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Availability and quality of vaccine cold chain equipment at healthcare facilities in Mtwara region, Tanzania: evidence from routine assessment of vaccine cold chain equipment

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Abstract

Background: The quality of vaccines is heavily dependent on maintaining proper cold chain equipment (CCE) throughout the supply chain. However, Tanzania faces significant challenges in this area. According to the Effective Vaccine Management Assessment (EVMA) of 2021, the country score was 73%, falling short of the 80% benchmark. The ongoing measles outbreak in several districts may be linked to the delivery of low-quality vaccines due to inadequate storage conditions. This study aimed to assess the availability and quality of CCE at healthcare facilities in the Mtwara region and identify areas for improvement.

Methods: A descriptive cross-sectional study was conducted, utilizing an updated vaccine CCE inventory from 263 healthcare facilities (HFs) across nine councils in the Mtwara region. The updated inventory was compiled into a single Microsoft Excel dataset, which was then analyzed to determine the frequency and functionality of CCE. The findings were presented in tables for comparative analysis.

Results: Routine immunization services were available at 263 out of 301 healthcare facilities (87.4%), with 234 (89%) of these being public facilities. Among them, 218 (82.9%) were dispensaries, and 209 (79.5%) were in rural areas. A total of 252 (95.8%) healthcare facilities had functional refrigerators, 115 (43.7%) of which were RCW 50EG models. Although all refrigerators met the World Health Organization's pre-qualification standards, 192 (76%) exhibited functional deficiencies. Additionally, 115 (43.7%) had been in use for over ten years, and 48 (19%) lacked temperature monitoring devices. While vaccine carriers were available, they showed deficiencies that made them unsuitable for effective vaccine storage.

Conclusion: Most cold chain equipment (CCE) in the Mtwara region was in sub-optimal condition, potentially compromising vaccine quality and hindering immunization services. This could result in canceling immunization sessions, leading to low vaccination coverage and a failure to protect recipients. Urgent action is needed to repair or replace non-functional, outdated, and inefficient CCE. In addition, regular refresher training for healthcare providers on assessing and maintaining vaccine CCE is recommended, as well as the procurement of refrigerator models that are suitable for local conditions in alignment with manufacturer guidelines.

Keywords: routine immunization, healthcare facility, cold chain equipment, vaccine refrigerator, vaccine quality, equipment inventory

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Introduction

Since the establishment of the Expanded Programs on Immunization (EPI) in 1974 (K Keja , C Chan, G Hayden, 1988), vaccination has always been one of the most cost-effective public health interventions for controlling vaccine-preventable diseases (VPDs). Vaccination contributed to the global eradication of smallpox and the elimination of wild poliovirus and Haemophilus influenza type B (Hib) in many countries (Rémy et al., 2015). Consequently, childhood vaccination reduced infant and childhood mortality (Bhandari et al., 2007; Bobo et al., 2022; Ndirangu et al., 2009; Shukla & Shah, 2018) and is currently estimated to avert about 2 to 3 million under-five deaths globally each year (Paul A, 2020; UNICEF, 2023). Vaccination remains a key channel for attaining the Sustainable Development Goal (SDG 3.2) (WHO, 2021). Moreover, vaccination contributes directly or indirectly to the achievement of the other 13 SDGs, such as ending poverty (SDG 1) by reducing out-of- pocket expenditure on treatment, reducing hunger (SDG 2) by preventing diseases that reduce nutrient absorption, and reducing inequalities (SDG 10) by avoiding inequity caused by epidemics (Decouttere et al., 2021).

Despite the lifesaving impact of vaccines, vaccine-preventable diseases (VPDs) are still prevalent, causing about 3 million deaths globally every year (Albright et al., 2005). In 2018, VPDs caused nearly 700,000 under-five mortalities worldwide, 99% of which occurred in low and middle-income countries (Nair et al., 2011). In recent years (2022–2023), both wild poliovirus and circulating vaccine-derived poliovirus type 2 (cVDPV2) outbreaks have recurred in some African countries, including Malawi (WHO Africa, 2022), Mozambique (GPEI, 2022; WHO, 2022b), Tanzania (WHO, 2023), the Democratic Republic of the Congo, and Burundi (GPEI, 2023). This situation has emerged behind the polio-free certification awarded to the World Health Organization (WHO) African Region on August 25, 2020 (WHO, 2023). Such outbreaks pose a public health threat and undermine the achievement of the global polio eradication initiative (GPEI 2022–2026) (GPEI, 2021) and immunization agenda (IA 2030) goals.

Several reports have attempted to identify probable reasons for these outbreaks. Among the identified reasons is the disruption of immunization services by the COVID-19 pandemic (Maltezou et al., 2020; Muhoza et al., 2021). The World Health Organization declared COVID-19 disease a global pandemic on March 11, 2020, with an immediate endorsement of control interventions such as physical distancing and transportation reductions (WHO, 2020). Adherence to these interventions reduced access to routine immunization, resulting in a drop in vaccination coverage rates and the accumulation of zero-vaccine doses and under-vaccinated children in many communities (Maltezou et al., 2020; Muhoza et al., 2021; WHO, 2022a). It is no wonder that the drop in vaccination coverage below the threshold for herd immunity increases the chance of the occurrence of VPD outbreaks. Amongst others, failure to adhere strictly to recommended specifications for vaccine storage and handling can render vaccines unable to prevent targeted diseases (Dairo & Osizimete, 2016; Paunio et al., 1998; Yeung et al., 2005). Suboptimal vaccine handling practices, CCE failure, and weak temperature monitoring and control systems have previously been reported in several studies (Dairo & Osizimete, 2016; Nestory et al., 2022; Sinnei et al., 2023; Yauba et al., 2019).

In Tanzania, for instance, EVMA-2021 reported a suboptimal country-wide score of 73% below the 80% benchmark on vaccine storage and transportation equipment (UNICEF, 2021). Therefore, the ongoing measles outbreaks in several councils of Tanzania (The Citizen, 2022) could be linked to the provision of low-quality vaccines to children due to sub-optimal storage conditions along the supply chain. In 2022, Tanzania attained 110% and 97% of MR1 and MR2 administrative coverage, respectively. These coverages exceeded the minimum target endorsed by the WHO in the Immunization Agenda 2030 (IA 2030) (WHO, 2021) and the 2012 Global Vaccine Action Plan (Zewdie et al., 2016). Therefore, this suggests that measles outbreaks could not be due to low coverage but likely due to vaccine quality issues related to cold chain management. Unless there were reporting or target issues with the administrative data.

Therefore, this study aimed to evaluate the availability and quality of vaccine CCE at the HF level in Mtwara region following routine CCE commissioning and decommissioning. Outcomes are intended to inform policy on CCE gaps and guide future repair, maintenance, replacement, and/or re-distribution plans.

Materials and Methods

Study Setting

This study was conducted in Mtwara, one of the coastal regions located in the southern part of Tanzania. The region shares borders with Mozambique, a country where the WHO reported several cases of both wild poliovirus and cVDPV-2 (GPEI, 2022). According to the 2022 national census, the region has approximately 1.6 million people living in nine councils, 76.3% of whom reside in rural areas where access to immunization services is challenging (Vasudevan et al., 2020). The region has a total of 301 HFs, out of which 17 (5.6%) are faith-based (FBO), 39 (13%) are private for-profit, and 245 (81.4%) are public HFs. The increment in the number of health facilities providing routine immunization services from 243 in 2022 to 263 in 2023, the occurrence of Measles Rubella outbreak in several councils in Mtwara, as well as the recommendations from the EVMA 2021, prompted the need to assess the quality of CCE currently used to store vaccines at the HFs in Mtwara.

Study design

A descriptive cross-sectional study was conducted using a periodically updated vaccine CCE inventory to ascertain the availability and quality of vaccine storage equipment at healthcare facilities across nine districts in Mtwara region. A detailed vaccine CCE inventory used in this study was obtained from District Health Management Teams (DHMTs) upon completion of the fourth-quarter inventory updates for the 2022/2023 fiscal year. From this inventory, this study assessed the common vaccine storage equipment used at 263HFs that are providing routine immunization services. This equipment included vaccine refrigerators, vaccine carriers, cool water packs, foam pads, a 30-day temperature recorder (30-DTR), i.e., fridge-tag devices (FT2), and remote temperature monitoring devices (RTMDs). In this context, availability meant the presence of vaccine storage equipment by the established standards, while parameters of quality checked out on each piece of equipment included physical condition (outer body, accessories, and fittings); the length of time a device has been used, and functional deficiencies as reported by users.

Data management and analysis

Upon receipt of updated vaccine CCE inventories from all districts, the Regional Health Management Team (RHMT) compiled individual vaccine CCE inventories to form a single Microsoft Excel dataset. The dataset was then analyzed in Microsoft Excel for frequencies and percentages representing the quantity and functionality of CCE. Then, the results were presented in tables for comparison. The primary outcome of the analysis was the availability and quality of CCE found in HFs providing immunization services.

Ethical approval

This study did not involve human subjects; we only assessed the availability, functionality, and quality of CCE; therefore, formal consent was not required. Furthermore, data were collected as part of routine monitoring and evaluation of government initiatives to improve quality health services as guided by the Ministry of Health. However, the permission for program data use and publication of the results was obtained from the Mtwara Regional Secretariat.

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Results

Demographic characteristics of health facilities providing routine immunization services

Routine immunization services were available in 263/301 (87.4%) of THE HFs found in Mtwara region. The government owned the majority of these facilities 234 or 89%). The analysis further indicated that routine immunization services were mostly provided in dispensaries 218 (82.9%). Nearly eighty percent 209 (79.5%) of vaccinating HFs were located in rural areas (
Table 1)

Table 1: Demographic characteristics of HFs providing RI services

Variables	Quantities	Percent (%)
Ownership		
FBO	17	6.5%
Private for Profit	12	4.6%
Public	234	89.0%
Facility location		
Rural	209	79.5%
Semi-Urban	20	7.6%
Urban	34	12.9%
Facility type		
Dispensary	218	82.9%
Health Center	36	13.7%
Hospital	9	3.4%

Condition of vaccine cold chain equipment

The study findings revealed that 252 (95.8%) HFs had functional refrigerators, 115 (43.7%) of these refrigerators being the RCW 50EG model, followed by 98 (37.3%) SunDanzer (BFRV 55) and 36 (13.7%) Haier HTC-110 model. Although all HFs were equipped with WHO-qualified refrigerators, over three quarters 192 (76%) of these refrigerators had functional deficiencies, including moisture formation 84 (33.3%); defective ignition coil 57 (22.6%); ruptured gasket rubber 21 (12.3%); defective cooling unit 10 (4.0%); defective unit control panel 9 (3.6%); and defective door lock 1 (0.4%). It was also found that the main sources of power for these refrigerators were solar 137 (52.1%), liquefied petroleum gas 85 (32.3%), and grid electricity 41 (15.6%).

The study further established that 43 (16.3%) of HFs had no power backup for continued cold chain management during power outages. Over half, 137 (52.1%) of HFs had solar direct drive (SDD) refrigerators that needed no external backup other than an internal battery. Of all electric refrigerators running on grid electricity, only 10 (24.4%) had a voltage stabilizer to safeguard the refrigerator from fluctuating power. The assessment also pointed out that the length of time a refrigerator has been in use was over ten years among 115 (43.7%) refrigerators, 0 to 4 years among 108 (41.1%) refrigerators, 5 to 10 years among 4 (1.5%) refrigerators, and less than 1 year among 36 (13.7%) refrigerators (Table 2).

Table 2: CCE models, functionality, alternative and main sources, installation dates, voltage stabilizer, and functional defects.

Variable	Quantity	Percent (%)
Refrigerator models		
TCW 3000 AC	1	0.4
MK 404 AC	1	0.4
VLS 054 DC	2	0.8
Vest frost VLS 200 AC	10	3.8
Haier HTC 110 DC	36	13.7
SunDanzer (BFRV 55) DC	98	37.3
RCW 50EG AC/Gas	115	43.7
Is a refrigerator functional?		
No	11	4.2
Yes	252	95.8
Refrigerator source of power		
Grid Electricity	41	15.6
Liquefied Petroleum Gas	85	32.3
Solar power	137	52.1
Type of power backup		
Solar inverter	1	0.4
Generator	4	1.5
LP Gas	36	13.7
Electricity	42	16.0
No power backup	43	16.3
In-built refrigerator battery	137	52.1
Availability of voltage stabilizers on electrical		
No	31	75.6
Yes	10	24.4
Vaccine refrigerators defects		
Defective door lock/hinge	1	0.4
Defective unit control panel	9	3.6
Defective cooling unit for RCW 50EG	10	4.0
Ruptured gasket rubber	31	12.3
Defective ignition coil for RCW 50 EG	57	22.6
A refrigerator forms a moisture	84	33.3
Length of time refrigerators have been used		
Over 10 Years	115	43.7
5-10 years	4	1.5
0-4 years	108	41.1
Less than a year	36	13.7

Almost all HFs, 99.6% (262/263),had a vaccine carrier, and over eighty percent,225 (85.6%) of these facilities had at least two vaccine carriers. Despite their adequate availability, some vaccine carriers had deficiencies, including the absence of a foam pad at 185 (70.3%) HFs; a short supply of cool water packs at 31 (11.8%) HFs; breaking belts at 27 (10.3%) HFs; cracks on the hard lids at 67 (25.5%) HFs; and cracks on the outer body at 63 (24%) HFs. None of the HFs had a cold box (Table 3).

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Table 3: Availability and physical condition of insulated containers at the HF

Variable	Quantity	Percent (%)
Is a vaccine carrier available?		
Yes	262	99.6
No	1	0.4
HF has ≥ 2 vaccine carriers		
Yes	225	85.6
No	38	14.4
Does a vaccine carrier have 4 cool water packs?		
Yes	232	88.2
No	31	11.8
A vaccine carrier has a foam pad		
Yes	78	29.7
No	185	70.3
A vaccine carrier has a belt		
Yes	236	89.7
No	27	10.3
A vaccine carrier has cracks on a hard lid		
Yes	67	25.5
No	196	74.5
A vaccine carrier has cracks on the outer body		
Yes	63	24.0
No	200	76.0
The health facility has a cold box		
Yes	0	0.0
No	263	100.0

The assessment of temperature monitoring devices highlighted that 52 (19.8) of all functional refrigerators had no temperature monitoring devices. A refrigerator was equipped with both 30 DTRs and RTMDs at 131 (49.8%) HFs. Although RTMDs were installed at the HFs in 165 (62.7%) refrigerators, the majority of 108 (65.5%) were not transmitting data to the https://tz.coldtrace.org data server (
Table 4).

Table 4: Temperature Monitoring Devices and Temperature Distribution in Vaccine Refrigerators

Variable	Quantity	Percent (%)
Is a functional 30-DTR available and inserted in the refrigerator?		
Yes	178	67.7
No	85	32.3
Is a remote temperature monitoring device (RTMD) installed?		
Yes	165	62.7
No	98	37.3
RTMD Data Transmission		
Vaccine refrigerators maintaining a temperature range of	39	23.6
RTMDs recorded the hot temperature from the vaccine	9	5.5
RTMDs recorded cold temperatures (below +2) in a	9	5.5
RTMDs transmitted no data	108	65.5
Are both functional 30-DTR and RTMDs available?		
Yes	131	49.8
No	34	12.9
A refrigerator has no temperature monitoring devices		

Yes	52	19.8
No	211	80.2

Discussion

Findings from this study pointed out that routine immunization services were unavailable in 38/301 (12.6%) of functional HFs, 71% of which were owned by private sectors. Although we did not explore factors limiting the introduction of routine immunization programs into these facilities, we advocate for strengthening public-private partnerships (PPP) to create a better environment for engaging the private sector in the provision of routine immunization (RI) services. Available evidence shows that providing RI services through the private sector contributes significantly to raising immunization coverage and the adoption of new vaccines (Levin & Kaddar, 2011). A health facility is a key place for storing vaccines and implementing RI programs (Pinaka et al., 2021; Sanghavi, 2007). The ongoing construction and/or renovation of HFs to expand the concept of primary health coverage (Kapologwe et al., 2020; MoH, 2021; Mtema, 2022; Mwenda, 2019) provides room for expansion of immunization services upon inclusion of reproductive and child health (RCH) units in the building plans. This will contribute to reducing barriers to immunization access caused by distance from HFs (Blas E, Sivasankara Kurup A, 2010) and/or poor geographical access (Marti et al., 2017; Vasudevan et al., 2020). In favor of 80.6% of vaccinating HFs located in rural areas where electricity is always a challenge (Moner-Girona et al., 2021), solar direct-drive vaccine refrigerators should be prioritized during the replacement and expansion of cold chain infrastructure.

The availability of adequate and well-functioning CCE at the HF ensures proper vaccine storage at all times and every stage until the moment they are given to children, adolescent girls, pregnant women, and adults coming for COVID-19 vaccines. On the contrary, it was observed in this study that 4.2% of HFs registered in VIMS for delivery of routine immunization services in Mtwara had either no vaccine refrigerator at all or were equipped with non-functional vaccine refrigerators. The absence of refrigerators or the presence of a non-functional vaccine refrigerator at the service delivery points interrupts immunization services and is therefore likely to cause missed opportunities for immunization (MOV) and distress to healthcare providers, similar to what was observed by Kimmel *et al* (Kimmel et al., 2003). To ensure the availability of functional refrigerators at the HF, there should be adherence to routine planned preventive maintenance (PPM), which was reported to be considerably low in Morogoro, Tanzania (Nestory et al., 2022), and Ethiopia (Feyisa, 2021). However, this will require understanding and solving available barriers such as low funding, the non-inclusion of PPM in the health facility's annual plans and budgets, and a shortage of biomedical technicians and refrigerator spare parts, as reported earlier (Sinnei et al., 2023; World Health Organization (WHO), 2013). As such, training healthcare workers on the basics of handling CCEs, recruiting and training local refrigerator technicians on refrigerator maintenance, and equipping HFs with sufficient CCE spare parts for easy access are paramount.

The presence of refrigerators with functional deficiencies in 76% of vaccinating HFs is a major turn-off to vaccine quality. It increases the likelihood that vaccines are exposed to damaging temperatures and the risk that vaccine recipients will not be protected against VPDs, as earlier reported (Dairo & Osizimete, 2016). The presence of broken refrigerators at HFs is not an uncommon challenge along the supply chain and was found to be higher in Mtwara than in Cameroon (Yauba et al., 2019). However, this difference might be due to differences in the parameters of the refrigerators assessed. Vaccine refrigerators with deficiencies were also reported to cause unusual vaccine wastages by Dairo *et al*. (Dairo & Osizimete, 2016). As such, there should be urgent efforts to rehabilitate or replace the broken and old refrigerators, preferably with solar direct-drive refrigerators. The WHO and UNICEF have both published guidelines stating that solar refrigerator technologies should be prioritized over absorption devices (World Health Organization (WHO), 2013). However, the environmental suitability and drawbacks of certain solar refrigerator technologies should be considered during all these processes.

The current study indicated that a voltage stabilizer was connected to only 24.4% of needy vaccine refrigerators in Mtwara. The absence of voltage stabilizers, also known as automatic voltage regulators, exposes equipment to power disturbances, which can cripple the equipment, place vaccines at risk, and cause tension among healthcare workers. Although the availability of voltage stabilizers at the HFs was low in Mtwara, the situation was more unpromising in Surat City, Western India, as reported by Naik *et al.* (Naik et al., 2013). Several other studies also reported a shortage of voltage stabilizers in (Bachani & Bansal, 1990; Mallik et al., 2011). This calls for the inclusion of voltage stabilizer procurement and maintenance in the health facility's annual work plans and budgets.

Refrigerator power backup during power outage emergencies among needy refrigerators was also a challenge in Mtwara, similar to what was reported in Morogoro, Tanzania, by (Nestory et al., 2022). However, initiatives taken by the Ministry of Health (MoH) to roll out SDD refrigerators in 52.1% of HFs have reduced this requirement. Unless there is still a need, consideration for the procurement of generators and solar inverters remains vital. The recommendations provided in the EVMA 2021 report should be amplified among decision-makers and controllers of health facility resources. This will ensure the inclusion of an effective vaccine management agenda in the health facility's daily operations. The absence of an alternative power source at the health facility is responsible for vaccine wastage, increased facility operational costs due to storage of vaccines at neighboring health facilities, and interruption of immunization services (Nestory et al., 2022).

The absence of an adequate number (at least two) of vaccine carriers in 14.4% hinders the delivery of simultaneously fixed immunization and outreach sessions and is likely the reason for the cancellation of outreach sessions in Mtwara region, as displayed on the Vaccine Information Management System (VIMS) dashboard at www.vims.moh.go.tz. Vaccine carriers are designed to keep vaccines and diluents cold during transportation from the collection store at the HF, on journeys to outreach sites, or for temporary storage during health post-immunization sessions. Therefore, deficiencies observed in some of the vaccine carriers in Mtwara render them unfit for effective vaccine storage and distribution at the health facility. Inadequacy and deficiencies in vaccine carriers were also reported in Kenya (Sinnei et al., 2023). Moreover, the shortage of both vaccine carriers and cold boxes is distressing to healthcare workers due to the lack of temporary storage of vaccines when a refrigerator is out of order or being manually defrosted. All these gaps in insulated containers are likely to impair vaccine potency and negatively impact vaccination services. Therefore, decision-makers need to take necessary actions, including procuring and distributing new vaccine carriers to the HFs. Further, healthcare workers should be trained on how to improvise foam pads from mattresses to extend storage time and prevent exposure of vaccine vials to damaging temperatures and/or light during sessions.

In addition, 19.8% of HFs in Mtwara region lacked any kind of temperature monitoring device (TMD) in vaccine refrigerators. The absence of a continuous temperature monitoring and control system has previously been reported in several studies (Nestory et al., 2022; WHO, 2022a; Yeung et al., 2005). This is detrimental regarding vaccine wastage and patient safety due to the failure to identify and correct possible temperature excursions as recommended in the Centers for Disease Control and Prevention Vaccine Storage & Handling Toolkit (CDC, 2023). Temperature excursions have been identified as a potential cause of vaccine wastage in several settings (Mukherjee et al., 2004; Setia et al., 2002). Investing in a reliable device is less expensive than replacing vaccines wasted due to the loss of potency that comes from storage at out-of-range temperatures. Therefore, this calls for the provision of functional TMDs for continuous monitoring of vaccine storage at HFs, as proposed by Falcon *et al.* (Falcón et al., 2020).

Gains observed in installing RTMDs in 165 (62.7%) HFs should be sustained and scaled up to all other vaccinating HFs in the region. The RTMDs' potential lies in their integration into VIMS, where they can easily monitor the performance of the CCEs and trigger alerts for any equipment failure. However, the RTMD reports in VIMS need to be enhanced to improve the reporting and utilization of the reported data, as suggested in the EVMA report 2021 (UNICEF, 2021).

Study limitations

This study had two limitations. One, researchers could not easily access refrigerator initial installation dates to assess the length of time a refrigerator has been in use. This is because refrigerators are being rotated within and between councils in the region during cold chain improvement struggles among HFs. Available installation details for certain models were extrapolated to all other similar models whose information was not easily accessible. Therefore, the active use of electronic cold chain inventory integrated into VIMS should be encouraged to ease future assessments. Second, this study only assessed the availability and status of vaccine cold chain equipment but did not assess the quality of vaccines being stored in the available CCE at the healthcare facility level. Therefore, findings from this study cannot be used to conclude its linkage with the occurrence of the ongoing VPD outbreaks in Mtwara. We recommend another study to assess the quality of vaccines during storage within the same HFs.

Conclusion and Recommendations

The findings from this study have revealed that most vaccine storage equipment were performing sub-optimally, which may impair the quality and potency of the vaccine and have a subsequent negative impact on the vaccination services, including cancellation of immunization sessions and vaccine failure to confer protection to the recipients. Therefore, efforts are needed to improve the availability and quality of vaccine storage equipment by rehabilitating or replacing the non-functioning and old equipment. Furthermore, we recommend frequent refresher training for healthcare providers in assessing and maintaining vaccine refrigerators and RTMDs, as well as procuring and using refrigerator models that are suitable for the local environment according to the manufacturer's guides.

Supporting information

Data requests may be made to Serveus Ruyobya Kamala (corresponding author), Health, Social Welfare, and Nutrition Services Section, Mtwara Regional Secretariat, P.O. Box 544, Mtwara, Tanzania, email: sekakamala@gmail.com, Tel: + 255718041765.

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