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Feasibility and completeness of standardized clinical records in three cholera treatment units in Lilongwe District of Malawi during the 2022 to 2023 outbreak

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Abstract

Background

Malawi's 2022–2023 cholera outbreak was the country's most severe in decades, with mortality exceeding World Health Organization targets. Although timely, patient-level clinical data are essential for assessing care and improving outcomes, such data are difficult to collect systematically during health emergencies. This study therefore evaluated the feasibility and completeness of standardized individual-level data collection in selected cholera treatment units, with the aim of identifying a practical, streamlined approach to support clinical decision-making and future outbreak response.

Methods

Between 2022 and 2023, the World Health Organization (WHO), in partnership with the Malawi Ministry of Health, piloted standardized patient records to record and extract patient-level data to enhance clinical information during the epidemic. The clinical Platform recorded clinical information at admission, daily review, and discharge in three health facilities in Lilongwe district. A laboratory investigation was possible among pediatric patients to assess electrolyte balance.

Results

Data from 125 patients were recorded, including children under 5 years (n = 43, 25%), and adults (n = 52, 42%). A total of 75 variables were collected at admission, and up to 95 at discharge. Data completeness was lowest for vital signs (65%), clinical features (74%), and laboratory test values (24%, although these were only available to pediatric patients). Vital signs and clinical features were the least complete modules across all the data.

Conclusions

The successful integration of electronic patient-level data capture during the cholera outbreak in Malawi demonstrates its viability within current health system infrastructures. The pilot demonstrated which data was most important; focusing on key markers of adherence to guidelines can reduce the data overhead and ensure relevance to the quality of patient care. Implementing a standardized or digital checklist may further improve data completeness, thereby supporting the collection of reliable and actionable clinical information.

Background

Cholera remains a global public health challenge(1). In 2024, 809,561 cases and 5895 deaths related to cholera or acute watery diarrhea were reported from 33 countries (18 in Africa) (2, 3). In the previous

year (2023), nine countries reported exceptionally large numbers (> 10,000 cases), including Malawi, representing a 71% increase in deaths, with eight of the nine African countries having case fatality rates (CFRs) exceeding 2% (3, 4). Guidelines for cholera treatment from the WHO (and Global Task Force for Cholera Control, GTFCC) are essentially unchanged over 30 years and have contributed to effective treatment outcomes(5, 6) .

Given aging populations, patients in recent outbreaks are likely to have more complex needs related to co-morbidity, e.g., hypertension. The contribution of comorbidity to adverse outcomes, including malnutrition in children, has been unclear, but recent data from Zambia suggest HIV as an important prognosticator (7, 8). In the absence of real-world data from cholera epidemics, we lose the opportunity to gain experience about how to save lives and prevent morbidity in treatment facilities. The 2018 WHO Health Emergencies and Disaster Risk Management (Health-EDRM) report identified a notable gap in the collection of quantitative data during and after health emergencies (9).

In 2022/23, Malawi had its worst cholera outbreak since 1988 (10) (REFERENCE). Nationally, 58,730 cases and 1,759 deaths were reported, giving a CFR of 3% which significantly exceeded WHO targets of < 1% (3). Malawi is cholera-endemic, with annual outbreaks usually occurring during the rainy season from November to May. However, the 2022/23 outbreak extended beyond this period, with higher case and death counts seen in the central region (CFR range of 2.8% – 6.6%) compared to the northern (CFR range of 0.6% – 3.8%) and southern regions (CFR range of 1.4% – 4.6%) of the country(11). Seven districts (mostly in the central region) reported CFR > 4%.

This cholera outbreak in Malawi provided an opportunity to explore and optimize clinical data collection and analysis at the individual level. The piloting of standardized patient records and digital data capture tools in selected cholera treatment units would refine data-driven insights and enhance response and preparedness plans (12, 13). We aimed to inform and improve future outbreak response strategies by focusing on the most relevant data points, streamlining data collection processes, and supporting the delivery of high-quality patient care through reliable, actionable clinical insights. We thus performed a cross-sectional pilot study to assess the practicality of collecting and analyzing individual-level patient data during a health emergency.

Methods

Setting

The study focused on three high-burden CTUs in Lilongwe district (Kamuzu Central Hospital (KCH/Area33), Area 25, Bwaila). Each had a WHO or MoH implementation team. Data was recorded from these three sites between 1st February 2023 and May 30th, 2023. According to policy at the time, all children under 5 with cholera in Lilongwe were referred for care to KCH, where laboratory testing was available. There was a significant influx and disruption to health worker deployment due to the changing nature of the epidemic over time.

Implementation

The Public Health Institute of Malawi (PHIM) collaborated with WHO to implement the collection of individual-level data in selected cholera treatment units (CTUs). Data were recorded using three standardized data collection forms (patient admission, monitoring and discharge), which were developed by the WHO and the Ministry of Health (MoH) Clinical Services Department, with guidance from the Global Task Force on Cholera Control (GTFCC), and deployed on tablets using REDCap (Vanderbilt, USA) (14, 15). Hardcopy forms were also available.

Data Collection

Patient data upon admission included demographic details, vital signs, and symptoms were captured on an admission form,just as frontline teams need for effective triage and case management in implementation settings. At discharge, treatment summaries, lab results, and cholera diagnoses were documented, along with pregnancy and newborn outcomes when relevant, reflecting essential data points for monitoring and evaluating health interventions. For children admitted to Kamuzu Central Hospital's CTU, blood testing was performed by the main lab, ensuring consistent procedures that can be replicated and assessed in other care models.

Data collection for this pilot entailed extracting this information from patient notes during and after their stay at the treatment facility over a three-month period from February 2023. Data collectors were trained in methods and principles of data abstraction from medical records before data collection commenced.

Data analysis

The analysis focused on data completeness and descriptive statistics (stratified by age group), aiming to refine the scope and relevance of future data collection, which informs care quality. Data were analyzed using STATA version 17 (StataCorp, USA).

Ethical Considerations

The protocol for this secondary analysis was approved by the Kamuzu University of Health Sciences Research Ethics Committee (KUREC) (approval number P.10/25-1908). The analysis formed one objective of a broader approved study on the collection and utilization of individual-level clinical data in health emergencies in Malawi. The study was conducted in accordance with international and national ethical guidelines and the requirements of KUREC. The data were collected routinely during the outbreak response. Permission to access the anonymized data was obtained from the Public Health Institute of Malawi (PHIM) and the Ministry of Health (MoH) under a data sharing agreement. Individual informed consent was not sought because the study used anonymized secondary data and involved no contact with patients.

Results

Data completeness – At key time-points, up to 75, 85 and 95 variables were collected at admission, monitoring, and discharge, respectively. At admission, the completion rate was 74% with vital signs and clinical features the least complete. For discharge, completeness was 62%, see Figure 1.

Demographic characteristics - Clinical data were collected from 125 patients (median age 13 years, interquartile range [IQR] 3–25), see table 1. Thirty-four per cent (n = 43) of patients were under 5 years, and only two patients (1%) were above 65 years old. Males comprised 63% (n=79), and prior oral cholera vaccine was reported in only 3% (n=4) of all the cases. The length of stay in the facility was a median (IQR) of 2 (1-2) days.

Table 1 Characteristics of patients admitted to Lilongwe high-burden treatment units during the Malawi 2022-2023 cholera outbreak.

	< 5 years (n=43)		5 to < 18 years (n=30)		18 to < 65 years (n=50)		≥ 65 years (n=2)		Overall (n=125)	
Sex										
Male	29	67.0%	16	54.0%	32	64.0%	2	100%	79	63.0%
Female	14	33.0%	13	43.0%	18	36.0%	0	0%	45	36.0%
Unknown	0	0%	1	3.0%	0	0%	0	0%	1	1.0%
Facility/ Site										
Area 33	36	84.0%	10	33.0%	0	0%	0	0%	46	37.0%
Area 25	4	9.0%	9	30.0%	22	44.0%	1	50%	36	29.0%
Area 18	3	7.0%	11	37.0%	28	56.0%	1	50%	43	34.0%
Oral Cholera Vaccine received										
Yes	1	2.0%	2	6.7%	1	2.0%	0	0%	4	3.2%
No	38	89.0%	26	86.6%	42	84.0%	2	100%	108	86.4%
Unknown	4	9.0%	2	6.7%	7	14.0%	0	0%	13	10.4%

Clinical features at admission - In the 24 hours preceding admission, median (IQR) episodes of diarrhea were 3 (2-4), and vomiting 3.2 (SD 2.1). All patients had dehydration, which was severe in 55% and

moderate in 31%. Diarrhea was the most prevalent symptom (n=116, 93%), followed by vomiting (n=111, 89%). Less prevalent included muscle cramps (n=13, 10%) and shortness of breath (n=8, 6%).

Therapeutic intervention – Medication was given to 94% of all patients (n=117), of which antibiotic treatment was the most common (n=88 of 117), Table 2. All patients aged above 65 received antibiotics, whereas for children under the age of 5, only 86% (n=37 of 43) received antibiotics (16) . The most used antibiotics to treat cholera were macrolides, which were given to 47% of all the patients, tetracycline, which was given to 31% of all the patients and cephalosporins, which were given to 15% of all the patients (14%, n=16). For some patients, multiple antibiotic combinations were given, especially macrolides and cephalosporins. Intravenous fluids were used to treat dehydration in 72% (n=125) of all the patients, and furosemide was used to treat fluid overload in 5% of the patients. Nasogastric tubes were used to feed 26 of the patients across all age groups during their admission. Most of the patients (96.8%) were discharged without any adverse outcomes, and only one fatality was recorded (0.8%).

Table 2 Therapeutic interventions among cholera patients by age group during the Malawi 2022–2023 outbreak.

	<5 years (n=43)		5 to <18 years (n=30)		18 to 65 years (n=50)		≥ 65 years (n=2)		Overall (n=125)	
Enteral feeding, n (%)	5	12%	6	20%	14	28%	1	50%	26	21%
Electrolyte supplementation, n (%)										
Potassium	19	44%	7	23%	5	10%	0	0%	31	29%
Glucose	0	0%	1	3%	2	4%	0	0%	3	2%
Zinc	36	84%	13	43%	3	6%	0	0%	52	42%
Fluid use										
ORS, n (%)	36	84%	26	86%	44	88%	2	100%	108	86%
iv. fluids, n (%)	32	74%	22	73%	35	70%	1	50%	90	72%
Total L iv fluid received, mean (SD)	2.6	(1.5)	7.5	(8.2)	7.6	(6.3)	0	0%	5.6	(6.1)
Prescribed medications, n	n=43		n=29		n=43		n=2		n=117	
Antibiotics, n (%)	37	86%	19	66%	30	70%	2	100%	88	75%
Antibiotic type, n (%)										
Penicillin	1	2%	0	0%	0	0%	0	0%	1	1%
Cephalosporin	13	25%	3	13%	0	0%	0	0%	16	15%
Macrolide	36	69%	11	48%	3	10%	0	0%	50	47%
Quinolone	2	4%	3	13%	0	0%	0	0%	5	5%
Cotrimoxazole	0	0%	1	4%	0	0%	0	0%	1	1%
Tetracycline	0	0%	5	22%	26	90%	2	100%	33	31%
Treatment for fluid overload, n (%)	n=41		n=26		n=37		n=2		n=109	
Furosemide	3	60%	1	20%	1	20%	0	0%	5	4%

Laboratory investigation - Serum sample analysis was possible for 30 pediatric patients. In keeping with severe hypovolemia, common life-threatening abnormalities were hypokalemia (n=18, 60%), hyperchloremia (n=22, 73%), and hyponatremia (n=21, 70%), Table 3, which require timely monitoring and intervention , as it can result in acute kidney failure(17,18). Hypokalemia was severe in 13% (n = 4,

K^+ < 2.5mmol/L), moderate in 33% (n = 10, K^+ 2.5 – 2.9 mmol/L) and mild in 4% (n = 4, K^+ 3.0 – 3.4). Anemia, defined as a Hemoglobin level of <11.5g/dL, occurred in n=17 patients (57%).

Table 3 Results of serum sample analysis of pediatric patients admitted during the Malawi 2022-2023 cholera outbreak.

N = 30		
Hemoglobin (Hb)		
Below LLN	17	57%
Normal	7	23%
Above ULN	6	20%
Sodium (Na^+)		
Below LLN	21	70%
Normal	9	30%
Above ULN	0	0%
Potassium (K^+)		
Below LLN	18	60%
Normal	12	40%
Above ULN	0	0%
Creatinine (Cr)		
Normal	21	70%
Above ULN	9	30%
Chloride (Cl^-)		
Below LLN	1	3.3%
Normal	7	23.3%
Above ULN	22	73.3%

Discussion

We demonstrated that standardized patient-level data can be systematically collected during a health emergency and used to identify clinically important gaps in care. Beyond its immediate value for cholera management, this capability is a component of health-system resilience: it enables services to detect deviations from recommended care, adapt clinical processes during a surge, and retain evidence for

preparedness and recovery. The findings raised important unanswered questions. For example, does the use of furosemide indicate pulmonary oedema related to fluid use in patients at risk, or a misguided intervention to improve urine output (19). he high rates of hypokalemia might be expected, but are potentially life-threatening; further work should establish whether it resolves sufficiently rapidly with usual treatment, or is specific potassium replacement. This concern is reinforced by evidence from the same outbreak showing that inadequate intravenous-fluid management during the first six hours of care was a major predictor of cholera mortality in Malawi (19). These treatment and monitoring questions should be interpreted against current WHO guidance on rehydration, electrolyte management, and surveillance for complications (20)

In terms of data capture, patient numbers in the targeted CTUs significantly exceeded the number of data entries. This gap illustrates that digital availability alone does not create a resilient information function. Electronic capture depended on paper source notes, tablet use compatible with infection prevention and control requirements, systematic record storage, and sufficient staffing despite rapid patient turnover and the absence of 24-hour data-entry coverage.

Completeness was particularly low for repeated monitoring and discharge variables, and unstructured patient notes further limited extraction despite the provision of proformas. Resilient implementation therefore requires a hybrid workflow that can continue during connectivity, staffing, or device constraints while preserving a small set of clinically actionable data elements. These barriers are consistent with evidence that successful electronic medical record implementation in low-resource settings depends on adequate infrastructure, staff training, human resources, and integration with clinical workflows (21, 22).

At scale, these limitations could be addressed through structured forms focused on essential clinical and quality-of-care indicators, comprehensive staff training, digital tools compatible with infection prevention and control standards, and regular audits of completeness and timeliness (23, 24). Data collection should be coupled with rapid facility-level feedback so that missing observations, departures from treatment guidance, and emerging complications can trigger corrective action during the response rather than being identified only after the outbreak.

We found it useful to distinguish an ideal digital architecture from a pragmatic and resilient minimum solution(see Table 4)(25, 26) The ideal system would capture data once at the point of care, validate entries, integrate clinical and epidemiological records through a unique identifier, and provide near-real-time dashboards to facilities and national response teams. Where infrastructure cannot support this model, a structured paper record with rapid electronic transfer of a limited dataset can preserve continuity, reduce duplicate transcription, and maintain compatibility with national platforms such as DHIS2. The objective is therefore not full digitization at any cost, but a dependable information pathway that continues to generate actionable data under emergency conditions.

Table 4
Proposed data collection approach in Cholera Treatment Facilities during an outbreak.

Data-related activity	**Prior situation / during the data collection period**	**"Perfect situation"**	**Pragmatic compromise *(being developed within the WHO Global Clinical Platform)***
Note keeping	Unstructured paper notes were held in different parts of the cholera treatment facility.	Directly on the electronic patient record (EPR), including intermittent observations, with entry validation and prompts to ensure completeness and accuracy.	Record keeping using a structured proforma kept systematically as a paper record, which systematically captures key aspects of treatment guidelines, and important patient details, using checklists where possible, while allowing additional details where required.
Data capture	Transcription to an offline electronic system with intermittent upload or low bandwidth data.	None required (EPR), but fully integrated with local and national systems (e.g., DHIS2)	Rapid electronic capture, with potential for machine-reading of photographed records.
Integration with epidemiological data	None.	Harmonization of two systems with a unique identifier to maximize epidemiological and clinical insights.	Both epidemiological and clinical data are collected on the same platform at the level of the facility.
Analysis	Feedback to the public health institute mid-way through the outbreak based on programmed analysis.	Interactive near-real-time dashboarding available to health facilities, and higher-level MoH / public health oversight (with appropriate access restrictions).	Online dashboards are available 24/7, limited only by data upload recency. These contain time and facility-filterable data giving insights into patient demographics, outcomes, and treatment adherence. Intermittent structured reports with the same content available offline.
Audit + learning	Feedback to the community of practice through presentations, seeking improvements in readiness for future outbreaks.	Regular structured debrief at multiple levels of the response pillar (facility and up). Benchmarked performance indicators using international guidelines as the reference standard. Mortality audit / "deep dives" triggered by excessive mortality.	As per "perfect situation."

Even within the pragmatic compromise, there are tensions. For example, clinicians typically describe a “gold standard” extensive clinical history which informs the design of case records. They are rarely fully completed outside of research settings, and this is not a desirable target during outbreaks when large volumes of patients present concurrently and when the largest benefits accrue from standardizing care processes (27). Electronic systems, while likely to improve data completion rates (28), may not be a favored solution, especially in temporary facilities, highly unstable environments, and where IT system failure with no redundancy would have an exceptionally large negative impact on care. Further field evaluation of the platform will address these issues.

While these data represent a small cohort, some interesting findings should lead to further implementation research. The predominance of male patients (63%) aligns with broader epidemiological surveillance and suggests that occupational and social determinants, such as increased exposure to poor sanitation among small-scale entrepreneurs and manual laborers, may influence cholera risk. This was similarly observed during the 2012 cholera outbreak in Sierra Leona (29). We found low vaccination rates, which are consistent with the expectations for early phases of outbreaks in newly affected regions. This is further compounded by constrained global supplies of oral cholera vaccine (OCV), which limit rapid intervention efforts (30, 31) .

Notably, although Malawi received approximately 4 million OCV doses in 2022/23, the vaccination campaign commenced after our data collection period(32, 33). Although two-dose regimens provide longer-lasting protection, evidence indicates that a single OCV dose can offer meaningful short-term protection during outbreaks(34), supporting its use when vaccine supplies are constrained (35). Future research should leverage similar data collection frameworks before, during, and after OCV roll-out to confirm the effectiveness(36), reach, and equity of vaccination implementation. Such insights could inform adaptive strategies for improving vaccine deployment and uptake in comparable settings.

The proposed model has distinct functions across the emergency cycle. During preparedness, standardized forms, trained personnel, agreed indicators, and interoperable platforms can be established and tested. During response, a concise dataset can support triage, guideline-adherence monitoring, resource allocation, and rapid detection of complications. During recovery, linked clinical and epidemiological data can support mortality review, evaluation of interventions, revision of protocols, and retention of institutional learning for subsequent outbreaks.

Our pilot study was confined to urban settings in Lilongwe, with limited generalizability to rural, temporary, and lower-connectivity treatment facilities, and the small number of older adults restricted assessment of comorbidity and outcomes in that population. The extensive variable set was intentional because it enabled identification of the information that was useful, feasible, and valued; however, the next iteration should test a reduced core dataset across more diverse settings. Future implementation research should assess data timeliness and use in decision-making, interoperability with routine systems, workforce and infrastructure requirements, offline continuity, cost, user acceptability, and whether feedback from the platform improves guideline adherence or patient outcomes. This study was

conducted as part of public health emergency response to cholera and no prospective sample size calculation was performed.

Finally, integrating standardized data collection into already existing health-system infrastructure was feasible, although pragmatic compromises were necessary. The principal contribution of the pilot is therefore not the adoption of a stand-alone digital tool, but the establishment of a learning function that can connect frontline documentation, analysis, feedback, and corrective action. If maintained between outbreaks and linked to routine information systems, this function could help services preserve continuity and quality of care during surges, retain lessons after the emergency, and iteratively strengthen preparedness for subsequent events.

Conclusions

Standardized patient-level data capture was feasible during Malawi's cholera response, but its value depended on integration with frontline workflows, a manageable core dataset, trained personnel, and reliable mechanisms for analysis and feedback. A pragmatic hybrid model combining structured documentation, rapid electronic capture, interoperability with routine information systems, and facility-level audit could strengthen continuity and quality of care during outbreak surges. Embedding this capability between emergencies would convert response data into institutional learning, thereby supporting preparedness, adaptive response, and recovery. Further multisite evaluation should determine whether the model improves data completeness and timeliness, guideline adherence, decision-making, and patient outcomes across diverse resource-constrained settings.

Abbreviations

CFR — Case fatality rate

Cl^- — Chloride

Cr — Creatinine

CRF — Case reporting form

CTF — Cholera treatment facility

CTU — Cholera treatment unit

DHIS2 — District Health Information Software 2

EPR — Electronic patient record

GTFCC — Global Task Force on Cholera Control

Hb — Haemoglobin

Health-EDRM — Health Emergency and Disaster Risk Management

HIV — Human immunodeficiency virus

IPC — Infection prevention and control

IQR — Interquartile range

IT — Information technology

IV — Intravenous

K^+ — Potassium

KCH — Kamuzu Central Hospital

LLN — Lower limit of normal

MoH — Ministry of Health

Na^+ — Sodium

OCV — Oral cholera vaccine

ORS — Oral rehydration solution

PHIM — Public Health Institute of Malawi

REDCap — Research Electronic Data Capture

SD — Standard deviation

STATA — Statistical software package used for data analysis

ULN — Upper limit of normal

WHO — World Health Organization

Declarations

Ethics approval and consent to participate

The protocol for this secondary analysis was approved by the Kamuzu University of Health Sciences Research Ethics Committee (KUREC), Malawi (approval number P.10/25-1908). The study was conducted in accordance with international and national ethical guidelines and the requirements of KUREC. The study used anonymised patient data collected routinely during the national cholera outbreak response. Permission to access and analyse the data was obtained from the Public Health Institute of

Malawi and the Malawi Ministry of Health under a data sharing agreement. No patients were contacted or recruited. Individual informed consent was therefore not sought for this secondary analysis.

Consent for publication

Not applicable. The manuscript does not contain identifiable individual-level information, images, or videos.

Availability of data and materials

The dataset analysed during this study is not publicly available because it contains patient-level clinical information but may be available from the corresponding author on reasonable request and with permission from the Public Health Institute of Malawi and the Malawi Ministry of Health.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

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All authors have approved the submitted version of the manuscript and agree to approve any substantially modified version that affects their contributions to the study. Each author accepts personal accountability for their own contributions and agrees to ensure that any questions concerning the accuracy or integrity of any part of the work, including areas in which they were not personally involved, are appropriately investigated and resolved, with the resolution documented in the literature where necessary.

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Figures

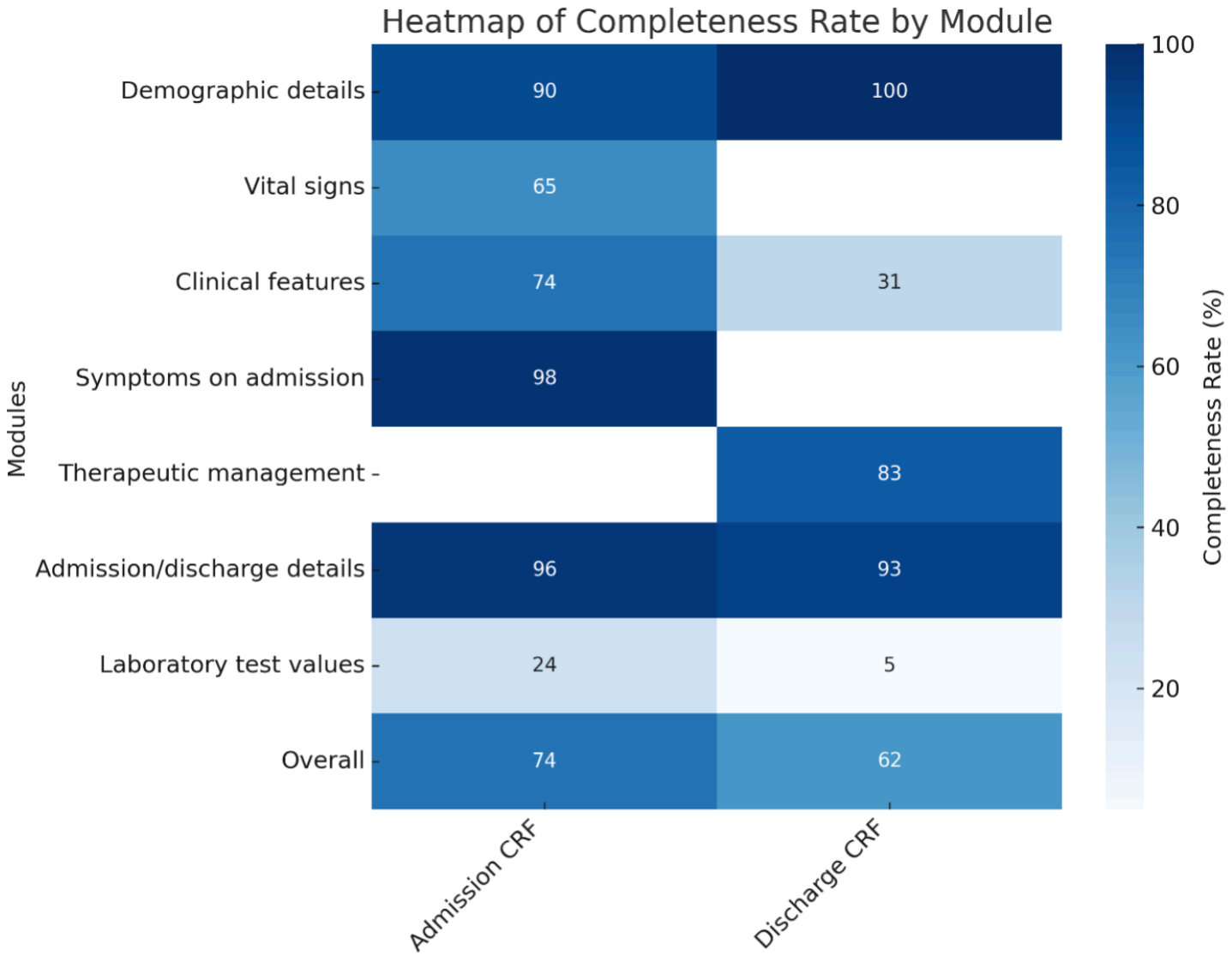


Figure 1

Completion rates for data elements collected during the hospital stay of patients admitted in three high-burden cholera treatment units in Lilongwe during the Malawi 2022-2023 cholera outbreak.

CRF = case reporting form; laboratory facilities were available for 25% of cases (those admitted to the pediatric unit of Kamuzu Central Hospital, cholera treatment unit only)