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EFFECTIVENESS OF STRUCTURED TRANSPORT OF NEWBORNS WITH SURGICAL CONDITIONS ON THEIR OUTCOMES
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EFFECTIVENESS OF STRUCTURED TRANSPORT OF NEWBORNS WITH SURGICAL CONDITIONS ON THEIR OUTCOMES

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ABSTRACT

Background: **Many surgical conditions in newborns are only amenable to surgery, which in resource-limited settings is only feasible in some tertiary-level hospitals, hence the need for appropriate referral and safe newborn transport.**
Objective: **To evaluate the effectiveness of a structured standard operating procedure (SOP) for newborn transport, on their referral and transport characteristics.**
Design: **A Cluster Randomized Controlled Trial.**
Setting: **Moi Teaching and Referral Hospital (MTRH).**
Methods: **Ten county hospitals that refer newborns with surgical conditions to the MTRH were selected and randomized into Intervention Group (A) and Control Group (B). A structured SOP for newborn transport was implemented in the hospitals in Group A. Thereafter, 126 newborns (63 in Group A and 63 in Group B) that were referred from the selected county hospitals were enrolled, upon their admission to MTRH. Data was collected and analyzed; and the outcomes of the newborns in the two groups were compared to assess the effect of the structured SOP.**
Results: **The median age at admission was 4.1 days in Group A, and 4.6 days in Group B. Twenty (31.7%) mothers in Group A and 26 (41.3%) mothers in Group B did not seek antenatal care during pregnancy. There were statistically significant differences ($p < .05$) in all the elements of pre-transport stabilization, and care during transport, of the newborns referred and transported from the two groups of county hospitals.**
Conclusion: **The structured SOP for newborn transport had a significant positive effect on their referral and transport characteristics at MTRH.**

INTRODUCTION

Surgical conditions in newborns include congenital malformations, surgically-treated-infections, and trauma. Congenital malformations alone comprise 9% of the global disease burden [1]. In L/MICs, 6.2% to 8.9% of all admissions to the Newborn Units of tertiary-level hospitals are due to surgical conditions [2, 3, 4]. At MTRH, a tertiary-level hospital in western Kenya, 30% of all referred newborns come for surgical care [5].

These conditions are amenable to newborn surgery, which in Kenya is only feasible in two tertiary-level hospitals, and hence the need for appropriate referral and safe newborn transport. Lack of ideal element of newborn transport in the L/MICs is a major gap in the provision of holistic newborn care. Whereas the exact contribution of improper newborn transport to the overall mortality is unknown, mortality rates of 25% – 35% have been reported in sick newborns transported to tertiary-level hospitals for specialized care [6, 7, 8].

This study aimed at evaluating the effectiveness of appropriate referral and transport of newborns with surgical conditions, on their referral and transport characteristics in a resource-limited setting, specifically the North Rift and Western regions of Kenya.

METHODOLOGY

The study was conducted as a cluster randomized controlled trial, a design that is suitable for evaluating a public health intervention in a fixed number of clusters. Ethical approval was obtained from the MU/MTRH Institutional Research Ethics Committee (FAN: IREC 1861).

The trial involved random selection of 10 clusters (county hospitals that refer newborns with surgical conditions to MTRH), that were further randomized into 2 groups (Intervention Group-A and Control Group-B) of 5 hospitals each. All the selected hospitals had shared characteristics that included infrastructure, medical equipment, and healthcare workforce indicators [9]. They, however, do not provide newborn surgical care, due to unavailability of specially trained surgeons, lack of specially equipped operating theatres, and lack of Newborn Intensive Care (NICU) facilities. In the entire North Rift and Western regions of Kenya, MTRH is the only tertiary-level hospital that offers surgical care to newborns.

The public health intervention strategy in this study was use of a structured SOP for newborn transport, which is based on the World Health Organization (WHO) guidelines on transfer and referral of sick neonates. The protocol was customized to incorporate locally innovative improvisations [10] and was deployed for use in the county hospitals in Group A via an education module.

One month after its deployment, a total of 126 newborns, who were admitted to the Newborn Unit of the MTRH for surgical care, as referrals from the county hospitals, were consecutively enrolled into the study (63 from the hospitals in Group A, and 63 from the hospitals in Group B). All the newborns were accorded standard care for their surgical conditions.

Data was collected and analyzed on their socio-demographic, referral, and transport characteristics. The statistical differences in the referral and transport characteristics of the newborns in the two groups were compared to assess the effect of the public health intervention strategy. Chi-square test, Fisher's exact test, and Wilcoxon rank sum test were

applied for statistical analysis, and P values < .05 were considered statistically significant.

RESULTS

Socio-demographic Characteristics of the Newborns

The median age at admission was 99 hours (IQR = 77,128), which was approximately 4.1 days, in Group A; and 112 hours (IQR = 75,137), which was approximately 4.6 days, in Group B. The male: female ratio was 1.1:1 in Group A, and 1:1 in Group B. The majority of the newborns (88.9% in Group A, and 92.1% in Group B) were delivered in health facilities. Table 1 shows the socio-demographic characteristics of the newborns by Group.

Table 1

Socio-demographic Characteristics of the Newborns

Variable	Group A (n=63)	Group B (n=63)	Test Statistic	p-value
Age at admission (Hours)			0.312[1]	
Median (IQR)	99 (77,128)	112 (75,137)		.755
Birth Weight (Grams)			0.342[1]	
Median (IQR)	2695 (2160,3100)	2700 (2300,3300)		.732
Weight at admission (Grams)			0.161[1]	
Median (IQR)	2600 (2100,3000)	2630 (2150,3100)		.872
Sex			0.127[2]	
Male (%)	33 (52.4)	31 (49.2)		
Female (%)	30 (47.6)	32 (50.8)		.722
Gestational age (Weeks)			2.154[2]	
Preterm (<37), (%)	28 (44.4)	20 (31.7)		
Term (≥37), (%)	35 (55.6)	43 (68.3)		.142
Place of Birth			0.368[3]	
Home (%)	7 (11.1)	5 (7.9)		
Health Facility (%)	56 (88.9)	58 (92.1)		.544

Note. 1. *Wilcoxon Rank Sum Test* ***(Z) 2.*** *Chi-Square Test* ***(χ^2) 3.*** *Fisher's Exact Test*

Maternal Characteristics

Maternal Socio-demographic Characteristics

The median maternal age was 23 years (IQR = 20, 28) in Group A, and 23 years (IQR = 19, 29) in Group B. The majority of the mothers in both groups had formal education but were unemployed. Table 2 shows maternal socio-demographic characteristics.

Table 2

Maternal Socio-demographic Characteristics

Variable	Group A	Group B	Test Statistic	p-value
Maternal Age (Years)	**n=63**	**n=63**	0.213[1]	
Median (IQR)	23 (20, 28)	23 (19, 29)		.832
Maternal Level of Education	**n=63**	**n=63**	8.698[3]	
Non-formal (%)	7 (11.1)	1 (1.6)		
Primary (%)	27 (42.9)	24 (38.1)		**.034***
Secondary (%)	23 (36.5)	23 (36.5)		
Tertiary (%)	6 (9.5)	15 (23.8)		
Maternal Occupation	**n=63**	**n=63**	2.450[2]	
No Employment (%)	43 (68.3)	37 (58.8)		
Self-Employment (%)	14 (22.2)	14 (22.2)		.294
Formal Employment (%)	6 (9.5)	12 (19.0)		

Note. 1. *Wilcoxon Rank Sum Test* ***(Z) 2.*** *Chi-Square Test* ***(χ^2) 3.*** *Fisher's Exact Test *Statistically Significant p-value*

Maternal Clinical Characteristics

Twenty (31.7%) mothers in Group A and 26 (41.3%) mothers in Group B did not seek antenatal care during pregnancy. A significantly higher number (39.7%) of mothers in group A had antenatal ultrasound scans done, and the scans detected congenital anomalies in 9 (36.0%) mothers in Group A and 1 (7.1%) mother in Group B. Table 3 shows clinical characteristics of the mothers of newborns with surgical conditions referred to the MTRH.

Table 3

Clinical Characteristics of the Mothers of Newborns with Surgical Conditions Referred to the Moi Teaching and Referral Hospital

Variable	Group A	Group B	Test Statistic	p-value
Antenatal Care Visits	**n=63**	**n=63**	1.233[2]	
None (%)	20 (31.8)	26 (41.3)		
<3 (%)	29 (46.0)	25 (39.7)		
≥3 (%)	14 (22.2)	12 (19.0)		.540
Antenatal Ultrasound Scan	**n=63**	**n=63**	4.258[2]	
Yes (%)	25 (39.7)	14 (22.2)		
No (%)	38 (60.3)	49 (77.8)		**.033***
Trimester of Ultrasound Scan	**n=25**	**n=14**	4.203[3]	
1st (%)	2 (8.0)	3 (21.4)		
2nd (%)	14 (56.0)	7 (50.0)		
3rd (%)	9 (36.0)	4 (28.6)		.122
Congenital Anomaly Detected	**n=25**	**n=14**	3.271[3]	
Yes (%)	9 (36.0)	1 (7.1)		
No (%)	16 (64.0)	13 (92.9)		**.041***
Mode of Delivery	**n=63**	**n=63**	0.321[3]	
Normal vaginal delivery (%)	55 (87.3)	57 (90.5)		
Caesarean Section (%)	8 (12.7)	6 (9.5)		.571
Personnel Conducting Delivery	**n=63**	**n=63**	0.772[3]	

Non-skilled Birth Attendant (%) (TBA, family or neighbor)	7 (11.1)	5 (7.9)		
Skilled Birth Attendant (%) (doctor, nurse or nurse-midwife)	56 (88.9)	58 (92.1)		.380

Note. 2. *Chi-Square Test* ***(χ²) 3.*** *Fisher's Exact Test *Statistically Significant p-value*

Referral and Transport Characteristics of Newborns

Pre-Transport Stabilization

Ninety-six-point eight percent (96.8%) of the newborns in Group A were adequately warmed prior to transport, compared to 63.5% of the newborns in Group B, and only 3.2% of the newborns in Group B were given supplemental oxygen prior to transport compared to 66.7% of the newborns in Group A. The differences in the elements of pre-transport stabilization of the newborns in the two groups were statistically significant. Table 4 shows distribution of the newborns according to their characteristics on pre-referral and pre-transport stabilization.

Table 4

Distribution of the Newborns According to their Characteristics on Pre-referral and Pre-Transport Stabilization

Variable	**Group A n=63**	**Group B n=63**	**Test Statistic**	**p-value**
Warmed the baby (%)	61 (96.8)	40 (63.5)	22.009³	**< .001***
Given 10% Dextrose (%)	42 (66.7)	12 (19.0)	29.196²	**< .001***
Given Oxygen (%)	42 (66.7)	2 (3.2)	55.876³	**< .001***
Given IV Fluids (%)	51 (81.0)	22 (34.9)	27.388²	**< .001***
Baby positioned appropriately (%)	59 (93.7)	20 (31.7)	56.591³	**< .001***

Note. 2. *Chi-Square Test* ***(χ²) 3.*** *Fisher's Exact Test * Statistically Significant p-value*

Referral and Transport Characteristics

In the majority (98.4% in Group A, 84.1% in Group B) of the referred newborns, MTRH was contacted prior to commencement of the referral and transport process, and the main mode of communication was written (95.2% in Group A, 84.1% in Group B). The majority of the newborns were transported using government-run road ambulances (98.4% in Group A, 93.7% in Group B), and were escorted by trained medical personnel (98.4% in Group A, 92.1% in Group B). The median duration of transfer was 2.8 (IQR=2.0, 4.0) hours for the newborns referred from the hospitals in Group A, and 4.0 (IQR=2.5, 6.0) hours for those referred from the hospitals in Group B. The elements of referral and transport characteristics that showed statistically significant differences ($P < .05$) between the two groups were: contact with MTRH prior to referral, mode of communication, and duration of transport.

Care during Transport

During transport, the majority (87.1%) of the newborns in Group A, who had naso-gastric tubes, had appropriate care of their tubes, with tube aspirations being done at intervals of between 30 minutes and 1 hour. None of the newborns in Group B had their naso-gastric tubes aspirated at intervals of less than 1 hour. The main methods of maintaining warmth during transport were *Kangaroo Mother Care* and use of polythene bag wraps for the newborns referred from the hospitals in Group A; and use of cotton wool wraps for the newborns referred from the hospitals in Group

B. Intravenous fluid infusion was maintained in 52 (85.0%) newborns in Group A, and 13 (20.6%) newborns in Group B. Adverse events during transport were recorded in 6 (9.5%) newborns referred from the hospitals in Group A, and 25 (39.7%) newborns referred from the hospitals in Group B. The differences in the elements of care during transport between the two groups were statistically significant. Table 5 shows the distribution of newborns according to their characteristics on care during transport.

Table 5

Distribution of the Newborns According to their Characteristics on Care during Transport

Variable	Group A	Group B	Test Statistic	p-value
Naso-gastric Tube Aspiration every:	**n=39**	**n=8**	48.814[3]	
30 Minutes (%)	1 (2.6)	0 (0.0)		
30 Minutes – 1 Hour (%)	34 (87.1)	0 (0.0)		
>1 Hour (%)	4 (10.3)	8 (100)		**< .001***
Method Used to Keep Baby Warm	**n=63**	**n=63**		
Kangaroo Mother Care (Skin-to-Skin) (%)	25 (39.7)	10 (15.9)		
Use of Polythene Bag (%)	15 (23.8)	5 (7.9)		
Use of Clothing (%)	14 (22.2)	5 (7.9)		
Use of Aluminium Foil (%)	7 (11.1)	1 (1.6)		
Use of Cotton Wool (%)	4 (6.3)	55 (87.3)		
Use of Infant Incubator (%)	3 (4.8)	0 (0.0)		
Baby Given Oxygen	**n=63**	**n=63**	13.049[3]	
Yes (%)	42 (66.7)	3 (4.8)		
No (%)	21 (33.3)	60 (95.2)		**.001***
Baby Given IV Fluids	**n=63**	**n=63**	18.801[2]	
Yes (%)	52 (82.5)	13 (20.6)		
No (%)	11 (17.5)	50 (79.4)		**< .001***
Medical Documents Sent from Referring Hospital	**n=63**	**n=63**	18.801[3]	
	13 (20.6)	1 (1.6)		
Consent for Surgery (%)	47 (74.6)	51 (80.9)		
Referral Note (%)	2 (3.2)	3 (4.8)		
Radiology Report (%)	1 (1.6)	8 (12.7)		**< .001***
None (%)				
Specimens Sent from Referring Hospital	**n=63**	**n=63**	14.496[3]	
None (%)	50 (79.4)	63 (100)		
Blood (%)	13 (20.6)	0 (0.0)		**< .001***
Adverse Events Reported During Transport	**n=63**	**n=63**	17.261[3]	
Airway Blocked (%)	0 (0.0)	1 (1.6)		
O_2 Supply Exhausted (%)	2 (3.2)	2 (3.2)		
Clinical Deterioration (%)	4 (6.3)	22 (34.9)		
None (%)	57 (90.5)	38 (60.3)		**.001***

***Note.* 2.** *Chi-Square Test* **(χ^2) 3**. *Fisher's Exact Test, *Statistically Significant p-value*

DISCUSSION

Socio-demographic Characteristics of the Newborns

The socio-demographic characteristics of the newborns with surgical conditions referred to and treated at the MTRH, from the county hospitals in both groups were largely similar. However, the median age at admission suggested a delay in accessing newborn surgical care, which could be explained using the 3-delay model that characterizes barriers to health care-seeking [11, 12, 13]. The delay was observed despite the majority of the newborns being born in health facilities, a finding that was similar to that reported in other MICs [14, 15]. The median birthweight in both groups was similar to that found in other studies [16, 17], and the median weight at admission denoted a median physiological weight loss of between 3.0% and 3.5%, which is normal.

Maternal Characteristics

On the place of delivery, the low proportion of home deliveries in both groups was comparable to those reported in similar studies, which ranged between 10.5% and 24.0% [13, 15, 16, 18]. This study found proportions of health facility deliveries in both groups, that were higher than the 66.1% overall health facility deliveries in Kenya [19], and the 56.9% reported in a similar study in Nigeria [15].

The young median maternal age has been associated with congenital anomalies such as gastroschisis and neural tube defects, which comprised the majority of the surgical conditions in the newborns [20, 21]. The majority of the mothers in both groups had formal education, but were unemployed. Low socio-economic status is a known major contributor to the first and second levels of delays in the 3-delays model that leads to high neonatal mortality [13].

There was a low uptake of antenatal care, with very few mothers in both groups having made the recommended optimal antenatal visits during pregnancy. Maternal age, level of education, and occupation are major determinants of the uptake of focused antenatal care [22].

During those antenatal visits, the use of antenatal ultrasound scans was low in both groups, with even lower detection rates of congenital anomalies. Goldsmit *et al* reported similar findings in Argentina [14]. Onyambu and Tharamba reported a much lower detection rate of 3%, of congenital fetal anomalies on routine antenatal ultrasound screening of low-risk pregnancies [23]. Evidence-based policies developed by WHO have suggested that antenatal ultrasound scans done in early pregnancy may increase the detection rate of congenital anomalies [24].

The majority of the newborns in both groups were born via normal vaginal delivery, which was conducted majorly by skilled birth attendants. Nonetheless, the newborns still had a significant delay in accessing surgical care at the MTRH. Upadhyay *et al* and Sachan *et al* reported similar findings in India [16, 18].

Referral and Transport Characteristics of Newborns

The majority of the newborns referred to MTRH from the county hospitals in which the health intervention strategy was deployed received appropriate pre-transport care. Aggarwal *et al* and Buch *et al* underscored the importance of stabilizing sick newborns before referral [25, 26].

On appropriate communication, MTRH was contacted prior to the start of the referral and transport process in the majority of the newborns, a characteristic that showed a statistically significant difference between the two groups. Use of referral notes was the main mode of communication, a finding that was in

contrast to that by Butt *et al* in Pakistan, in which only 11.1% of the referred newborns had referral letters [27]. Proper medical note-keeping and referral documentation are key pillars of appropriate newborn transport. Mutlu and Aslan in Turkey found that 71% of the referred neonates had referral notes [28].

The majority of the newborns were transported by road ambulances. Prior to the devolution of healthcare system in Kenya, Barker *et al* reported that the number of road ambulances per hospital in Kenya was at 0.06 – 3.63 [9]. The sudden rise in the number of road ambulances in the counties could perhaps explain this finding, which was similar to that found in India [17]. In the contrary, a study in Nigeria reported the use of road ambulances at 4% [15].

The majority of the newborns were accorded escort by trained medical personnel during transport, which was appropriate, contrary to that found by Buch *et al* in India [25]. Aggarwal *et al* noted that newborn survival was better when trained medical personnel accompanied newborns during transport [26].

The median duration of pre-transport preparation of the newborns referred from the county hospitals in both groups showed no statistically significant difference, however, transport delays do contribute significantly to neonatal mortality [13, 16]. Mori *et al* in Japan noted that transported newborns with long duration of transport had 85% higher hazard of death [29].

Care of the newborn during transport is vital in mitigating the risks of adverse events [30]. In this study, the majority of the newborns referred from the county hospitals where the health intervention strategy was deployed had optimal care during transport. This included proper management of their naso-gastric tubes during transport which was critical in mitigating respiratory adverse events.

The main methods of maintaining warmth during transport were *Kangaroo Mother Care* and use of polythene bag wraps for the newborns referred from the county hospitals in Group A; and use of cotton wool wraps for those referred from the county hospitals in Group B. Maintaining newborn's core temperature at 36.5^0C-37.5^0C minimizes energy consumption and improves survival [31]. Innovative improvised methods of maintaining warmth during transport that included the *Kangaroo Mother Care*, polythene bag wraps, and aluminium foil wraps, were used more by the county hospitals where the health intervention strategy was deployed. Furthermore, the use of infant transport incubators was very low, perhaps owing to their unavailability at the county hospitals. Similar findings were reported in a study in Nigeria [15].

Joshi *et al* in India demonstrated that effective thermal control can be achieved using cheap and easily fabricated neonatal carriers [32], an innovative technology that could be vital in improving newborn survival, particularly in low/middle-income settings. The incidence of adverse events was low in newborns referred from the county hospitals where the health intervention strategy was deployed.

Effect of a Structured SOP for Newborn Transport, on their Referral and Transport Characteristics

There were statistically significant differences ($P < .05$) in the elements of referral and transport characteristics between the two groups of newborns. There is sufficient evidence that educational programs on newborn transport do improve their outcomes at the tertiary-level hospitals. Kumar *et al* noted significant improvement in the clinical status of the newborns at admission following an intervention on pre-transport stabilization [33]. Spector *et al* in Panama, and Martínez *et al*

in Mexíco, further demonstrated improvements in the outcomes of transported newborns at tertiary-level hospitals, that directly resulted from the implementation of neonatal provider educational programs - *Sugar and Safe Care, Temperature, Airway, Blood, Lab work, and Emotional support* (S.T.A.B.L.E.), and newborn transport guidelines respectively [34, 35]. A similar study in India reported a significant improvement in the quality of referral letters, and a decrease in the proportion of newborns seen at triage with physiological decompensation, following a referral education module [36]. However, the study findings need to be interpreted in the light of the study limitations that are often associated with cluster-randomized design.

In conclusion, the structured SOP for transport of newborns with surgical conditions, a health intervention strategy that is context-appropriate, implementable and scalable, had a significant positive effect on their referral and transport characteristics, and by extension, their overall outcomes at the MTRH. We recommend adoption/use of the structured SOP for transport of newborns with surgical conditions for improved survival, more so in resource-limited settings.

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