Methodology for monitoring data quality in cluster studies: application to the *TIMCI* project

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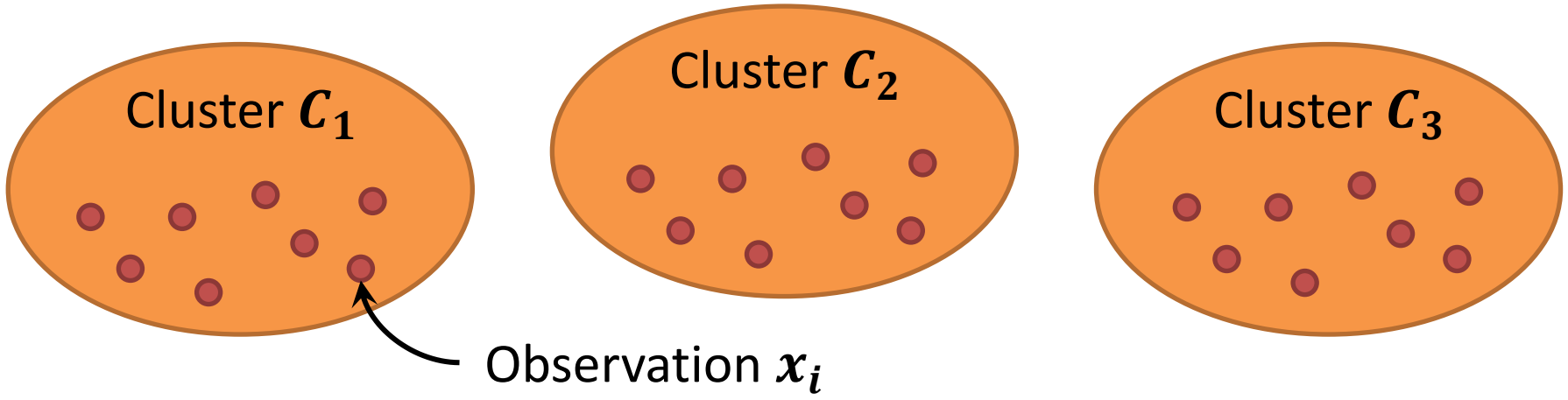
Presentation outline

- Introduction
- Methodology
- TIMCI project
- Results (application to TIMCI)
- Conclusion

Cluster studies

- individual observations **nested in a hierarchical structure** (*clusters*) [1]



- very common in **implementation research**, including **pragmatic studies**[2], to evaluate interventions in **real world** settings

[1]Galbraith S, Daniel JA, Vissel B. "A study of clustered data and approaches to its analysis." *J Neurosci. 2010 Aug 11;30(32):10601-8*. https://doi.org/10.1523/JNEUROSCI.0362-10.2010
[2]Weinfurt K. "What Is a Pragmatic Clinical Trial?: Why Are We Talking about Pragmatic Trials?" *Rethinking Clinical Trials: A Living Textbook of Pragmatic Clinical Trials 2024. Bethesda, MD: NIH Pragmatic Trials Collaboratory*. https://doi.org/10.28929/089.

Data quality in cluster studies

- essential to ensure valid and reliable research findings
- **variability across clusters**
  e.g., natural epidemiological variations, human factors (individual practices)
- specific challenges associated with **real-world data sources**, including **adaptation** of data collectors to practices within their cluster based on their understanding

Need for a **practical methodology** for **monitoring data quality** in **cluster studies**

Cluster- time partitioning

Full dataset $\mathcal{D} = \begin{bmatrix} C_1 & t_1 & x_1 \\ \cdots & \cdots & \cdots \\ C_K & t_M & x_N \end{bmatrix}$

N observations $x_{i=1,\ldots,N}$
K clusters $C_{k=1,\ldots,K}$
M time periods $t_{m=1,\ldots,M}$

Partition $\mathcal{D}_{C_k,t_m} = \{x_i | \ \mathbf{cluster}(x_i) \in C_k \cap \mathbf{time}(x_i) \in t_m\}$

	t_1	t_2	$\cdots$	t_M
C_1	$\mathcal{D}_{C_1,t_1}$	$\mathcal{D}_{C_1,t_2}$	$\cdots$	$\mathcal{D}_{C_1,t_M}$
C_2	$\mathcal{D}_{C_2,t_1}$	$\mathcal{D}_{C_2,t_2}$	$\cdots$	$\mathcal{D}_{C_2,t_M}$
$\cdots$	$\cdots$	$\cdots$	$\cdots$	$\cdots$
C_K	$\mathcal{D}_{C_K,t_1}$	$\mathcal{D}_{C_K,t_2}$	$\cdots$	$\mathcal{D}_{C_K,t_M}$

Statistical dispersion

Quality as a measure of **dispersion** of **clustered summary statistics**

Absolute modified z-scores

$$z_{C_k,t_m} = 0.6745 \times \frac{\left|\mathrm{X}_{C_k,t_m} - \tilde{\mathrm{X}}_{t_m}\right|}{\mathrm{MAD}_{t_m}}$$

X_{C_k,t_m} summary statistics for observations x_i in partition $\mathcal{D}_{C_k,t_m}$

$\tilde{\mathrm{X}}_{t_m}$ median of summary statistics X_{C_k,t_m} across all clusters for time period t_m

MAD_{t_m} median of absolute deviation $\left|X_{C_k,t_m} - \tilde{\mathrm{X}}_{t_m}\right|$ across all clusters for time period t_m

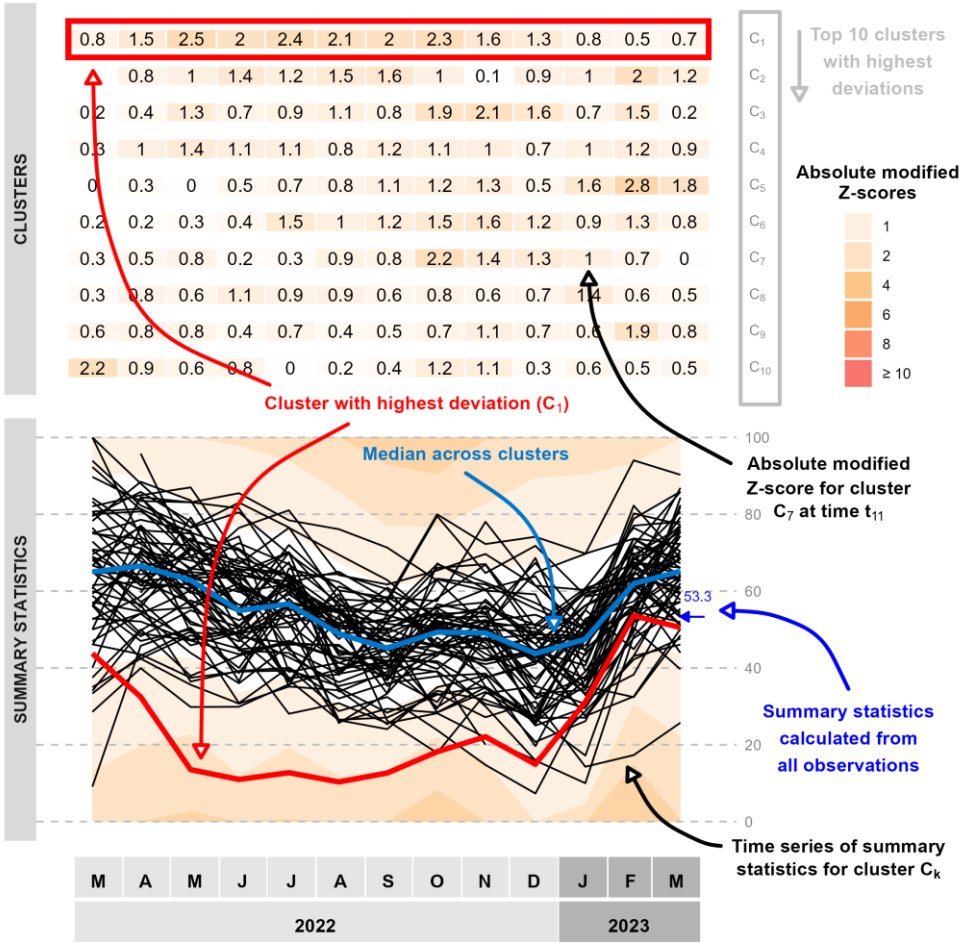
Iglewicz B, Hoaglin D. "How to Detect and Handle Outliers". *The ASQC Basic References in Quality Control: Statistical Techniques. 1993. In: Mykytka, E.F., Eds., How to Detect and Handle Outliers, ASQC Quality Press, Milwaukee, Vol. 16*.

Dispersion visualisation

- Heatmap of 10 **clusters with highest modified z-scores**

  outliers ⇒ $z_{C_k,t_m} \geq 3.5$

- Time series of **patterns of summary statistics** by individual clusters



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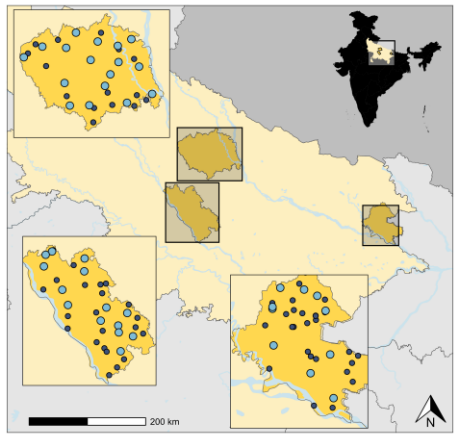
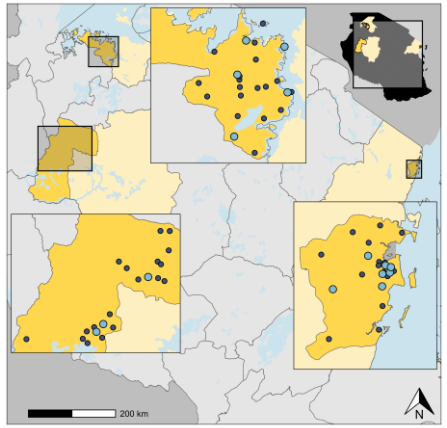
Project overview

TIMCI
Tools for Integrated Management of Childhood Illness

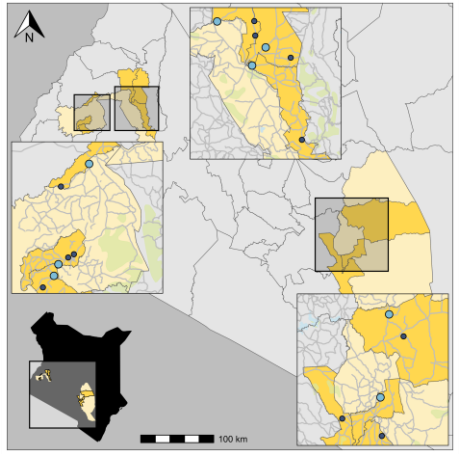
INDIA



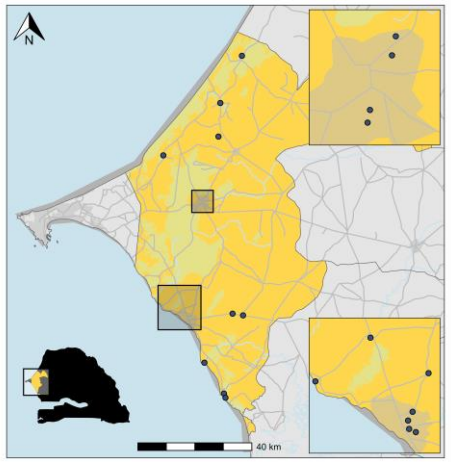
TANZANIA



KENYA



SENEGAL



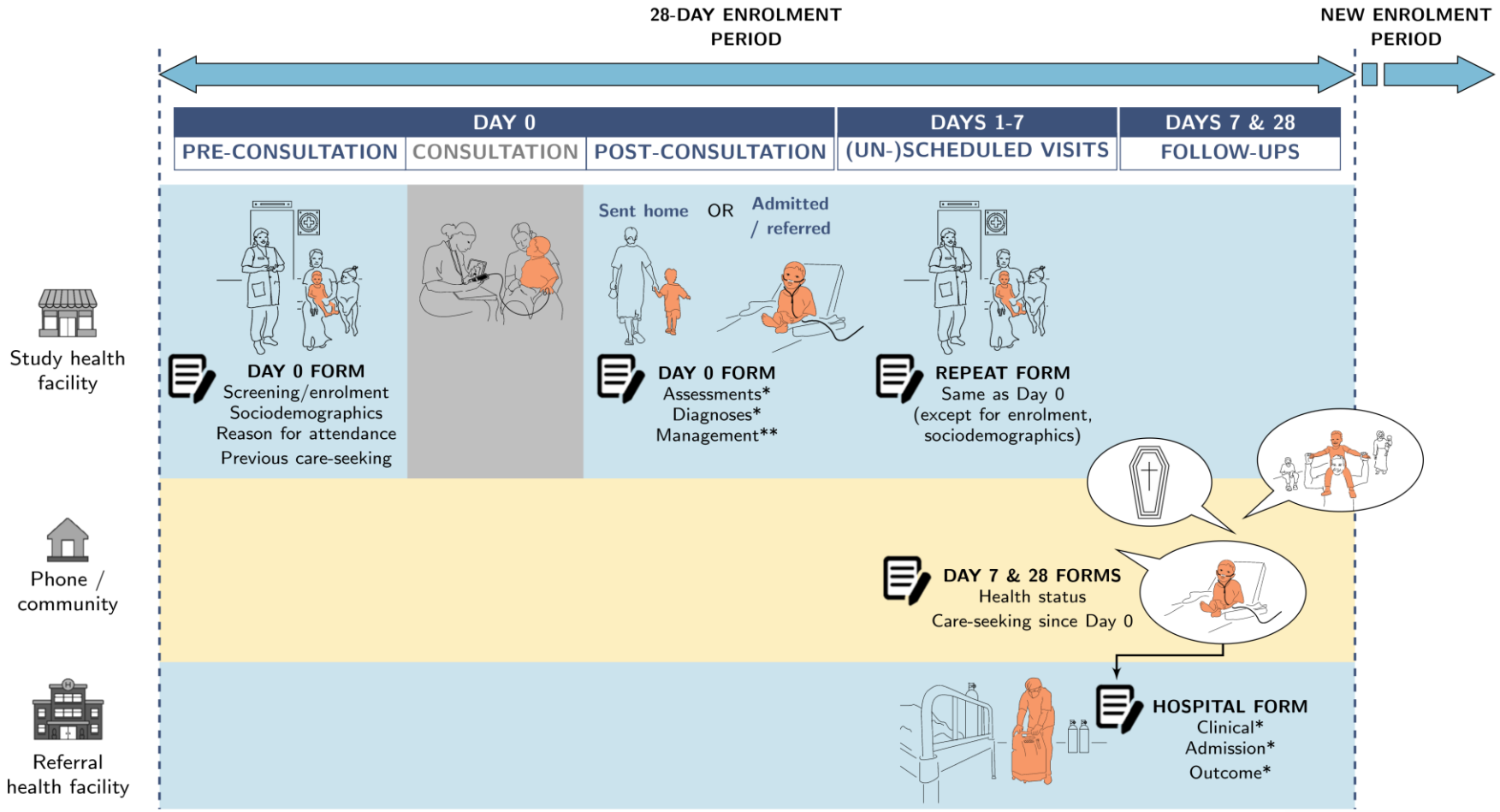
210 clusters (facilities)
209'269 children 0-59 months

- A **pragmatic cluster RCT**
  - NCT04910750
  - 106 facilities in India (9 months)
  - 66 facilities in Tanzania (12 months)
- A **quasi-experimental pre-post** study
  - NCT05065320
  - 19 facilities in Kenya (15 months)
  - 20 facilities in Senegal (18 months)

Beynon F, Langet H, Bohle LF et al. "The Tools for Integrated Management of Childhood Illness (TIMCI) study protocol: a multi-country mixed-method evaluation of pulse oximetry and clinical decision support algorithms." *Glob Health Action. 2024 Dec 31;17(1):2326253*. https://doi.org/10.1080/16549716.2024.2326253

Data collection flow

TIMCI
Tools for Integrated Management of Childhood Illness



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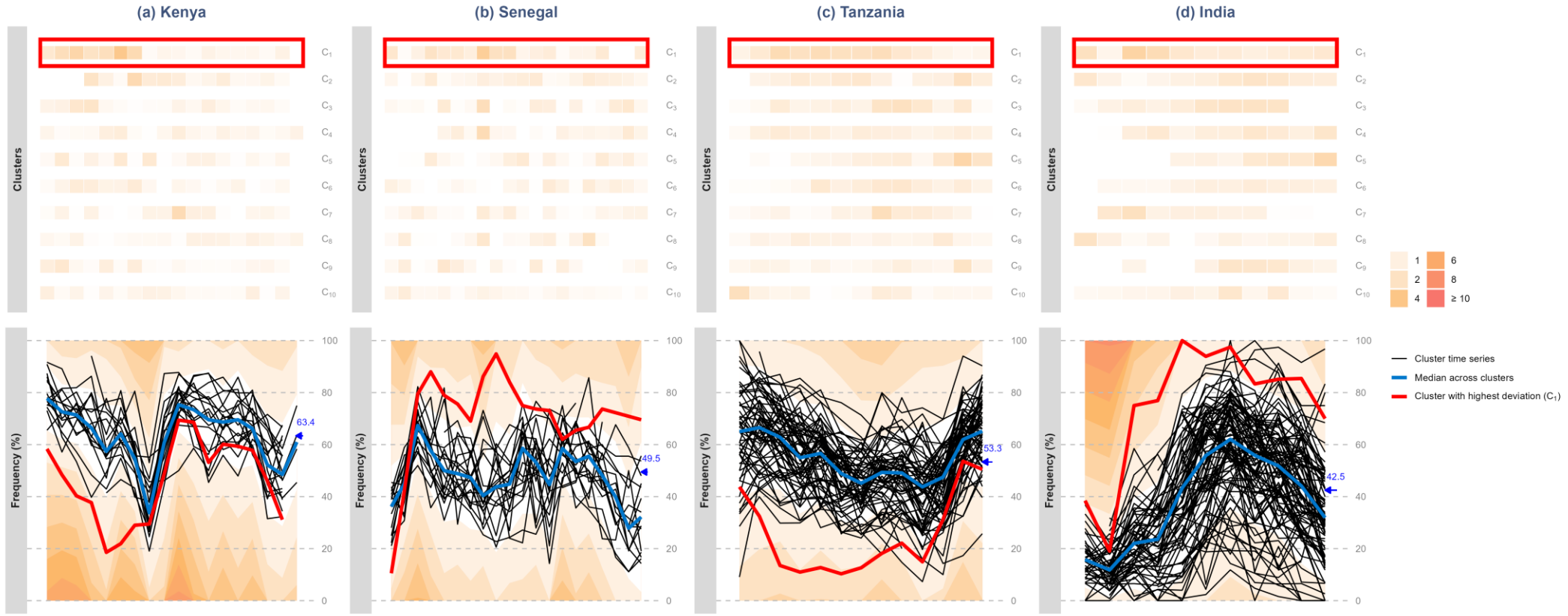
Results (application to TIMCI)

Review of a common event with natural epidemiological variations

Pre-consultation
Variable: **cough**
Source: **caregiver**
Statistics: **frequency**



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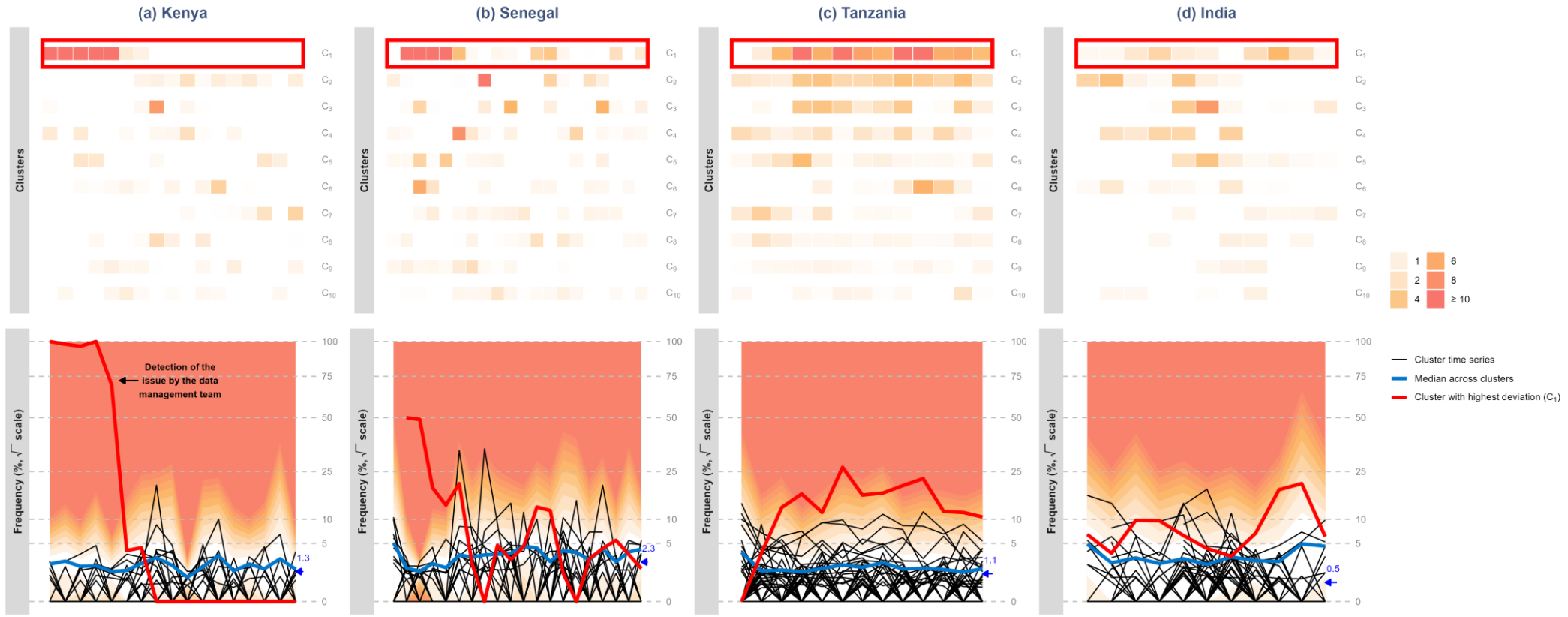
Results (application to TIMCI)

Review of a rare event

Post-consultation
Variable: **referral**
Source: **caregiver**
Statistics: **frequency**



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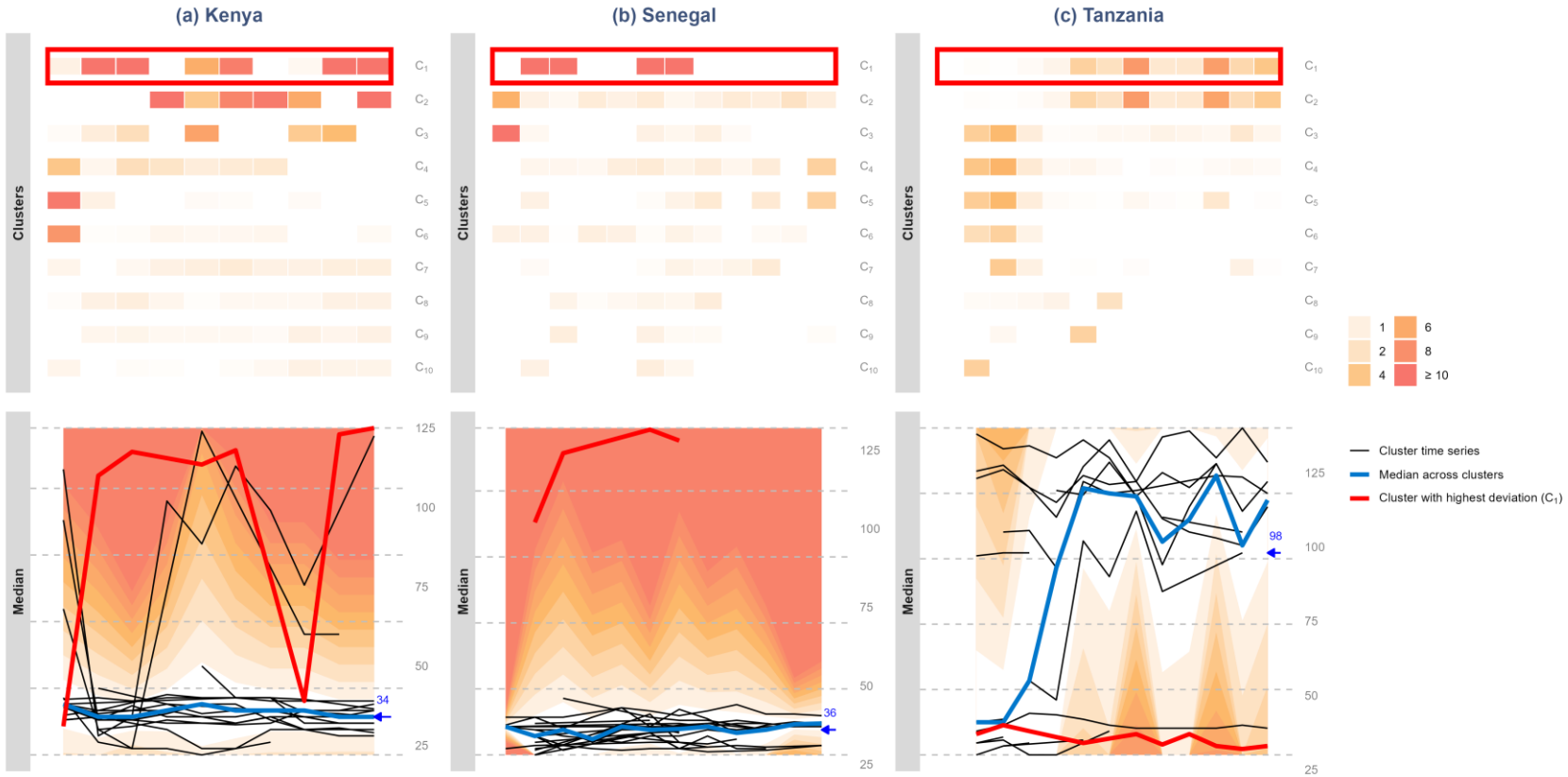
Results (application to TIMCI)

Review of a measurement

Post-consultation
Variable: **respiratory rate**
Source: **register**
Statistics: **median**



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Conclusion

- Targeted **identification** and **investigation** of potential data quality issues
- **Optimization** of the quality by adopting the approach early on and proactively implementing corrective measures throughout the **data acquisition process**
- Generation of **new knowledge**: findings can further inform the analysis and interpretation
- Can be adapted to integrate **other statistics**

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