Uptake of Key Sanitation Practices on Prevalence of Diarrhoea in Tharaka Nithi County, Kenya: *A Comparative Analysis of two study sites.*

Cornellius Muendo, Isaac Mwanzo & Mohammed Karama

ABSTRACT

Background: Diarrhoea is among the leading causes of morbidity and mortality in children under five years in Kenya. Poor sanitation practices considerably contribute to the disease burden. In Tharaka Nithi County, the reported cases of diarrhoea remain significantly high despite the roll out of Community Health Strategy interventions in 2006. The Kenya's Community Health strategy is an approach of Healthcare service provision where individual households and communities are empowered to take a leading role in disease prevention and control initiatives.
Objective: To determine the influence of uptake of key sanitation practices on diarrhoea prevalence in Tharaka Nithi County, Kenya.
Methods: This analytical cross-sectional study enlisted a total of 394 primary respondents, including 196 respondents from the Community Health Strategy implementing sites and 198 from non-implementing sites. Interview schedules were employed in collection of quantitative data while focused group discussions and key informant interviews elicited qualitative information. A ***p*** value of less or equal to 0.05 ($p \leq 0.05$) was considered statistically significant.
Results: The study found a statistically significant higher diarrhoea prevalence amongst households that did not have access to improved sanitation facilities ($\chi^2 = 6.443$, df=2, p=0.04); that did not have handwashing facilities ($\chi^2 = 19.423$, df=2, p<0.001); that did not use soap in washing hands ($\chi^2 = 18.052$, df=2, p<0.001); that practiced unsafe disposal of children faeces ($\chi^2 = 24.252$, df=2, p<0.001) and those with a comparatively less knowledge on the steps of washing hands ($\chi^2 = 7.726$, df=2, p=0.021).
Conclusions: There was a significant associating between the uptake of key sanitation practices and prevalence of diarrhoea in the study sites.
Recommendation: The study underscores the need to increase demand for key sanitation practices in order to stem off cases of diarrhoea diseases in the County.

Index Terms: Community Health Strategy, Diarrhoea, Sanitation, Tharaka Nithi County and under five children.

1.0 INTRODUCTION

1.1 Background to the Study

Diarrhoea diseases account for 1 in 9 child deaths worldwide, making diarrhoea the second leading cause of death among children under the age of five years. The severity of diarrhoea is even worse in children infected with HIV whereby the death rate has been recorded at 11 times higher than the rate for children without HIV. Despite these sobering statistics, strides made over the last 20 years have shown that, in addition to rotavirus vaccination and breastfeeding, diarrhoea prevention focused on safe water and improved sanitation is not only possible, but cost effective. Every $1 invested in improving water and sanitation yields an average return of $25.50 (https://www.cdc.gov/healthywater/global/diarrhea-burden.html). A recent nationwide Kenya Demographic and Health Survey (KDHS) report indicated that overall, 15 percent of children under age five had diarrhoea, with 2 percent having diarrhoea with blood. However, few cases were reported among children who used improved sanitation facilities (11 percent) than among those who use non-improved sanitation

facilities (16 percent each) [1]. In response to the worsening disease trends, the Ministry of Health (MoH) in Kenya has over the years implemented several community focused programmes. For instance, in 2006 Kenya developed and adopted Community Health Strategy (CHS), a new approach aimed at improving health indicators through actively engaging communities in managing their own Health [2]. Since then, the Government and other development partners in the Health sector including civil society organizations (CSOs) have supported the initiative through establishing and operationalizing Community Health Units [3]. Despite these interventions, Tharaka Nithi County (TNC) has continued to record high cases of diarrhoea (prevalence rate of 20.5% in children under age five years compared to a National average of 15%) [1]. The objective of this study was, therefore, to determine the influence of uptake of key sanitation practices on prevalence of diarrhoea within Community Health Strategy implementing sites and non-Community Health Strategy implementing sites in Tharaka Nithi County, Kenya.

2.0 METHODS

2.1 Study Site: The study was conducted in Tharaka Nithi County (TNC). TNC is one of the 47 Counties in Kenya and covers an area of 2,662.1 Km^2; including the shared Mt Kenya forest estimated to have 360Km^2. The area borders Embu County to the South and South West, Meru County to the North and North East, Kirinyanga and Nyeri Counties to the West and Kitui County to the East and South East [4]. The County is sub-divided into four administrative sub-counties including Tharaka North, Tharaka South, Chuka Igambang'ombe and Maara Sub-counties. However, data was collected in Maara (Magutuni and Nkangani sub-locations) and Chuka Igambang'ombe (Kathatwa and Kanyakini sub-locations) Sub-counties, based on purposive sampling

2.2 Research Design: Analytical cross-sectional study design was deployed to concurrently measure the study variables in Community Health Strategy implementing sites and non-implementing sites. A Community Health Strategy implementing site constituted an administrative sub-location in which a functional Community Health Unit had existed for more than three years. Contrary, a non-implementing site constituted a sub-location where no efforts had been instituted to establish a Community Health Unit. The non-implementing areas were selected to mirror the characteristics of the Community Health Strategy implementing areas but, far enough (outside 5km radius) to control for spillover effects.

2.3 Study Variables

2.3.1 Coverage of Sanitation Facilities: This was calculated as a proportion based on the total number of households with sanitation facilities (both improved and unimproved facilities) within a Community Health Strategy implementing site or non-Community Health Strategy implementing site divided by the total households within the same site

2.3.1 Diarrhoea Prevalence: Diarrhoea was defined as the passage of three or more loose or liquid stools in a day. The study recorded diarrhoea episodes in children less than five years based on a fourteen day recall period and calculated the prevalence as a proportion of all reported cases compared to the total responses.

2.3.2 Coverage of Handwashing Facilities: The handwashing facilities included any water facility installed inside or immediately after a sanitation facility and dedicated solely for purposes of washing hands after visiting the sanitation facility. The coverage was calculated as a proportion of all the households with handwashing facilities compared to the total households within the study site.

2.3.3 Solid Waste Disposal Methods: The approaches deployed by the respective households to manage any domestic garbage or rubbish. The households were appraised on the basis of the method they used to dispose their domestic wastes, whether composting, burying, burning or indiscriminate dumping, among others.

2.3.4 Open Defeacation Sites: Open defecation was defined as defecation in fields, forests, bushes, bodies of water or any other open spaces

2.3.5 Knowledge: This entailed the examination of any facts, information and skills acquired by the households about sanitation related matters and conditions. The households were asked a set of knowledge questions, each aligned to possible correct answers on which the respondents were scored.

2.3.5 Study population
The study included residents of the selected study sites. In particular, the respondents were adults aged eighteen years and above; residents of Tharaka Nithi County; able and willing to provide informed consent and; had at least a child below the age of five years.

2.4 Sample Size determination
The following formula was used to calculate the sample size;
$n = D [(Z\alpha + Z\beta)^2 * (P1 (1 – P1) + P2 (1 – P2) / (P2 – P1)^2]$, [5].

Whereby;
n = required minimum sample size per study site
D = design effect, which provided a correction for the loss of sampling efficiency resulting from the use of clusters, this was set at 1.3, based on the estimates of design effect for similar characteristics in the 2010 Community Health Strategy evaluation report [6].
P1 = the estimated level of an indicator measured as a proportion for the non-Community Health Strategy implementing site (P1 was estimated at 0.328 in consideration of the population with access to improved sanitation in Tharaka Nithi County [7].
P2 = the expected level of the indicator at the Community Health Strategy implementing sites, such that the quantity (P2 – P1) is the size of the magnitude of change desired for detection. The sample size was calculated with an intention to capture a difference of 10 percentage points in the critical indicators.
Zα= the Z-score corresponding to the degree of confidence with which it is desired to be able to conclude that an observed change of size (P2 - P1) would not have occurred by chance (α is the level of statistical significance, set at 1.645 at 95% significance level), and
Zβ = the z-score corresponding to the degree of confidence required to detect a change of size (P2 – P1) if one actually occurred (β is the statistical power, estimated at 0.840 at 80% statistical power)

These parameters yielded a sample size of **373.5**. Apparently, the sample size was rounded to **400,** and distributed in a ratio of 1:1 amongst the Community Health Strategy implementing sites and non-Community Health Strategy implementing sites. This resulted into **100** primary respondents in each of the Community Health Strategy implementing sites (Magutuni and Kathatwa CHUs) and **100** primary respondents in each of the non-Community Health Strategy implementing site (Nkangani and Kanyakini sub-locations).

2.5 Sampling Techniques
A purposive sampling was used to select two Community Health Strategy implementing sites and two appropriate non-Community Health Strategy implementing sites. The selected Community Health Strategy implementing sites included Magutuni Community Health Unit (CHU) in Maara sub-County and Kathatwa CHU in Chuka Igambang'ombe Sub-County, while the non-Community Health Strategy implementing sites included Nkangani sub-location and Kanyakini sub-location in Maara and Chuka Igambang'ombe Sub-Counties respectively. The selection of the CHS implementing sites and the non-CHS implementing sites was based on the dynamics of Tharaka Nithi County and in particular the differences in socio-demographic characteristics, cultural practices, economic standing and geographical factors. Also, the selection took into consideration the households' livelihood characteristics and population density. Simple random sampling was used to identify the households' level respondents from both the selected Community Health Strategy implementing sites and the non-implementing sites. In this case, household registers (MOH 513) were used to compute the study population for the Community Health Strategy implementing sites, while the projected housing and population

census report of 2015 and sub-chiefs' population registers (where appropriate) guided the study population in the non-Community Health Strategy implementing sites. The key informants, including the participants of the focused group discussions were purposively selected taking into account their knowledge and exposure on community health services.

2.6 Data Collection Techniques

Data collection from primary respondents was organized in units embodying one Community Health Unit or a sub-location in the case of a non-Community Health Strategy implementing site. In this case, the research assistants first established the total number of households within every unit. All the households within every unit were listed separately and assigned a numerical value based on the order of appearance in the list. A random number generator application (software) installed in the smart phones of the research assistants was then used to randomly identify the participating households. In every selected household, an appropriate respondent was examined based on the established eligibility criteria. In cases where consent was denied, the study team thanked the concerned household and proceeded to the next selected household.

2.7 Data Analysis

The study generated both quantitative and qualitative data. Quantitative data gathered from the household level respondents' was analyzed using computer software (IBM SPSS, version 20) and MS Excel (version 2010). The sample characteristics were described using frequencies and percentages, while a chi-square test was used to infer the sample characteristics at the population level. A ***p*** value of less or equal to 0.05 (i.e. $p \leq 0.05$) was considered statistically significant. The qualitative information, mostly gathered from the key informants and focused group discussions were analyzed manually using thematic network analysis technique. The interpretations of the data were shaped based on the source and the themes emerging from the coded transcripts.

2.8 Ethical Considerations

Ethical clearance was obtained from Kenyatta University Ethics Review Committee (KUERC-KU/R/COMM./51/648). In addition, informed consent was sought from all the study participants prior to any data collection. Research permit was granted by the National Commission for Science, Technology and Innovation (NACOSTI/P/16/51833/10197). Participation in the study was purely voluntary and confidentiality of collected information was ensured at all stages.

3.0 RESULTS

3.1 Socio-demographic Characteristics of the Study Respondents

In all the respondents, the majority were household heads (42.1%), had attained at least primary education (42.1%), were females (56.6%) and currently married (65%). In addition, 93.9% of all the respondents were Christians.

3.2 Estimated Diarrhoea Prevalence

The study indicated that 15.1% of children in the Community Health Strategy implementing sites had experienced diarrhoea compared to 25% of children in the non-Community Health Strategy implementing sites. The differences in diarrhoea prevalence between the two study sites was statistically significant ($\chi^2 = 8.542$, df=2, p=0.003). The results are illustrated in the following diagram (figure 2).

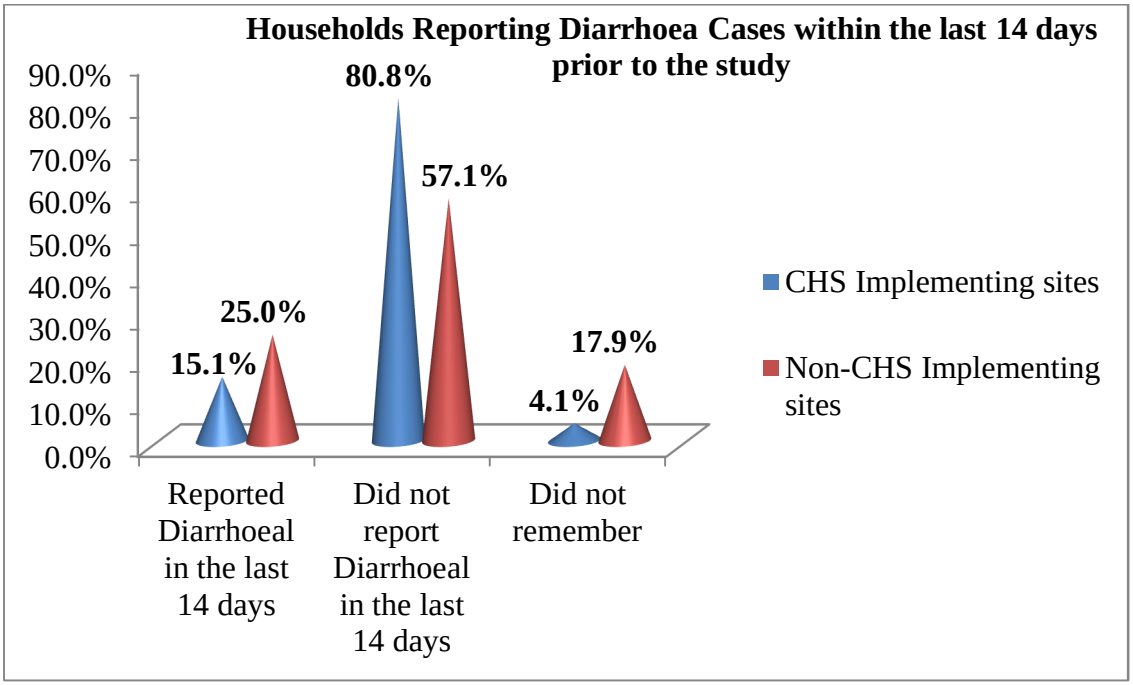

Figure.2: Reported Diarrhoea Cases within two Weeks Prior to the Survey

3.3 Type of Latrine Owned by the Household

The study found higher diarrhoea prevalence amongst households that used unimproved sanitation facilities compared to those that used improved sanitation facilities. A significant majority of 73.9% of all reported diarrhoea cases were recorded in households using unimproved sanitation facilities (χ^2 = 6.443, df=2, p=0.04). The findings are illustrated in Table 1.

Table 1: A comparison between Diarrhoea Prevalence and Type of Sanitation Facility

Type of Latrine owned by the Household * Reported Diarrhoea Incidences * Respondent Category Cross tabulation

% within Reported Diarrhoea Incidences

Respondent Category			Reported Diarrhoea Incidences			Total
			Yes	No	Don't Know	
CHS Implementing site	Type of Latrine owned by the Household	Unimproved	54.5%	34.5%	0%	36.2%
		Improved	45.5%	65.5%	100.0%	63.8%
Non-CHS Implementing site	Type of Latrine owned by the Household	Unimproved	91.7%	62.1%	71.4%	70.8%
		Improved	8.3%	37.9%	28.6%	29.2%
Total	**Type of Latrine owned by the Household**	**Unimproved**	**73.9%**	**44.0%**	**50.0%**	**50.4%**
		Improved	**26.1%**	**56.0%**	**50.0%**	**49.6%**

3.4 Availability of Hand Washing facilities

According to the study findings, 96% of all diarrhoea cases were reported in households that did not have a handwashing facility. Evidently, there was a statistically significant association between the availability of

handwashing facility and the reported diarrhoea prevalence ($\chi^2 = 19.423$, df=2, $p<0.001$). The low incidences of the reported diarrhoea in households that had handwashing facilities is attributable to theoretical reasoning that households with access to handwashing facilities will more likely wash hands after visiting a sanitation facility and at the four critical times than households without handwashing facilities.

Table 2: A comparison of the Availability of Hand Washing Facilities and Reported Diarrhoea Incidences

Availability of Hand Washing facility * Reported Diarrhoea Incidences * Respondent Category Cross tabulation

% within Reported Diarrhoea Incidences

Respondent Category			Reported Diarrhoea Incidences			Total
			Yes	No	Don't Know	
CHS Implementing site	Availability of Hand Washing facility	Yes	9.1%	64.4%	66.7%	56.2%
		No	90.9%	35.6%	33.3%	43.8%
Non-CHS Implementing site	Availability of Hand Washing facility	Yes	0.0%	18.8%	0.0%	10.7%
		No	100.0%	81.2%	100.0%	89.3%
Total	**Availability of Hand Washing facility**	**Yes**	**4.0%**	**48.4%**	**15.4%**	**36.4%**
		No	**96.0%**	**51.6%**	**84.6%**	**63.6%**

3.5 Use of Soap for Hand Washing

A statistically significant proportion (60%) of all diarrhoea incidences were reported in households that did not use soap in washing their hands ($\chi^2 = 18.052$, df=2, $p<0.001$). The results are presented in Table 3.

Table 3: A comparison of the Use of Soap for Hand Washing and Reported Diarrhoea Incidences

What the Households Use for Washing Hands * Reported Diarrhoea Incidences * Respondent Category Cross tabulation

% within Reported Diarrhoea Incidences

Respondent Category			Reported Diarrhoea Incidences			Total
			Yes	No	Don't Know	
CHS Implementing site	What the Households use for washing hands	Nothing/Ash/Sand/ Others	63.6%	11.9%	0.0%	19.2%
		Soap	36.4%	88.1%	100.0%	80.8%
Non-CHS Implementing site	What the Households use for washing hands	Nothing/Ash/Sand/ Others	57.1%	31.2%	60.0%	42.9%
		Soap	42.9%	68.8%	40.0%	57.1%
Total	**What the Households use for washing hands**	**Nothing/Ash/Sand/ Others**	**60.0%**	**18.7%**	**46.2%**	**29.5%**
		Soap	**40.0%**	**81.3%**	**53.8%**	**70.5%**

3.6 Access to Sanitary Facilities

The study did not find a significant association between diarrhoea and access to sanitation facilities.

Table 4: Comparison between Access to Sanitation Facilities and Reported incidences of Diarrhoea

Where the Respondent defeacated last time * Reported Diarrhoea Incidences * Respondent Category Cross tabulation

% within Reported Diarrhoea Incidences

Respondent Category			Reported Diarrhoea Incidences			Total
			Yes	No	Don't Know	
CHS Implementing site	Where the Respondent defeacated last time	Toilet	81.8%	94.9%	66.7%	91.8%
		Bush, open area	18.2%	5.1%	33.3%	8.2%
Non-CHS Implementing site	Where the Respondent defeacated last time	Toilet	71.4%	90.6%	90.0%	85.7%
		Bush, open area	28.6%	9.4%	10.0%	14.3%
Total	**Where the Respondent defeacated last time**	**Toilet**	**76.0%**	**93.4%**	**84.6%**	**89.1%**
		Bush, open area	**24.0%**	**6.6%**	**15.4%**	**10.9%**

3.7 Methods Used for Solid Waste Disposal

The study found statistically significant difference in reported diarrhoea incidences between the methods used to dispose domestic solid wastes, with households disposing their solid wastes through crude ways accounting for approximately 60% of all the reported diarrhoea cases (χ^2 = 11.413, df=2, p=0.003).

Table 5: Comparison between Reported Diarrhoea Incidences and Households' Solid Waste Disposal Practices

How Households dispose their domestic wastes * Reported Diarrhoea Incidences * Respondent Category Cross tabulation

% within Reported Diarrhoea Incidences

Respondent Category			Reported Diarrhoea Incidences			Total
			Yes	No	Don't Know	
CHS Implementing site	How Households dispose their domestic wastes	Composting/Burying	36.4%	81.4%	100.0%	75.3%
		Burning/Crude dumping/Others	63.6%	18.6%	0.0%	24.7%
Non-CHS Implementing site	How Households dispose their domestic wastes	Composting/Burying	42.9%	62.5%	70.0%	58.9%
		Burning/Crude dumping/Others	57.1%	37.5%	30.0%	41.1%
Total	**How Households dispose their domestic wastes**	**Composting/Burying**	**40.0%**	**74.7%**	**76.9%**	**68.2%**
		Burning/Crude dumping/Others	**60.0%**	**25.3%**	**23.1%**	**31.8%**

3.8 Methods Used to Dispose Children Faeces

Households that disposed children faeces in unsafe ways accounted for more than 56% of all the reported diarrhoea cases. These findings points to a highly statistical association between the reported incidences of diarrhoea and the methods used to dispose children faeces (χ^2 = 24.252, df=2, p<0.001). The results are illustrated in Table 6.

Table 6: Comparison between Reported Diarrhoea Incidences and the Methods used to Dispose Children Faeces

Where did you dispose the faeces from your child * Reported Diarrhoea Incidences * Respondent Category Cross tabulation

% within Reported Diarrhoea Incidences

Respondent Category			Reported Diarrhoea Incidences			Total
			Yes	No	Don't Know	
CHS Implementing site	Where did you dispose the faeces from your child	Dropped into toilet	36.4%	89.5%	100.0%	81.7%
		Disposed in the open ground/Indiscriminately	63.6%	10.5%	0%	18.3%
Non-CHS Implementing site	Where did you dispose the faeces from your child	Dropped into toilet	50.0%	87.5%	80.0%	76.8%
		Disposed in the open ground/Indiscriminately	50.0%	12.5%	20.0%	23.2%
Total	**Where did you dispose the faeces from your child**	**Dropped into toilet**	**44.0%**	**88.8%**	**84.6%**	**79.5%**
		Disposed in the open ground/Indiscriminately	**56.0%**	**11.2%**	**15.4%**	**20.5%**

3.9 Households Knowledge on the Critical times of Washing Hands

The study findings indicated that 72% of all the reported diarrhoea cases occurred in households that did not know all the critical times of washing hands. However, inferential statistics did not point to any statistically significant association between the occurrence of diarrhoea and the knowledge on the four critical times of washing hands (χ^2 = 0.651, df=2, p=0.722), as presented in table 7.

Table 7: Comparison between Reported Diarrhoea Incidences and the Households' Knowledge on the Four Critical times of Washing Hands

Respondents knowledge on the four critical times to wash hands * Reported Diarrhoea Incidences * Respondent Category Cross tabulation

% within Reported Diarrhoea Incidences

Respondent Category			Reported Diarrhoea Incidences			Total
			Yes	No	Don't Know	
CHS Implementing site	Respondents knowledge on the four critical times to wash hands	Knew all the four critical times	36.4%	28.8%	33.3%	30.1%
		Didn't Know all the four critical times	63.6%	71.2%	66.7%	69.9%
Non-CHS Implementing site	Respondents knowledge on the four critical times to wash hands	Knew all the four critical times	21.4%	40.6%	20.0%	32.1%
		Didn't Know all the four critical times	78.6%	59.4%	80.0%	67.9%

Total	**Respondents knowledge on the four critical times to wash hands**	**Knew all the four critical times**	**28.0%**	**33.0%**	**23.1%**	**31.0%**
		Didn't Know all the four critical times	**72.0%**	**67.0%**	**76.9%**	**69.0%**

3.10 Households Knowledge on the steps of Washing Hands

The study found statistically significant low diarrhoea incidences in households that knew four or more steps of washing hands compared to those who knew three or less than three steps. Approximately, 76% of all reported diarrhoea incidences were recorded in households that knew three or less than three steps of washing hands (χ^2 = 7.726, df=2, *p*=0.021). The results are summarized in Table 8.

Table 8: Comparison between Reported Incidences of Diarrhoea and Knowledge on Steps of Washing Hands

Knowledge on Hand Washing * Reported Diarrhoea Incidences * Respondent Category Cross tabulation

% within Reported Diarrhoea Incidences

Respondent Category			**Reported Diarrhoea Incidences**			**Total**
			Yes	**No**	**Don't Know**	
CHS Implementing site	Knowledge on hand washing	Knew more than four steps of handwashing	36.4%	61.0%	66.7%	57.5%
		Knew one, two to three steps of hand washing/Didn't know any step	63.6%	39.0%	33.3%	42.5%
Non-CHS Implementing site	Knowledge on hand washing	Knew more than four steps of handwashing	14.3%	37.5%	20.0%	28.6%
		Knew one, two to three steps of hand washing/Didn't know any step	85.7%	62.5%	80.0%	71.4%
Total	**Knowledge on hand washing**	**Knew four or more than four steps of handwashing**	**24.0%**	**52.7%**	**30.8%**	**45.0%**
		Knew none, one, two or three steps of hand washing	**76.0%**	**47.3%**	**69.2%**	**55.0%**

4.0 DISCUSSION

The study found a higher prevalence of diarrhoea amongst households that used unimproved sanitation facilities compared to those that used improved sanitation facilities. Existing empirical evidence points to the importance of improved sanitation in prevention of sanitation related diseases. An analysis of Demographic and Health surveys from 51 countries also established a higher association between diarrhoea prevalence and shared sanitation [8]. According to the findings of this study, 96% of all diarrhoea cases were reported in households that did not have a handwashing facility. Similarly, amongst all reported diarrhoea incidences, 60% were found in households that did not use soap in washing their hands. These results are consistent with the findings by Ejemot-Nwadiaro et al [9]. In their study, handwashing in schools was estimated to prevent more than 30% of diarrhoea episodes. Kamm, et al [10] also found a statistically significant reduction of diarrhoea incidences in households with soap compared to those without soap. In this study, households that disposed their domestic

wastes by crude dumping accounted for more than 63% of reported diarrhoea cases. The findings strengthen the public health argument that indiscriminate dumping of domestic wastes is a risk factor in childhood diarrhoea. In their assessment of Hygiene and sanitation risk factors of diarrhoea diseases among under-five children, Oloruntoba et al (2014) found significantly high diarrhoea prevalence in households that were exposed to breeding sites for flies. A study conducted in Ethiopia also found a statistically significant association between diarrhoea prevalence and households that had poor solid waste disposal systems [11]. Also, this study has established a highly statistical association between incidences of diarrhoea and methods used to dispose children faeces. The findings mirror a study in India that estimated the odds of diarrhoea incidences at 11% higher in households that disposed the children faeces unsafely [12]. Likewise, in Indonesia, a study found a strong association between unsafe disposal of children faeces and increased diarrhoea incidences [13]. Approximately, 72% of all the reported diarrhoea cases in this study occurred in households that did not know the critical times of washing hands. However, inferential statistics did not point to any statistically significant association between the occurrence of diarrhoea and the knowledge on the four critical times of washing hands. Similarly, the study did not find a statistically significant association between diarrhoea and access to sanitation facilities.

5.0 CONCLUSIONS

This study has demonstrated that uptake of key sanitation practices have a strong influence on the prevalence of diarrhoea. Such findings are significant in the context of interventions driven by the Kenya's Community Health Strategy.

6.0 RECOMMENDATIONS

The fact that households within Community Health Strategy implementing sites recorded low diarrhoea prevalence suggests the need to intensify and ensure increased uptake of sanitation practices. More significantly, the County Government should strengthen the capacity of Community Health Strategy workforce to fully intervene at the household level. The reasons for poor access to sanitation facilities should be thoroughly investigated and appropriate interventions initiated.

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9.0 CONFLICT OF INTEREST DISCLOSURE

The authors declare that there was no conflict of interest in the course of this study

10. AUTHORS

Cornellius Musembi Muendo; MPH, BSc; Tharaka Nithi County Government, Kenya; E-mail: corn.muendo@gmail.com;Mobile contacts: +254 726 238 582

Isaac Mwanzo; BA, MA, PhD. Department of Community Health, Kenyatta University, Kenya. E-mail: mwanzojm@gmail.com. Mobile contacts: +254 729 932 026

Mohamed Karama; PhD, MPH, Kenya Medical Research Institute – Nairobi, Kenya;E-mail:mhmdkarama@gmail.com, mhmdkarama@yahoo.com, Mobile contacts: +254 722 885 366

Corresponding Author
Cornellius Musembi Muendo; E-mail: corn.muendo@gmail.com;Mobile contacts: +254 726 238 582