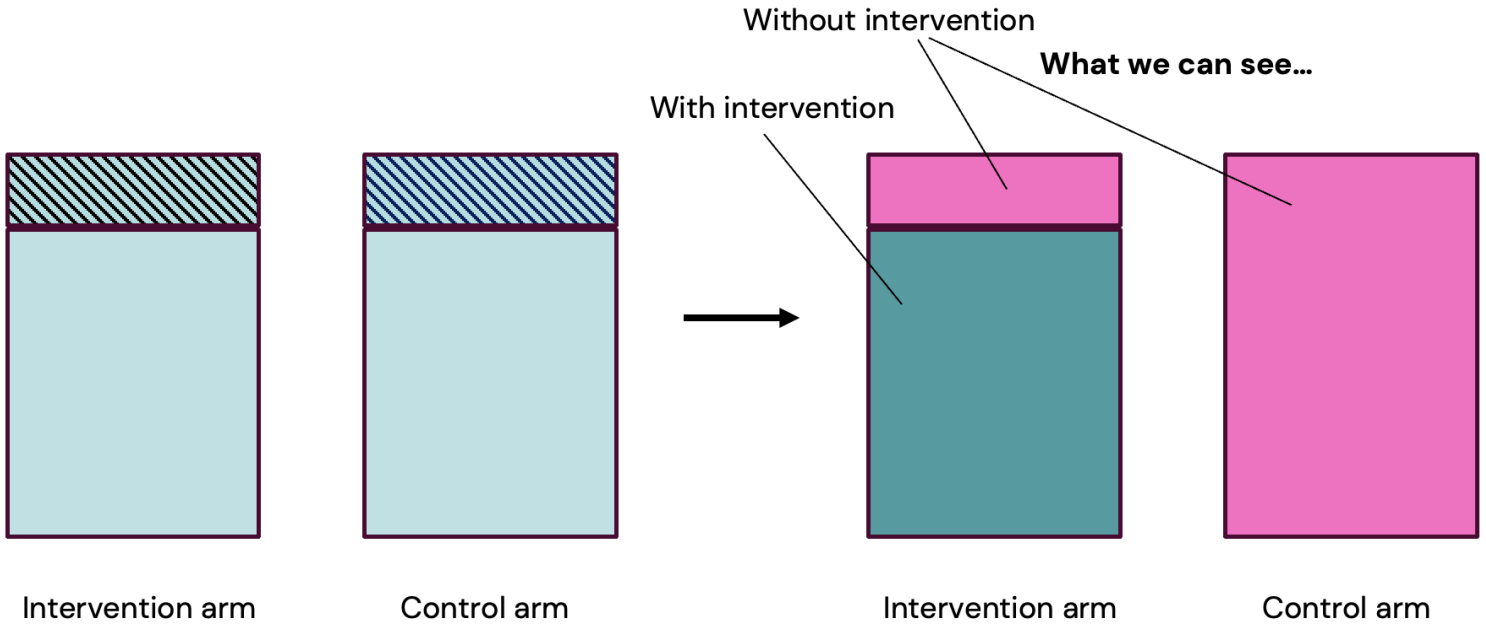
Analyse CRT data

1. Non-complier
2. Measurement errors

Non-complier

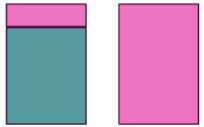


Non-complier

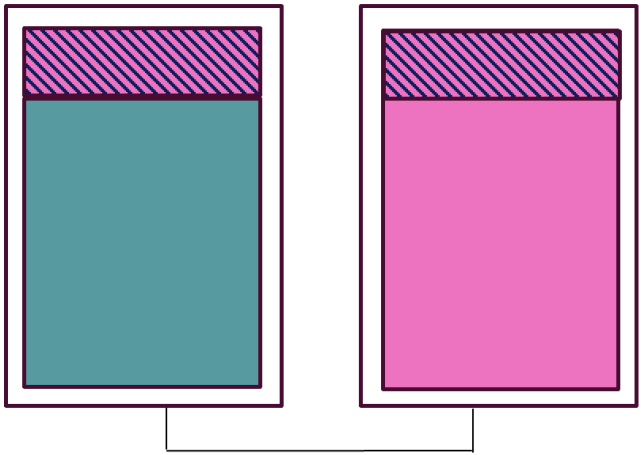


ITT vs PP

What we can see...

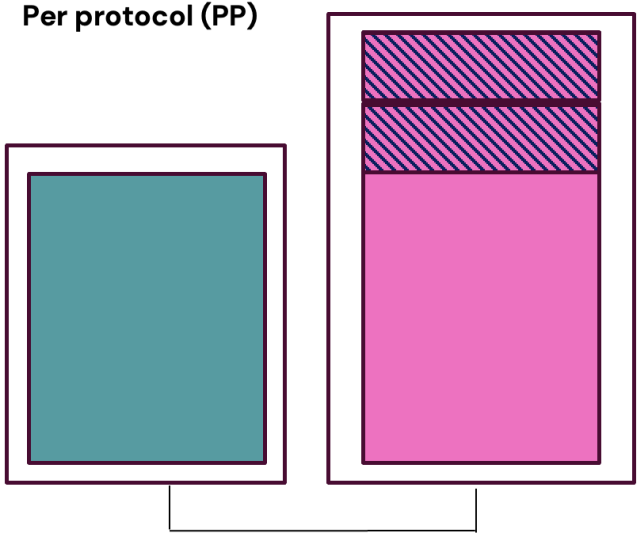


Intention to treat (ITT)



Underestimate the effect

Per protocol (PP)



Overestimate the effect

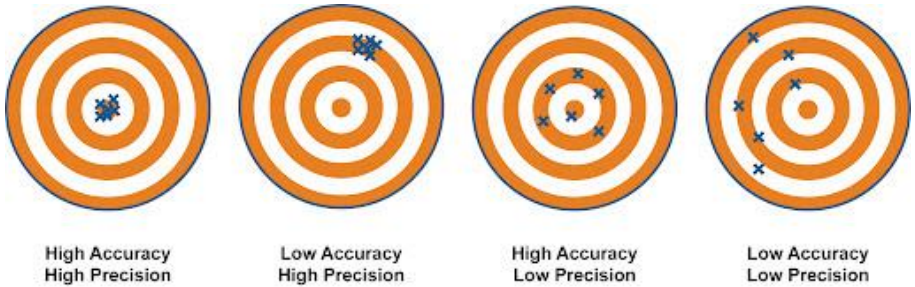
Measurement errors

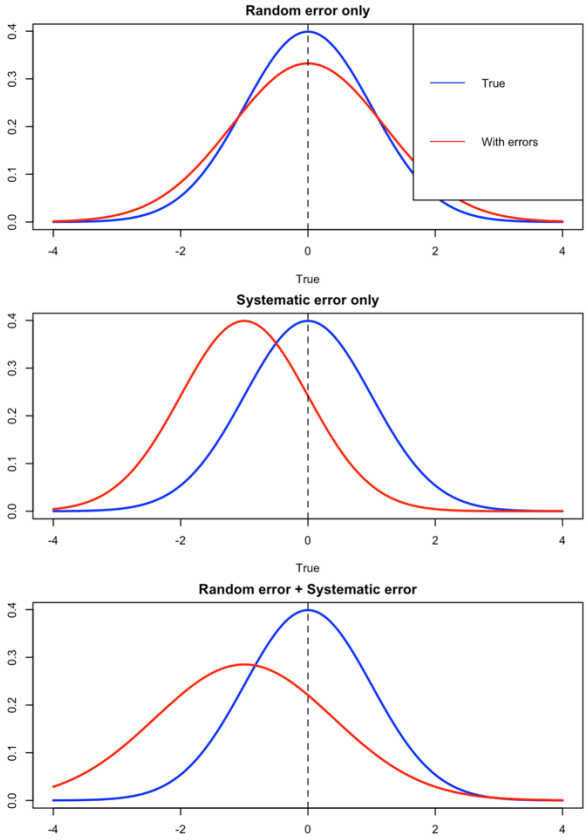
- **Random error**

Precision ↓ : 95% CI ↑

- **Systematic error**

Accuracy ↓ : cause biased estimates





Anticipated errors

1. Missing data

- Was the participant absent, or did they simply forget to record the data?
- Didn't know the info, or did they simply forget to record the data?

2. Incorrect data

- Missclasification of treatment or outcome
- Data recorded for the wrong person
- Unusual values (e.g., "1900/12/31", "2030/1/1", Body temperature: 47.1 °C)

Recommendations:

- A well-prepared data recording system to prevent incorrect data entry
- Regular data quality check and communication with field staff

Summary

1. Cluster randomized trial is the gold standard to evaluate new tool against malaria

2. Two measure bias source even after randomization:
    - Non complier
    - Measurement error

3. Intention-to-treat (ITT) is recommended to avoid overestimating efficacy

4. Measurement errors can be minimized by:
    - Careful preparation of data collection tools
    - Frequent data quality checks and communication with local staff