

Comparison of Ice Lined Refrigerators of the different types used in Western part of India under the Universal Immunization Program

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ABSTRACT

Background & Objective: The effectiveness of Ice-Lined Refrigerators (ILRs) is crucial in maintaining the cold chain for vaccines, particularly in India's Universal Immunization Program (UIP). This cross-sectional study aimed to compare the performance of top-and front-opening ILRs in Gujarat, focusing on temperature stability, holdover time, and functionality. **Methods:** A total of 123 ILRs from various manufacturers were assessed across urban and rural health facilities. Key parameters such as ambient temperature, breakdown frequency, ease of use, and temperature fluctuations during door openings were recorded. Mann-whitney U test/ t-test and Binary logistic regression model were used as statistical methods. **Results:** Analysis indicated that top-opening ILRs, which made up 72.4% of the sample, performed significantly better in maintaining temperature stability and had a longer holdover time (mean: 5.4hours) compared to front-opening ILRs (mean: 4.3hours). Temperature breaches were more frequent in top-opening models (34.8%) compared to front-opening ones (5.9%), but the front-opening ILRs exhibited a greater temperature rise during door openings. Logistic regression analysis revealed a strong association between longer holdover time and top-opening ILRs. The study also found infrastructure and training gaps at some facilities, with only 57.7% of ILRs equipped with functional temperature monitoring systems, and many health workers lacking updated training. **The findings suggest that top-opening ILRs are more reliable for cold chain management, though further investigation into front-opening models is warranted. Conclusion:** For future cold chain management, prioritize top-opening ILRs for their reliability, increase AMC coverage for consistent maintenance, and enhance training for personnel on ILR handling, especially with newer models. Additionally, invest in backup-power and temperature monitoring equipment to prevent temperature breaches, particularly in remote areas.

KEYWORDS

Cold Chain, Immunization, Program Efficiency

INTRODUCTION

India's vaccination program stands as a global public health success story. Annually, it reaches an impressive 3.04 crore pregnant women and 2.7 crore newborns, conducting over 1.2 crore immunization sessions. (1) This cost-effective intervention has significantly reduced vaccine-preventable diseases, leading to a commendable

drop in India's Under-five mortality rate from 45 per 1000 live births in 2014 to 32 per 1000 live births in 2020 (2,3).

All Vaccines are temperature sensitive and must be stored and transported at a narrow temperature range of 2-8°C to preserve their potency.(4) Therefore, the cold chain system must be optimized for a potent and effective vaccination across all

levels. Effective cold chain management is crucial for the success of the vaccination program (5). A system of Cold chain equipment (CCE) stores and delivers vaccines from fixed centers to outreach sessions using the following infrastructure: Cold Chain Points: around 30,000 vaccine storage points [Hospitals, Community Health Centres (CHCs), Primary Health Centres (PHCs), Health facilities] with around 1,06,964 ice-lined refrigerators (ILRs) and Deep Freezers (DF) to store vaccines, and around 432 walk-in cooler (WIC) and walk-in freezer (WIF) to store vaccines at bulk storage locations (6). An ILR stores vaccines and maintains a cabinet temperature between +2°C and +8°C (5). Different manufacturers are available in the market, and they provide ILRs from time to time as per the government's needs. So, we may find different ILRs being used in the cold chain points at in the peripheral health care facilities. Despite WHO PQS (performance, quality, and safety) certification, the effectiveness of different ILRs may vary depending on their build, model, and manufacturer etc. Moreover, second-generation ILRs, which are front-opening devices, have recently been introduced believed to have ease of access and technological advances. However, until now, no proper study has compared the different ILRs for their efficiency. The present study, which aims to compare the effectiveness of various ILRs, especially front and top opening systems used in Gujarat under the Universal Immunization Program (UIP), is essential to understand the efficiency of the cold chain.

MATERIAL & METHODS

Study Design and Study Area: This cross-sectional descriptive study, unique in its focus on the effectiveness of ILRs, was conducted at cold chain points in the western part of India (Gujarat). The study was initiated after obtaining approval from the Institutional Ethics Committee of the All-India Institute of Medical Sciences, Rajkot (AIIMS.Rajkot/IEC/02/2023) and registration with the Clinical Trial Registry India (CTRI/2023/09/072821). Permission from the respective department of the state was also obtained before the start of the study. Only functional ILRs currently used within UIP and supplied by the Government of India were included in this study.

Sample size and sampling technique: The sampling units for the study were ILRs, which stored the vaccines at various levels. All ILRs in the selected district were identified {a total number of ILRs (N): 2211}. A pilot study to calculate the sample size showed that 8% of ILRs breached the temperature range in one week, which was used as an indicator to calculate the sample size. Considering the above

factors, the calculated sample size was at a 95% confidence level, and design effect 1 was 110. This sample size was calculated using OpenEpi software (version 3), using the formula of $[DEFF * Np(1-p)] / [(d2/Z21-\alpha/2 * (N-1) + p * (1-p))]$. However, a sample size of 123 was taken to increase its validity.

The list of ILRs, location, model name, capacity, and installation date was obtained from the State Immunization Cell. This comprehensive list was then used to segregate the ILRs of Gujarat based on the technology used, manufacturer, and model number. A total of 123 ILRs were then selected randomly using a computer-generated random number table, ensuring a representative sample from the entire list of ILRs of the state. If the selected ILR was not in working condition, it was excluded from the study, and the next ILR on the list was chosen.

Study duration, training, and evaluation components: This study was conducted between October 2023 and March 2024. Before data collection, community and family medicine experts and a vaccine management expert trained the medical officers (MOs) to familiarise them with a pre-designed assessment format. These MOs visited each ILR to assess and record various parameters for evaluating performance and efficiency. The distribution of ILR to visit was done using random allocation using chit method to avoid bias. These parameters included the human resources, installation of ILRs as per the standard criteria, types of stored vaccines, the capacity to maintain cold chain temperature, hold-over time, and ambient temperature etc. The assessment also included the ease of use of the ILR, the frequency of breakdowns, downtime following a breakdown, and recovery time after power restoration etc. The team measured the time elapsed after opening the door until the ILR temperature exceeded 8°C and evaluated the effects of power outages or door openings. Holdover time: To measure this, all the vaccines from the ILR was transferred to cold boxes, then the ILR was switched off, and the temperature of the ILR was continuously measured. The seasonality or regional power supply variation was also considered in site selection. The holdover time is the duration taken by ILR from cutting off the power supply till the temperature reaches 8 degrees Celsius. VCCMs (Vaccine and Cold Chain Manager) were asked about the ease of ILR use.

Data analysis: Data were entered into Microsoft Excel and analyzed using Epi Info and Jamovi software. Continuous variables were presented as means and standard deviations. The normality of the data distribution was assessed using the Shapiro-Wilk test before applying appropriate statistical tests. A t-test was utilized for parametric

data to compare means between groups, while the Mann-Whitney U test was applied to non-parametric data. Binary logistic regression analysis was conducted to determine the association between the type of ILR, hold-over time, and the temperature difference between the opening and closing of the ILR. A p-value of less than 0.05 was considered statistically significant.

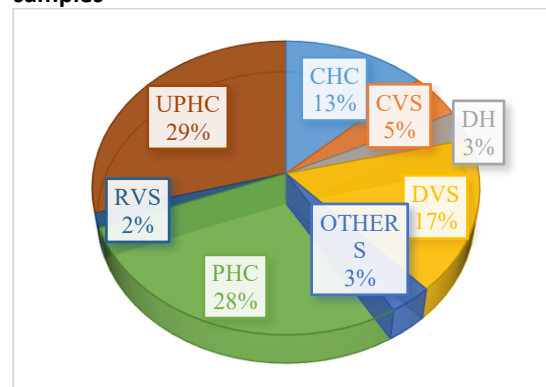
RESULTS

Types of vaccine facility, Infrastructure, and Human Resources:

123 facilities were included to compare the ILR of the different manufacturers in Gujarat under UIP. Of the 123 facilities, 36 (29.3%) were Urban Primary Health Centres (UPHC), and 34 (27.6%) were Primary Health Centres (PHCs). Around one-fourth [21 (17.1%)] were District Vaccine Stores (DVS), and 16 (13%) Community Health Centres (CHC) were included in the study. 6 (4.9%) Corporation Vaccine Stores (CVS), 4 (3.3%) District Hospitals (DH), and 2 (1.6%) Regional Vaccine stores (RVS) were included for the evaluation of ILR (figure 1). Out of the total 123 facilities, more than half of them [71 (57.7%)] were situated in the urban area, while 52 (42.3%) were in the rural areas of Gujarat. Nearly half of the facilities, 57 out of 123 (43.3%), lacked a functional power backup system. Medical officers were posted at 94 (76.4%) facilities; of them, only 19 (20.2%) were trained in the Routine Immunization module for Medical Officers 2016. Out of the total 123 facilities, 98 (79.7%) had regular full-time

vaccine and cold chain handlers (VCCH); of them, the majority [91 (92.9%)] were trained for the VCCH Immunization module 2016, while 7 (7.1%) were not trained for the same. In 25 (20.3%) facilities VCCH had an additional charge; 18 (72%) were trained, and 7 (28%) were not trained for the same.

Figure 1: Health facility-wise distribution of the samples



ILR type, installation, and functionality: In this study, four manufacturers supply ice-lined refrigerators (ILRs) to cold chain points. Among the 123 facilities, 48 have ILRs from manufacture - 3, all of which are top-opening models. manufacture - 4 provides 37 ILRs, all of which are also top-opening. manufacture - 2 supplies 36 ILRs, with 34 being front-opening and 2 being top-opening. The remaining 2 ILRs are from manufacture - 1, both top-opening models. Of 123 ILRs, only 58 units (47.1%) were under an annual maintenance contract (AMC). (Table 1)

Table 1: manufacturer distribution of the type of opening, AMC, and Breakdowns of ILR

Manufacturer	Total n (%)	Type of ILR		Under an annual maintenance contract n (%)	Breakdowns in the last year n (%)
		Front Opening n (%)	Top Opening n (%)		
Manufacturer - 1	2 (1.6)	0	2 (1.6)	2 (1.6)	2 (1.6)
Manufacturer - 2	36 (29.3)	34 (27.6)	2 (1.6)	17 (13.8)	16 (13)
Manufacturer - 3	48 (39)	0	48 (39)	21 (17.1)	2 (1.6)
Manufacturer - 4	37 (30.1)	0	37 (30.1)	18 (14.6)	7 (5.7)
Total	123 (100)	34 (27.6)	89 (72.4)	58 (47.1)	27 (21.9)

The mean minimum and maximum ambient temperature of the ILRs during the year was $19.2 \pm 7.28^{\circ}\text{C}$ (95% confidence interval (CI): 17.9, 20.5°C) and $35.5 \pm 5.29^{\circ}\text{C}$ (95% CI: 34.3, 36.2°C) respectively. The mean minimum ambient temperatures for the ILRs from different manufacturers are as follows: manufacture - 2 units have a mean minimum ambient temperature of 19.4°C , manufacture - 3

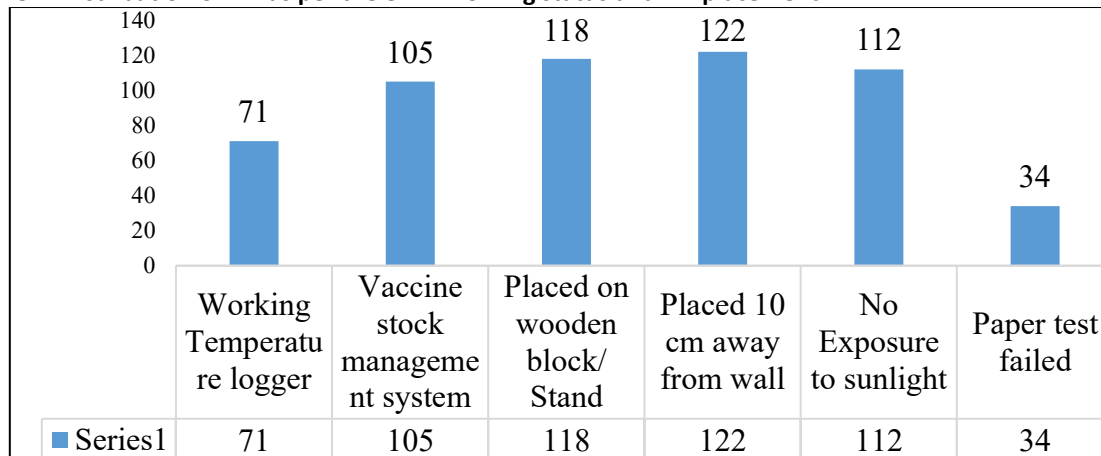
units have 19.9°C , manufacture - 4 units have 18.5°C , and manufacture - 1 units have 13°C . manufacture - 2 and manufacture - 3's mean maximum ambient temperature was 35.9°C , the manufacture - 4 model's temperature was 34.1°C , and Bluestar had a maximum ambient temperature of 31.5°C .

Of 123 ILRs, only 71 (57.7%) had a working temperature logger Electronic Vaccine Intelligence

Network (e-Vin) system. One hundred five units (85.4%) have an operational vaccine stock management system. Regarding the placement of ILRs as per the program guidelines, 118 ILRs (95.9%) are placed on a wooden block or stand. One

hundred twenty-two units (99.2%) were positioned 10 cm away from the wall, and 112 units (91.1%) were placed without direct sunlight exposure. (Figure 2)

Figure 2: Distribution of ILR as per the e-vin working status and ILR placement



Approximately 91.2% of front-opening ILRs are used exclusively for routine immunization (RI) vaccines. In comparison, about 8.8% are used to store additional items such as other vaccines, medicines, food, ARVs (Anti-Rabies Vaccines), or ASVs (Anti-Snake Venom). While 95.5% of top-opening ILRs are used exclusively for RI vaccines, about 4.5% are used to store additional items. In almost all of the ILRs [121 (98.4%)], the vaccine was kept in the order suggested by program guidelines, while only 2 (1.6%) ILRs didn't keep the vaccine as per the guidelines. Upon conducting the paper test, which involved inserting paper between the lid and body, it was found that 34 ILRs (27.6%) failed the test. Of these, 31 ILRs (31/89: 34.8%) had a top opening, and 3 ILRs (3/34: 8.8%) had a front opening. The application of the chi-square test revealed a statistically significant difference with a p-value of 0.004, suggesting that the type of opening may play a crucial role in the efficiency of the ILRs.

Over the past six months, there were 33 recorded instances of temperature breaches where the temperature fell below 2°C or rose above 8°C. Among these breaches, 2 occurred in ILRs with front openings (2/34: 5.9%) and 31 in ILRs with top openings (31/89: 34.8%). This difference was found to be statistically significant ($p = 0.008$). Analysing the causes of these breaches provides further

insight into potential areas for intervention. Prolonged opening and voltage fluctuations were the most common reasons, followed by malfunctioning ILRs, while accidental switch-off and electricity interruptions were less frequent causes. The temperature difference during the opening and closing of the ILR was recorded by opening the ILR for 2 minutes. The mean temperature recorded for the front opening was 6.19°C (standard deviation; SD: 4.13). In contrast, the top opening showed a mean temperature of 4.08°C (SD: 2.74). The front opening exhibited a higher mean temperature difference than the top opening. Mann-Whitney U test was used to compare the mean differences between the two types of ILR openings; the p-value obtained was 0.006, indicating a statistically significant difference. The study included 88 top-opening ILRs and 34 front-opening ILRs for hold-over time calculation. The mean holdover time for top-opening ILRs was 5.4 ± 2.4 hours, while the mean holdover time for front-opening ILRs was 4.3 ± 2.5 hours. The t-test calculated for the comparison was 2.25, with a p-value of 0.03, indicating a statistically significant difference. The top-opening ILRs demonstrated a longer mean holdover time (5.4 hours) than front-opening ILRs (4.3 hours). (Table 2)

Table 2: Association between type of ILR opening with hold over time and temperature difference during the opening and closing of the ILR

Type of ILR	N	Mean \pm SD	Shapiro-Wilk test value / P-value	Test of significance	p-value
The temperature difference during the opening and closing of the ILR					
Front Opening	34	6.19 \pm 4.13	0.325 / <0.001	U=1016#	0.006*

Type of ILR	N	Mean \pm SD	Shapiro-Wilk test value / P-value	Test of significance	p-value
Top Opening	88	4.08 \pm 2.74			
Hold over time (in hours)					
Front Opening	34	4.3 \pm 2.5	0.67 / 0.41	t=2.25 [^]	0.03*
Top Opening	88	5.4 \pm 2.4			

#Mann-Whitney U test, [^]t-test

The binary logistic regression model shows that the odds ratio (Exp(B)) of 0.938 indicating that for every additional hour of hold-over time, the odds of the ILR being a top-opening model increase, assuming all other variables are constant. The result is statistically significant ($p < 0.001$), implying a strong relationship between hold-over time and type of

ILR. For the temperature difference during the opening and closing of the ILR, the odds ratio (Exp(B)) of 0.898 indicates that for every unit increase in temperature difference, the odds of the ILR being a front-opening model increase by 10.2%. However, the result is not statistically significant ($p = 0.087$). (Table 3)

Table 3: Binary Logistic regression of type of ILR with Hold over time and temperature difference during opening and closing of the front /Top opening ILR

Variables of ILR	B	S.E.	Cox & Snell R ²	Nagelkerke R ²	p-value	Exp (B)	95% C.I. for EXP (B)	
							Lower	Upper
Hold – over time (in hours)	-0.064	0.013	0.293	0.416	<0.001*	0.938	0.915	0.962
Temperature difference	-0.107	0.063	0.024	0.035	0.087	0.898	0.794	1.016

In the past year, 27 breakdowns (21.9%) were reported. Manufacture - 2 units accounted for the most breakdowns, with 16 incidents (16/36: 44.45%), followed by manufacture - 4 units, with 7 incidents (7/37: 18.9%). The mean response time after the breakdown was 26 ± 11.8 hours, and the mean downtime time was 61 ± 55.6 hours.

The ease of use of ILRs was assessed based on various criteria; results indicate that most users find ILRs user-friendly in arranging items, maintenance, lid operation, and vaccine retrieval. Over 75% of respondents rated these aspects positively, suggesting that the design and functionality of the ILRs are well-suited to the users' needs in most cases. However, a small minority (1.6%) of respondents reported difficulties with front-opening ILRs, finding them not as easy to use as top-opening models.

DISCUSSION

ILR is one of the basic essential but crucial cold chain equipment required at any health facility to run efficient cold chain maintenance (7). It preserves vaccines to ensure their availability and potency, narrowing the gap between vaccinated and immunized (7). This study compared the effectiveness of 123 ILRs, especially front/top opening systems used in Gujarat under the UIP. Out of 123 ILRs, four manufacturers supplied them, most of which were top models (72.4%), and the rest were front openings (27.6%), all of which were of manufacture - 2.

Regarding the Placement of ILRs per the program guidelines, most (almost 95%) were installed per the recommendation, which concurs with a study from Chandigarh and Surat. (8,9) It is recommended that ILRs be used exclusively for vaccines. In our study, over 90% of ILRs (front and top-opening) were solely used for routine immunization (RI) vaccines, which was considerably higher than in other studies. (10, 11) 71 (57.7%) had a working temperature logger e-win system, almost similar to those reported in different studies. (12-16) In nearly all ILRs [121 (98.4%)], the vaccine was kept in the order suggested by program guidelines, which is higher than the studies by Krishnappa et al., Sharma et al., and Tushar et al. (7,17,18)

Upon conducting the paper test, 27.6% of ILRs failed (34.8% of top-opening and 8.8% of front-opening). Temperature breaches occurred more frequently in top-opening ILRs (34.8%) than front openings (5.9%). Also, the mean temperature difference during the opening and closing of the ILR was significantly higher in the front opening than in the top opening. Even the mean holdover time for top-opening ILRs was considerably higher in front-opening ILRs as compared to front-opening ILRs. This suggests that top-opening ILRs efficiently maintain a stable internal temperature over an extended period. This may be because, in the front opening device, hot air rushes into the device whenever the door is open, causing the temperature to rise. (19) The manufacturer provided plastic strips, curtains, and plastic

containers for vaccine storage at an additional cost to mitigate this issue. Despite all this, a pilot study reported high-temperature excursions in these ILRs, likely due to more frequent openings. (19) This pilot study also noted the problematic usage of front-opening ILRs in uneven power supply. (19) Our study also reported frequent breakdowns in front-opening ILRs, suggesting the robustness of top-opening ILRs. The manufacturer recommended an external voltage stabilizer (range 110-280V) to address this issue. Therefore, before considering wider-scale deployment, it is essential to consider a coordinated repair plan.

Most users find all ILRs user-friendly for arranging items, maintenance, lid operation, and vaccine retrieval. However, a small minority (1.6%) of respondents reported difficulties with front-opening ILRs, finding them less easy to use than top-opening models. Although front-opening ILRs are very similar to standard refrigerators, the difficulty of a minority of the respondents in operating front-opening ILRs might be due to their familiarity with top-opening ILRs for so long. (19)

CONCLUSION

The study comparing Ice-Lined Refrigerators (ILRs) of different manufacturers under Gujarat's Universal Immunization Program (UIP) has revealed significant findings regarding the performance, temperature control, and overall efficiency of ILRs. Top-opening ILRs, which accounted for the majority of the models studied, demonstrated better performance in maintaining temperature stability and holdover time compared to front-opening ILRs. The top-opening ILRs were also found to have fewer temperature breaches and breakdowns. However, both types of ILRs, when installed and maintained correctly, fulfilled their primary purpose of maintaining the cold chain for vaccines.

This study also highlighted gaps in training and infrastructure at some cold chain points. A considerable proportion of facilities lacked a functional power backup system and trained medical officers, underscoring the need for capacity-building initiatives. The paper test results and temperature breach data also suggest that more rigorous monitoring and maintenance of ILRs are necessary to ensure vaccine safety.

RECOMMENDATION

- Preference for Top-Opening ILRs: Given their superior performance in maintaining cold chain integrity and fewer breakdowns, top-opening ILRs should be preferred for future deployments,

especially in areas with inconsistent power supply.

- Strengthening Maintenance Contracts: Only half of ILRs were under annual maintenance contracts (AMC). Expanding AMC coverage will ensure regular servicing and timely repairs, minimizing downtime and temperature breaches.
- Enhanced Training for Personnel: Regular and comprehensive training programs for vaccine cold chain handlers and medical officers should be instituted, focusing on proper ILR use and maintenance, particularly for new front-opening models.
- Improved Infrastructure: Investments in infrastructure, such as backup power systems and functional temperature monitoring equipment (e.g., e-vin systems), are critical to preventing temperature breaches, especially in remote areas.

LIMITATION OF THE STUDY

This study has a few limitations. The findings are based on ILRs from a single state in western India, which may limit generalizability to other regions with different environments or cold-chain practices. Temperature monitoring depended partly on e-VIN data, and since not all ILRs had functional loggers, some measurement bias may have occurred. Hold-over time and temperature-change assessments were performed under controlled field conditions that may not fully reflect routine operational use. Some information, such as ease of use and reasons for breakdowns, relied on staff reports and may include recall bias. Finally, as a cross-sectional study, causal relationships between ILR type and performance outcomes cannot be established.

RELEVANCE OF THE STUDY

This study provides valuable evidence on the real-world performance of different ILR types used under the Universal Immunization Programme in India. By systematically comparing hold-over time, temperature stability, installation practices, and operational challenges across manufacturers, it highlights critical gaps that can directly impact vaccine potency and program efficiency. The study also identifies infrastructure and human-resource factors—such as inadequate power backup, suboptimal training, and AMC coverage—that influence ILR functionality. These findings contribute to strengthening cold chain management by informing procurement decisions, guiding corrective actions and supporting policy

improvements for more reliable vaccine storage systems.

AUTHORS CONTRIBUTION

BM led the study design, data collection, and initial drafting of the manuscript. KJ developed the methodology and critically reviewed the manuscript. VK assisted in data collection and interpretation. SS provided technical guidance on cold chain systems and contributed to data analysis. KJ (Krishna Jasani) supported statistical analysis, manuscript editing, and preparation of tables/figures. KP managed administrative permissions, logistics, and final manuscript review. All authors approved the final manuscript.

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Nil.

CONFLICT OF INTEREST

The authors declares no conflicts of interest

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DECLARATION OF GENERATIVE AI AND AI ASSISTED TECHNOLOGIES IN THE WRITING PROCESS

During the preparation of this manuscript, the authors used ChatGPT (OpenAI) to assist with editing, language refinement, and improving clarity of the text. After using this tool, the authors thoroughly reviewed, verified, and edited the content as required. The authors take full responsibility for the integrity, accuracy, and originality of the final content presented in this publication.

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