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EVALUATING THE EFFICACY OF A SCHOOL-
BASED HAND HYGIENE PROGRAMME FOR
CHILDREN IN MALAWI, SUB-SAHARAN
AFRICA: A CLUSTER RANDOMISED
CONTROLLED TRIAL

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Evaluating the Efficacy of a School-Based Hand
Hygiene Programme for Children in Malawi, Sub-
Saharan Africa: A Cluster Randomised Controlled
Trial

Chingatchifwe Balwani-Mbakaya

A thesis submitted in partial fulfilment of
the requirements for the degree of Doctor of
Philosophy

June 2018

CERTIFICATE OF ORIGINALITY

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ABSTRACT

Title

Evaluating the efficacy of a school-based hand hygiene programme for children in Malawi, sub-Saharan Africa: A cluster randomised controlled trial.

Background

Infectious diseases remain responsible for significant global morbidity and mortality. Communities continue to confront a serious threat from infectious diseases. This threat imposes a serious disease burden and has a tremendous impact on the healthcare system globally. Diarrhoea and respiratory infections are the two most common causes of mortality among children, especially in developing countries. The estimated deaths associated with acute respiratory infection and diarrhoea among children in resource-limited countries are 5.5 million. Nearly 2,195 children die of diarrhoea every day, more than from acquired immuno-deficiency syndrome, malaria and measles combined. Diarrhoea accounts for one in every nine-child deaths in the world, making it the second leading cause of death among children. Children in school settings are at a higher risk for infectious diseases because they spend most of their time in school, mix with other children, and get exposed to many infections. In addition, they have poor hand hygiene practices. A hand hygiene programme including proper handwashing technique is the single most effective method of infection control. Hence, it

is important to set up hand hygiene protocols and provide adequate handwashing facilities in schools through the whole-school approach of the health-promoting school framework.

Schools are responsible for education; they do not expect to provide expert advice on prevention and management of infectious diseases, rather it is the role of healthcare professionals and local health authorities to develop hand hygiene protocols and deliver health education on the prevention and control of communicable diseases in schools. Effective and appropriate hand hygiene practice for primary school students is important in preventing diarrhoea and influenza, consequently leading to a reduction in school absenteeism. Efforts in promoting cognitive health through cognitive activities such as training and stimulation should start at an early age in order to maximise their cognitive function and overall health outcomes. Healthy living and lifestyle choices should introduce early in life. Research has shown that intellectual engagement and lifelong learning are associated with positive cognitive outcomes. Thus, it is important that healthy lifestyle behaviours such as proper handwashing technique should introduce in the early developmental stage to promote healthy lifestyle choices. This is possible to achieve in children because they have had less time to establish poor hygiene habits, unlike adults, whose habits are firmly grounded and difficult or unlikely to change.

Hand hygiene, especially proper handwashing technique, is given little attention due to limited resources, especially in developing countries. As such, there is a lack of a structured school-based handwashing programme

and available resources for children in primary schools in Malawi and other developing countries, especially in sub-Saharan Africa. Evidence of proper hand hygiene practice in schools in developing countries, including Malawi, remains scarce because very few evidence-based studies such as randomised controlled trials (RCT) conducted on hygiene among schoolchildren in developing countries. In addition, there is little evidence of a handwashing technique or procedure suitable for use by children in school settings to enhance the adoption of proper handwashing technique and compliance. A systematic review on hand hygiene intervention strategies to plan, implement and evaluate hand hygiene programme in developing countries identified that multilevel interventions were the most effective strategy to improve health outcomes. The components of multilevel interventions identified in this systematic review included formulating health policy/protocol, providing adequate training, creating supportive environments at different levels and ensuring resources availability by targeting different contextual levels, such as individual, group, community and organisation levels, to improve health outcomes. Thus, the researcher has adopted a multilevel interventions approach based on the concepts from the Bronfenbrenner ecological systems theory's five environmental systems (microsystem, mesosystem, exosystem, macrosystem and chronosystem). Bronfenbrenner's theory defines complex 'layer' of the environment and how each layer interacts with each other within the five systems. Thus, it is important to not only examine the child's immediate environment, but also at the interaction of the larger environment as each layer influences a child's own development (see figure below). Not only base on the concepts of Bronfenbrenner's theory as it aligns with the three focus areas of

intervention in the whole-school approach of the World Health Organisation (WHO)'s Health-Promoting School (HPS) framework. Thus, the study conceptual framework is the theoretical guide of this study (see below figure). The three intervention areas of the HPS framework are 1) school curriculum, teaching and learning; 2) school ethos, environment and organization; and 3) school community partnerships and services.

Aim

The aim of this study was to evaluate the efficacy of a school-based hand hygiene programme (SBHHP) using a multilevel interventions approach targeting schoolchildren, schools and their families in the intervention group versus the routine hand hygiene practice in the control group at four-time point (T₀, T₁, T₂ & T₃) for schoolchildren who participated in this study in Malawi, sub-Saharan Africa.

Objectives and hypotheses

Primary outcome measure

Objective 1: To appraise the impact of a SBHHP on schoolchildren's handwashing compliance (knowledge, skills and cleanliness) at four-time point.

(i.e. knowledge refers to the scores of handwashing quiz; skills/technique refer to the scores of handwashing observational checklist; and hand cleanliness refers to the scores of the fluorescent stain test on both hands).

Hypothesis 1.1: The group by time effect on knowledge score would be statistically significant after implementing SBHHP.

Hypothesis 1.2: The group by time effect on technique score would be statistically significant after implementing SBHHP.

Hypothesis 1.3: The group by time effect on hand cleanliness score would be statistically significant after implementing SBHHP.

Hypothesis 1.4: The mean scores of handwashing quiz, the mean scores of observational checklists on proper handwashing technique and the hand cleanliness mean scores of the fluorescent stain test would be higher (better) after implemented the SBHHP using a multilevel interventions approach in the intervention group than in the control group at post-tests.

Secondary outcome measures

Objective 2: To assess the impact of the SBHHP on reducing children's sickness-related school absenteeism by evaluating the number of sick leave days.

Hypothesis 2: The number of sick leave days would be lower after implemented the SBHHP using a multilevel interventions approach in the intervention group than in the control group at post-tests.

Objective 3: To explore the acceptability of a multilevel interventions approach (i.e. formulating hand hygiene health policy/protocol, providing behavioural-change training on proper handwashing technique, creating supportive environments for schoolchildren at school and home settings, and ensuring the availability of physical and human resources to implement the programme) to plan and implement the SBHHP in primary schools in Malawi.

Evaluation 3: To conduct focus group discussions with schoolchildren, school teachers, school principals and parents, to evaluate the acceptability (i.e. formulating hand hygiene health policy/protocol, providing training on proper handwashing technique, creating supportive environments and ensuring resources availability) of the planning and implementation of the SBHHP in primary schools in the communities of Mzuzu City, Malawi.

Conceptual framework

Based on the review and concepts building from Bronfenbrenner's ecological systems theory and the interventions from HPS framework, a conceptual framework proposed for this study (see Figure 4). The theoretical foundation guiding this study are Bronfenbrenner's ecological system theory. The study of the children's environment conceptualizes from the ecological system theory. The ecological systems perspective or theory places emphasis on the interrelationships across levels of activity and includes not only the impact the individual has on his/her environment, but also the impact the environments have on the individual.

In this study, the researcher adopted a multilevel interventions approach based on the concepts of the Bronfenbrenner's ecological systems theory that examines a child's development within the context of the systems environment and the relationships that form his or her surrounding environments, such as school environment, home environment and community environment. The researcher in this study planned and implemented hand hygiene programme by targeting more than one contextual factor that influence the schoolchildren's environments, including at the individual, group, community and organisational levels, to improve their health outcomes. This work included formulating the hand hygiene protocol, providing behaviour-change training on proper handwashing technique, creating a supportive school environment to practice the handwashing technique and ensuring the availability of handwashing resources, including adequate workforce, for planning and implementing the SBHHP for schoolchildren in participated primary schools in Malawi.

The term multilevel interventions refer to those that affect at least two levels of influence for example, the child level, and the family level to improve health outcomes. An intervention is a specified strategy or set of strategies designed to change the knowledge, perceptions, skills, and behaviours of individual, groups or organization, with the goal to improve health outcome. The purpose of multilevel interventions is to affect the critical contextual issues and create a more efficient, effective, and coordinated public health care delivery system that achieves relevant patient outcomes, including improved hand hygiene care to prevent infectious outbreaks, to reduce

school absenteeism and increase school attendance, to enhance health-related quality of life, at a reduced cost of all involved.

In this study, the strategies of the multilevel interventions approach base on the findings of the researcher's systematic review conducted by Mbakaya and colleagues including policy development, behaviour-change training, supportive environments and resource availability. The researcher also examined beyond the individual's systems level for the planning and implementation of this SBHHP based on the concept of Bronfenrenner's social system theory and the three areas of intervention within the schools and outside the communities of the WHO's HPS framework. The three areas of intervention of the HPS framework are 1) school curriculum, teaching and learning, 2) school ethos, environment and organisation, and 3) school community partnership and services. Thus, the components of a multilevel interventions approach for the planning and implementation of the SBHHP consisted of development of hand hygiene protocol, integration of hand hygiene care into school curriculum targeted more than one contextual levels for example the children, families and community across the school systems level rather than one single level as described in the followings. In this hand hygiene study, the strategies to plan and implement the multilevel interventions targeting different levels of system in the child's environment. They were the integration of teaching and learning materials of hand hygiene programme into the school curriculum targeting schoolchildren and their families, formulation of hand hygiene protocol targeting school policy and community, creation of health promoting environment targeting children and their families, behaviour-change training

on proper hand washing technique targeting individual child, peers and their families, development of stickers and posters of the simplified 5-step handwashing technique targeting children and families, make available handwashing resources in school and home settings, and partnership with health policy makers, community leaders and parents. The principles of the Bandura's social learning theory and Ajzen's theory of planned behaviour adopted to facilitate the schoolchildren's behaviour change in order to promote proper handwashing technique. On the other hand, schoolchildren in the control group were encouraged to continue with their usual practice of handwashing, in which the WHO's 7-step handwashing technique was expected to be followed. The hand hygiene resources were given to control group.

Methods

Study design

A cluster randomised controlled trial (RCT) design adopted in this study. The study sample randomised into intervention and control groups. There were four-time points in this study: at the baseline (T_0), at the 3rd month immediately after students participated in the SBHHP (T_1), at the 6th month compliance evaluation (T_2) and at the 9th month for sustainability testing (T_3). Six focus group discussions with 37 participants, including parents, school staff, and primary school students were nested in a cluster RCT to enhance the quality of data and to explore the perception and the impact of the multilevel interventions approach targeting more than one level of

system using strategies such as policy development, behaviour-change training, supportive environments and resource availability. The primary outcome measure of this study was the primary school students' compliance with proper handwashing technique (knowledge, skill and cleanliness), and the secondary outcome measures were the reduction in the school absenteeism (sick leave days) and the acceptability of the implementation of the SBHHP using a multilevel interventions approach.

Sampling and Setting

Six schools were randomly selected and allocated to intervention (3 schools) or control (3 schools), with 375 schoolchildren. All eligible schools (12) were included in the randomisation process for selection using an online randomisation process to generate a randomisation plan. An independent person came up with sequentially numbered, opaque, sealed envelopes (SNOSE) for allocation concealment. Malawi's population estimated at 19,107,706 people. Mzuzu locates in the northern region of Malawi. It is the third largest city in Malawi, with a total area of 26,931 square kilometres and a total population of 175,345 people. The city has 55 elementary/primary schools, of which 41 are government owned and 14 are private schools. This study took place in six private primary schools in Mzuzu from September 2016 to July 2017. Private primary schools have better hygiene and sanitation facilities compared to government primary schools in the city in terms of toilet facilities, water facilities, rubbish disposal around the school and the bodily hygiene of students.

Study instruments

The first of the six study instruments used the demographic sheet, which was used to collect information on the age, class, gender, and location of schools. Second, the handwashing quiz used to collect information on students' knowledge regarding handwashing. Third, the observational checklist used to monitor the schoolchildren's competency in adoption of the simplified 5-step handwashing technique. The fourth study instrument used the fluorescent stain test, which was used to check the schoolchildren's compliance in terms of the cleanliness of the hands, with four rating scores. The fifth study instrument was the sick leave record form, which was used to collect data on students' sick leave day. Lastly, the guide of focus group discussion developed from the literature review used to collect qualitative data to enhance the quality of study data.

Data Analysis

IBM's SPSS statistics 23 software used to analyse the data. The principles of intention to treat (ITT) was applied. Little's MCAR test was insignificant (chi square = 201.44, $df = 381$, $p > .05$). The hierarchical structure of the original data considered when analysing the data, and the multilevel model was used to analyse the effects of each level such as school and students. A generalised linear mixed model (GLMM) used to model the fixed effects of time, group, grade, and their interaction with time; the residual effects across time; and the random effects of the intercepts of the schools on target variables, including knowledge score, technique score and hand cleanliness. The random effect was the intercepts of the schools. The significance level (alpha) was set at .05. No assumptions (homoscedasticity, normality and

linearity) violated. Absence records for a full academic year (2016/2017) extracted from the school attendance register and used as input data. Generalised estimating equations (GEE) used to analyse number of sick leave days between groups across school terms.

Finally, thematic analysis used to analyse the data obtained through focus group discussion on the acceptability of the multilevel interventions approach of the SBHHP focusing on the implementation of the hand hygiene protocol, training in the handwashing technique, and the availability of hand hygiene resources. Meanings coded, and themes were emerged to ensure that the formulated meaning accurately reflected their true intention. Two coders, the researcher and another doctoral student, identified themes independently and compared codes, and a third person (another doctoral student) resolved any differences raised by the two coders to ensure rigour.

Results

The study findings show that implementation of the SBHHP using multilevel interventions approach had a significant impact on hand hygiene compliance and its sustainability among primary school students in the intervention group. There was a statistically significant improvement in the handwashing quiz scores (knowledge) in the intervention group compared to the control group ($p < 0.05$) at the 3rd month immediately after students participated in the SBHHP (T₁), at the 6th month for compliance evaluation (T₂) and at the 9th month for sustainability testing (T₃).

Compared with the control group, the intervention group had better knowledge scores ($B=1.97$, 95% CI [1.16, 2.79], $p < .001$). In addition, there was a statistically significant improvement in the handwashing observational checklist (technique score) in the intervention group compared to the control group ($p < 0.05$) at the 3rd month immediately after students participated in the SBHHP (T_1), at the 6th month for compliance evaluation (T_2) and at the 9th month for sustainability testing (T_3). The intervention group achieved better 5-step technique scores than the control group ($B=5.14$, 95%CI [4.48, 5.54], $p < .001$). In terms of their fluorescent stain score (hand cleanliness), the improvement was statistically significant at the 6th month for compliance evaluation (T_2) and at the 9th month for sustainability testing (T_3) ($p < 0.05$). Compared with the control group, the intervention group was associated with better hand cleanliness scores ($OR=21.51$, 95%CI [4.38, 105.72], $p < .001$). Compared with the 3rd term/semester, the 1st term/semester was significantly associated with higher number of sick leave days ($B=8.417$, 95%CI [.948, 15.885], $p=.027$). At baseline, the number of sick leave days was lower in control group, but the number decreased across time in the intervention group.

The synthesis of the themes and sub-themes from the focus group discussions indicates that implementation of the SBHHP using a multilevel interventions approach had high acceptability and potential for sustainability of proper handwashing technique among primary school students in the school communities in Malawi.

Discussion

The results of the SBHHP show significant effect on the study outcomes at different contextual levels such as organisation (resource mobilisation, hand hygiene protocol, training), community (community/family linkage, supportive environment), group (group and social influence) individual level (improved hand hygiene compliance, reduced sick leave days).

The SBHHP based on the concepts of Bronfenbrenner's social systems theory, a socioecological model for understanding the multilevel contributors to improve schoolchildren's ecological outcomes. This model recognises the importance of policy, environment and social influences on population level that is much greater than that of individually targeted interventions. For example, study findings in Finland reported that tobacco use declined over ten years after launched a community-wide multilevel intervention to reduce cardiovascular diseases.

Overall, the study findings show that implementation of a SBHHP had significant effects on schoolchildren's handwashing compliance, including increased scores in knowledge ($p < .001$), handwashing technique ($p < .001$) and hand cleanliness ($p < .001$). There was also a significant decrease in the number of school absenteeism days across time in the intervention group ($p = .027$). The results of this study also agree with similar studies conducted previously in other countries like Netherlands, Thailand and Hong Kong in different contextual levels.

For the organization level, the outcome of the SBHHP was evident through incorporating the hand hygiene protocol into the school curriculum, hand hygiene resource mobilization, and training. Incorporating hand hygiene protocol into the school curriculum, which is in line with the WHO's HPS framework is a significant step in achieving and scaling up the implementation of SBHHP in Malawi and other developing countries. The study findings are similar to a study conducted by Lee and colleagues in Hong Kong. They found that students in the Hong Kong Healthy Schools Award (HSA) scheme were better in hygiene practice, knowledge on health and hygiene, as well as access to health information. HSA schools reported to have better school health policy, higher degrees of community participation, and better hygienic environment.

For the individual outcome of the SBHHP upheld in the intervention group at the 9th month follow-up assessment for sustainability testing (T₃) on hand hygiene compliance and reduced school absenteeism (sick leave days). The study findings are similar to a study conducted by Lee and her colleagues, as they found that intervention group experienced a significant increase in the rating of their handwashing quality. The intervention school also experienced a significantly lower absenteeism rate than the control group in the same academic year.

For the family level, the SBHHP had an effect on creating a linkage with the family members. Results from focus group discussion show that parents provided hand hygiene resources for their children. The family also provided a supportive environment for their child to continue with hand

hygiene practice. In the current study (SBHHP), the researcher linked the student's family through leaflet containing information on when, why and how to wash hands (take home package). Parents also participated in the focus group discussion.

The study findings are similar to a study conducted in Appalachian Ohio on the uptake of human papilloma virus (HPV) vaccine by Paskett and colleagues. Participants in the intervention group received a take home package on HPV information. The comparison group received influenza vaccine information sheets. They found that by six months, more daughters of intervention participants received the first HPV vaccine shot compared to daughters of comparison group participants.

This is a significant indicator for behavioural change and compliance with proper handwashing technique among schoolchildren regarding hand hygiene practice. The findings of this trial also suggest that using simple techniques such as the simplified 5-step technique for washing hands, as well as the provision of expert advice and necessary resources in schools could improve the adoption/practice of and compliance with proper handwashing technique. The SBHHP has potential to implement in Malawi, because the primary school students, staff and parents, as evidenced by quantifiable results and verbatim quotes in the data from the focus group discussions have already accepted it. The new knowledge generated by this study relates to the application of multilevel interventions approach based on Bronfenbrenner's ecological systems theory to examine the five layers of environmental influences on schoolchildren in planning and implementing a

SBHHP. Each layer interacts with the others. To study a child's development in Bronfenbrenner's ecological systems theory, it is important to examine not only the child and his or her immediate environment, but also the interaction of the larger environment as well. This aligns with the three areas of intervention of the WHO's whole-school approach in the HPS framework. The study limitations were the observational bias (Hawthorne effect), which may have resulted in increased proper handwashing, including skill display, because participants knew that they were being observed through photographic and video capturing. The study population included only schoolchildren from private schools in the developing countries, thus the generalisation of the study findings is limited. Single-blinded assessor was used to score the 5-step handwashing technique (skill acquisition) of schoolchildren. As such, no inter-rater correlation for reliability analysis was calculated.

Conclusion

The implementation of the SBHHP adopts the multilevel interventions approach based on the concepts of the Bronfenbrenner's environments theory, which aligns with the three areas of intervention of the WHO's whole-school of HPS framework. This is an effective strategy in improving hand hygiene compliance, school attendance and reducing school absenteeism (sick leave days) among schoolchildren. The results of this study suggest that the planning and implementation of a SBHHP targeting the schoolchildren, family, community groups and school and government organisations have shown evidence of improved study outcomes at different contextual levels such as organisation (resource mobilisation, hand hygiene

protocol, training), community (community/family linkage, supportive environment), group (group and social influence) individual level (improved hand hygiene compliance, reduced sick leave days).

The results of this study show that the strategies to implement SBHHP using a multilevel interventions approach including the partnership between education and school sectors to plan and formulate the hand hygiene protocol and provide behavioural-change training on proper handwashing technique in a supportive school environment that is essential for the implementation of SBHHP. It is the most effective interventional strategy to go beyond the individual to promote and sustain schoolchildren's competency and compliance in performing proper handwashing technique in schools, especially in developing countries. Adopting a multilevel interventions approach in this study has provided an impetus for health promotion campaigns target beyond the individual's environment such as assessing the schoolchildren's surrounding by various environments in the system level targeting specific groups to improve their health outcomes after behavioural change. The design and implementation of SBHHP using multilevel interventions facilitated by input from the school community. Research findings support that it is useful to assess and evaluate the impact of interventions at multiple levels, rather than using a single-level intervention to improve population health outcomes. More advanced study methods and measure need to evaluate the impact of the various levels and components of such interventions.

Key words

Multilevel interventions approach, school-based hand hygiene programme, schoolchildren, handwashing technique, compliance, sick leave days

LIST OF PRESENTED AND PUBLISHED WORK

Refereed journal articles published from this thesis

1. **Mbakaya B.C.**, Lee P.H., & Lee R.L. (2017). Hand Hygiene Intervention Strategies to reduce diarrhoea and respiratory infections among children in developing countries: A systematic review. *International journal of Environmental Research and Public Health*. DOI: [Int. J. Environ. Res. Public Health 2017, 14\(4\), 371](#)

2. **Mbakaya B.C.** & Lee R.L. (2018). Promoting hand hygiene care in Malawi, Southern Africa: A qualitative study on school children's, school teachers' and family caregivers' attitudes, roles and experiences. *Journal of Advanced Nursing*. (Submitted for peer-review).

Conference presentations

1. **Mbakaya B.C.**, Lee P.H., & Lee R.L. (2018). Impact of a multicomponent hand hygiene intervention in the school communities of Malawi sub-Saharan Africa: A cluster randomized trial. [Abstract and Poster presentation] The 4th Asia-Pacific Biennial School Nurses/School Health Conference 3-5 August 2018, Taiwan

2. **Mbakaya B.C.**, Lee P.H., & Lee R.L. (2017). Designing and evaluating a school-based handwashing programme in Malawi: A Cluster Randomized Controlled Trial. *Collective Conversation: Education, Quality & Research in Nursing & Midwifery Practice*. [Abstract and Oral presentation] The 3rd Australian Nursing & Midwifery Conference.

(September 15, 2017). Newcastle Exhibition & Convention Centre, Newcastle, NSW, Australia.

3. Mbakaya B.C., Lee P.H., & Lee R.L. (2016). Factors affecting handwashing practice among schoolchildren in developing countries: A Systematic Review. [Abstract and Poster presentation]. Global Network of World Health Organisation Collaborating Centers Conference. (July 28, 2016), Glasgow Caledonian University, Glasgow, Scotland.

4. Mbakaya B.C., Lee P.H., & Lee R.L. (2016). Interventions to Support Multimodal Implementation Strategies of Hand Hygiene Programmes to reduce infectious diseases and school absenteeism among schoolchildren in Developing Countries: A Systematic Review: [Abstract and Oral presentation]. International Community Health Conference. World Health Organization Collaborative Centre for Community Health Services. (May 21, 2016), Zhengzhou University, Hanan, China.

Institutional presentations

1. Mbakaya B.C. Designing and evaluating a school-based hand hygiene programme in Malawi: A Cluster Randomized Controlled Trial. School Research Seminar (April 2016), School of Nursing, The Hong Kong Polytechnic University, Kowloon, HONG KONG.

2. Mbakaya B.C. Hand hygiene intervention strategies to reduce diarrhea and respiratory infections among schoolchildren in developing countries: A systematic review. School Research Seminar (March 2017), School of Nursing, The Hong Kong Polytechnic University, Kowloon, HONG KONG.

3. Mbakaya B.C. Designing & evaluating the efficacy of a hand hygiene programme for schoolchildren in Malawi: A Cluster Randomized Controlled Trial. School Research Seminar (December 2017), School of Nursing, The Hong Kong Polytechnic University, Kowloon, HONG KONG.

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LIST OF ABBREVIATIONS

(In alphabetical order)

ACS	Average of the Change Score
AIDS	Acquired Immuno-Deficiency Syndrome
CDC	Centres for Disease Control
CIOMS	Council for International Organizations for Medical Sciences
cRCT	cluster Randomized Controlled Trial
DCCs	Day Care Centres
DEMO	District Education Management Office
GLMM	Generalised linear mixed model
HHP	Hand Hygiene Programme
HPS	Health-promoting school
HPV	Human papillomavirus
HAS	Health School Award
HWP	Handwashing Programme
ISAMA	Independent Schools Association of Malawi
ICC	Intra-cluster Correlation Coefficient
ID	Infectious Disease
IPC	Infection Prevention and Control
LOESS	Locally Weighted Scatter-plot Smoother
MCAR	Missing Completely at Random
MDHS	Malawi Demographic and Health Survey
MMoH	Malawi Ministry of Health
MPH	Master of Public Health

NGOs	Non-Governmental Organizations
NHSRC	National Health Sciences Research Committee
PLUM	Polytomous Universal Model
RCT	Randomized Controlled Trial
SBHHP	School-based Hand Hygiene Programme
SNOSE	Sequentially Numbered Opaque Sealed Envelopes
SPSS	Statistical Package for the Social Sciences
UNICEF	United Nation International Children's Emergency Fund
WASH	Water Sanitation and Hygiene
WFP	World Food Programme
WHO	World Health Organization

CHAPTER ONE

INTRODUCTION

1.0 Introduction

The continuously high prevalence rate of respiratory diseases and the outbreaks of infectious diseases among schoolchildren globally have raised public health concerns in the school community (Centres for Disease Control [CDC], 2013). Despite three decades of hand hygiene (HH) campaigns and initiatives, schoolchildren's proper handwashing technique rates remain low (<35%). The prevalence and outbreak of infectious diseases are still rising globally, especially in developing countries, due to inadequate evidence and scientific data, and lack of policies, training and resources (Langford, Bonell, Jones, Pouliou, Murphy, Waters,, & Campbell, 2014; UNICEF, 2015; WHO, 2014; 2009).

This chapter therefore provides a background on public health concerns related to outbreaks of infectious diseases and current issues in schoolchildren's hand hygiene behaviour. In addition, it gives an overview of the purpose/aim, objectives and significance of this study. It also defines the concepts as used in this study (operational definitions). Finally, the chapter describes the structure and organisation of the whole thesis.

1.1 Public health concerns regarding outbreaks of infectious diseases among children

Diarrhoea accounts for most child deaths in the world, making it the second leading cause of death among children (CDC, 2015). It accounts for nearly 11% of child deaths globally (CDC, 2015). Hands are common vectors in the transmission of many infectious diseases, such as diarrhoea and influenza. Diarrhoea is a serious global public health problem (Ejemot, Ehiri, Meremikwu, & Critchley, 2008). Gastrointestinal and respiratory infections are the most commonly occurring illnesses among schoolchildren because of improper handwashing techniques in the school community, which is a global concern in the public health agenda (World Health Organisation [WHO], 2009). Epidemiological evidence indicates that the most significant risk factors for transmission of diarrhoea and respiratory infection are human behaviours such as lack of proper handwashing technique (Curtis, Danquah, & Auger, 2009). Nearly 2,195 children die of diarrhoea daily, which is like losing nearly 32 school buses full of children every day. This is more than that for acquired immuno-deficiency syndrome (AIDS), malaria and measles combined (CDC, 2015). Diarrhoea accounts for 1 in every 9 child deaths in the world, making it the second leading cause of death among children (CDC, 2015). In addition, diarrhoea is the second most common cause of death among school-aged children in sub-Saharan Africa (Rao, Lopez, & Hemed, 2006).

1.2 Current issues in children's hand hygiene behaviour in school settings

Infectious disease outbreaks in school communities often go unrecognised and unappreciated, placing a tremendous burden on the public health agenda (WHO, 2009). Gastrointestinal and respiratory infections are the most commonly occurring illnesses among kindergarten, pre-school and primary school students, because of their poor hand hygiene. Children in school settings are 18 times more likely to contract pathogens, such as those causing gastrointestinal and respiratory infections (Bylinsky, 1994).

Poor hand hygiene practices cause 272 million days of school absenteeism, as well as other health conditions, such as diarrhoea and respiratory disorders, in the general population (World Vision International, 2017). Diarrhoea has a detrimental impact on childhood growth and cognitive development, thereby affecting school performance in two ways, through absenteeism and cognitive performance (CDC, 2015). In addition, there is poor collaboration between the education and health sectors to promote hand hygiene in schools to reduce infectious disease outbreaks and school absenteeism, especially in developing countries (Langford et al., 2014; WHO, 1996).

Availability of water and sanitation coverage in schools in developing countries was at 51%, compared to 89% in developed countries (United Nations International Children's Emergency Fund [UNICEF], 2015). UNICEF (2014) has reported that only 21% of schools in developing

countries had handwashing facilities. In addition, nearly two-thirds of schools in developing countries have inadequate sanitation (UNICEF, 2010), yet it is a fundamental right of every child to have a safe and healthy learning environment, including clean water, sanitation and hygiene services (UNICEF, 2013). Inadequate water sanitation and hygiene (WASH) services affect the attendance and performance of children in schools, because children will not wash their hands and thus in turn will contract infectious diseases such as diarrhoea and influenza, leading to poor health and school absenteeism.

The Malawi Demographic and Health Survey (MDHS) Education Data Survey (2002) indicates that 97% of students in Malawi were absent one or more times during the 2001 school academic year, and that 86% cited illness as a reason for their absenteeism. Diarrhoea and respiratory infections are among the leading causes of illnesses that affect primary school students in developing countries, including Malawi (Black, Morris, & Bryce, 2003; MDHS, 2010). These infectious diseases affect primary school students and the community in general, mainly because of their poor hygiene practices that lead to cross-contamination of the causative organisms of influenza and diarrhoea. This poses a great threat to the public, especially to schoolchildren, who are more vulnerable because of their immature immunity and thus their limited ability to defend themselves against infection, and because of the school setting in which they spend most of their time, mix with other children, and exposed to many infections. These infections can further transmit to their family members and the general community through cross-contamination, leading to serious outbreaks of

various forms of infectious disease and making the school setting an important place for infectious disease transmission, prevention and control.

Training helps to predict behavioural intention because it influences one's attitude, subjective norms and perceived behavioural control (Ajzen, 1991). In addition, training influences self-efficacy by raising positive awareness, influencing their attitude, and affecting their practice/behaviour, making it more likely for the child to learn a new behaviour (Bandura, 1997). In addition, for both learning and behaviour change to take place, students need a support system that embraces a multi-sectoral approach, allowing them to learn through observation (Ajzen, 1991; Bandura, 1997). It is important to provide adequate training on proper hand hygiene and resources, as well as a supportive environment in school settings, because in these settings, children are often crowded together and can easily contaminate each other with pathogens that cause influenza and diarrhoea, leading to outbreaks. In addition, children often have poor hand hygiene practices because of their young age and the complexity of the handwashing technique.

A supportive environment with available resources to promote hand hygiene in the very early years is very important in making changes to their health behaviours. Lifestyle and behavioural choices should develop during childhood (Eshuchi, 2013; State Government of Victoria, Australia, 2017). In addition, the hand hygiene behaviours that children learn at school are skills they are likely to practise as adults and pass on to their own children in future (WHO, 2009). This is possible to achieve in children because their

poor hygiene habits are less established, unlike adults, whose habits are firmly grounded and difficult or unlikely to change (Eshuchi, 2013). Children are also more eager to learn and are role models for their younger siblings, with the potential to affect their behaviour since they are able to share information learnt at school when they get home to their families (Eshuchi, 2013). However, ensuring proper hand hygiene practice/behaviour and making supplies and infrastructure available for primary school students remain a major challenge (Zhang, Mosa, Hayward, & Mathews, 2013). Some of the significant challenges in promoting correct hand hygiene practices include successfully transforming knowledge into behaviour change among at-risk populations, such as schoolchildren, and ensuring the affordability, availability, and accessibility of handwashing supplies and infrastructure (Zhang et al., 2013). These challenges call for multilevel research that advocates for policy development, adequate training, environment and resource mobilisation to promote hand hygiene compliance (International Union for Health Promotion and Education [IUHPE], 2008).

Evidence on planning and implementing proper hand hygiene programmes in school settings, especially in developing countries such as Malawi, remains scarce. As reported in the two systematic reviews conducted by Mbakaya, and colleagues (2017), Langford, and colleagues in 2014 state that there were very few evidence-based studies conducted with the design of an RCT. On the other hand, the previous studies only examined the single-level intervention on individual without assessing beyond the systems level as suggested by Bronfenbrenner's ecological systems theory (1987).

For example, three studies (Patel et al., 2012; Talaat et al., 2011; Zhang et al., 2012) used only two levels of training and resources in their implementation of the hand hygiene programmes. Besides that, two studies (Luby et al., 2005; Luby et al., 2004) did not implement their hand hygiene programme at the contextual levels of the community and organisation. In addition, there is little evidence of using a whole-school approach of the WHO's HPS to address the three areas of intervention within schools and the local communities. There are also few research studies on designing, implementing and evaluating the impact of a SBHHP on children's health outcomes using a rigorous design such as an RCT, especially in developing countries such as Malawi and other sub-Saharan African countries (Langford et al., 2014; WHO, 1996).

The growing number of epidemics of emerging infectious diseases has raised the importance of the settings-based approach, including the HPS framework, to promote better health and wellbeing for the schoolchildren (Lee et al., 2008).

1.3 Study significance

Mbakaya and colleagues (2017) conducted a systematic review revealing that both hard- and software resources to support and promote hand hygiene practice were inadequate. This review identified the key essential components of multilevel interventions as formulating health policy, providing adequate training, supportive environment, and having available resources to implement health promotion interventions. In addition, the

review found that there was no reinforcement of a validated handwashing technique practised among children in primary schools in Malawi and other developing countries, especially in sub-Saharan Africa. The uptake of and compliance with hand hygiene practice was very low among primary school students.

Besides the gaps identified in the systematic reviews discussed above, the authors identified that multilevel interventions were the most effective way to deliver hand hygiene programmes. Langford and her colleagues (2014) directed a Cochrane systematic review of the WHO's health-promoting schools (HPS) framework (1996) to identify the 'gold standard' by reviewing those studies to evaluate the intervention effectiveness using cluster RCT (Langford et al., 2014). After identifying and reviewing 67 trials that met the inclusion criteria, the review concluded that there were very few studies, especially in sexual health, handwashing, eating disorders and others, that measured the impact of the intervention on students' attendance or academic achievement. These two systematic reviews had identified the gaps in the planning, collaborating, implementing and evaluating of intervention effectiveness in promoting handwashing without adopting multilevel interventions. They used a single-level intervention only and the sustainability of the hand hygiene programme was questionable.

Thus, it was therefore important to adopt the multilevel intervention strategies in planning, implementing and evaluating the impact of a SBHHP in order to provide new evidence in planning health education and health promotion activities in developing countries. School is influenced by

systems; thus, it is important to use broader system-level elements that may impact local implementation barriers and support uptake of WHO's HPS approach rather than adopting a single-level approach. This was done through the implementation of a SBHHP using Bronfenbrenner's ecological systems theory (1987) and the three areas of interventions of the WHO's HPS framework (see Figure 1). This study is also important because it will form a basis for the development of future research frameworks in planning, implementing and evaluating the impact of a SBHHP, especially in developing countries, with an emphasis on utilisation of a multilevel interventions approach. Enforcing a SBHHP could improve handwashing compliance (knowledge gain, skills acquisition/technique and cleanliness of hands) among schoolchildren in developing countries, guiding policy makers toward the adoption of a multilevel interventions approach.

Whitby and colleagues (2007) contend that human behaviour in regards to health education can influence beyond the individual (intrapersonal) or the microsystem according to Bronfenbrenner; interactions between individuals (interpersonal) or the mesosystem; and the community or the macro system (Sincero, 2012a). Intrapersonal factors are individual qualities concerning intellect, attitudes, beliefs, and personality traits. In interpersonal roles, social identity, a support network, and role definition of family, friends, and peers are fabricated (Whitby et al., 2007). Whitby and colleagues (2006) found that biological characteristics, environment, education, and culture all had multiple influences over human behavior. Thus, the researcher adopted the underlying concepts of Bronfenbrenner's ecological systems theory (1987) and WHO's HPS framework (1996) to implement a SBHHP in

Malawi. Bandura's social cognitive theory (Bandura, 1977) and Ajzen's theory of planned behaviour (Ajzen, 1988) had been adopted to facilitate the behavioural-change in providing training to schoolchildren and their peers.

1.4 Study aims, objectives and hypotheses

1.4.1 Aim of the study

The aim of this study was to evaluate the efficacy of a school-based hand hygiene programme (SBHHP) using a multilevel interventions approach targeting schoolchildren, schools and their families in the intervention group versus the routine hand hygiene practice in the control group at four-time point (T₀, T₁, T₂ & T₃) for schoolchildren who participated in this study in Malawi, sub-Saharan Africa.

1.4.2 Objectives and hypotheses

1.4.2.1 Primary outcome measure

Objective 1: To appraise the impact of a SBHHP on schoolchildren's handwashing compliance (knowledge, skills/technique and cleanliness) at four-time point.

(i.e. knowledge refers to the scores of handwashing quiz; skills/technique refer to the scores of handwashing observational checklist; and hand cleanliness refers to the scores of the fluorescent stain test on both hands).

Hypothesis 1.1: The group by time effect on knowledge score would be statistically significant after implementing SBHHP.

Hypothesis 1.2: The group by time effect on technique score would be statistically significant after implementing SBHHP.

Hypothesis 1.3: The group by time effect on hand cleanliness score would be statistically significant after implementing SBHHP.

Hypothesis 1.4: The mean scores of handwashing quiz, the mean scores of observational checklists on proper handwashing technique and the hand cleanliness mean scores of the fluorescent stain test would be higher (better) after implemented the SBHHP using a multilevel interventions approach in the intervention group than in the control group at post-tests.

1.4.2.2 Secondary outcome measures

Objective 2: To assess the impact of the SBHHP on reducing children's sickness-related school absenteeism by evaluating the number of sick leave days.

Hypothesis 2: The number of sick leave days would be lower after implemented the SBHHP using a multilevel interventions approach in the intervention group than in the control group at post-tests.

Objective 3: To explore the acceptability of a multilevel interventions approach (i.e. formulating hand hygiene health policy/protocol, providing behavioural-change training on proper handwashing technique, creating supportive environments for schoolchildren at school and home settings, and ensuring the availability of physical and human resources to implement the programme) to plan and implement the SBHHP in primary schools in Malawi.

Evaluation 3: To conduct focus group discussions with schoolchildren, school teachers, school principals and parents, to evaluate the acceptability (i.e. formulating hand hygiene health policy/protocol, providing training on proper handwashing technique, creating supportive environments and ensuring resources availability) of the planning and implementation of the SBHHP in primary schools in the communities of Mzuzu City, Malawi.

1.5 Operational definitions

Several definitions and concepts used in this study. This section highlights the operational meanings for this study. The following operational definitions were used for this study.

1.5.1 School-based hand hygiene programme

School-based hand hygiene programme means that the hand hygiene programme implemented at school. However, the primary students were encouraged to practise hand hygiene at home and all the time, to influence

their behaviour change. In addition, parents were involved through an information sheet, written consent allowing their child to participate, and the children's take-home package. The intervention delivered at school, including the assessment of the primary and secondary outcome measures.

1.5.2 Hand hygiene

A general term applying to the use of soap or solution, which could be non-antimicrobial or have an antimicrobial effect, and water or a waterless antimicrobial agent, to the surface of the hands.

1.5.3 Simplified handwashing

Using the 5-step handwashing technique modified from the conventional 7-step handwashing technique by the WHO. The simplified 5-step handwashing technique modified and validated in a study conducted among Chinese children with mild intellectual disability in Hong Kong (Lee & Lee, 2014).

1.5.4 Schoolchildren

Children studied in primary schools in grades one and six, ages ranging from 4 to 13, attending private primary schools in the city of Mzuzu, Malawi, in sub-Saharan Africa.

1.5.5 Four time points

Baseline (T₀), at the 3rd month immediately after students participated in the SBHHP (T₁), at the 6th month compliance evaluation (T₂) and at the 9th month for sustainability testing (T₃). The four time points spread at three-month intervals were based on an intensive systematic literature review performed on eight randomised trials on hand hygiene intervention strategies to reduce diarrhoea and respiratory infections among schoolchildren in developing countries (Mbakaya et al., 2017). In addition, the period was in line with one full academic year calendar for primary schools in Malawi, which normally has three academic terms/semesters of three months each. Hence, the timing was convenient in terms of aligning with the school calendar.

1.5.6 World Health Organization's Health-Promoting School Framework

The concept of health-promoting school (HPS) is defined as schools that are constantly strengthening its capacity as a healthy setting for living, learning and working (WHO, 1996). The WHO HPS framework focuses on three areas of intervention within the school and its local community. They are: 1) school curriculum, teaching and learning, 2) school ethos, environment and organisation, 3) school community participation and services.

1.5.7 Whole-school approach

The whole-school approach is a concept that promotes a collaborative approach to learning and health, taking into account the needs of the whole child. It emphasises the following components in order to meet the health needs of students: 1) physical education and physical activity; 2) nutrition environment and services; 3) health education; 4) health services: counselling, psychological, and social services; and 5) employee wellness. These help to support healthy behaviour in students (social and emotional school climate, physical environment, family engagement, and community involvement) (The Association for Supervision and Curriculum Development [ASCD] & CDC, 2014). It refers to an approach that goes beyond learning and teaching in the classroom to pervade all aspects of the life of a school (WHO, 1997).

1.5.8 Multilevel interventions approach

A multilevel interventions approach refers to an intervention using different forms of involvement, such as policy development and organisation participation, in order to improve health outcomes on various contextual levels (individual, group, community, and organisation) (Edwards et al., 2012; Taplin et al., 2012). In this study, a multilevel interventions approach includes formulating hand hygiene policy/protocol, providing adequate training, creating a supportive environment and ensuring resource availability by targeting four contextual levels: individual, group, community and organisation.

1.5.9 Bronfenbrenner's ecological systems theory

Bronfenbrenner's ecological systems theory (1987) stresses the quality and context of the child's surroundings and explains how the inherent qualities of a child and his environment interact to influence how he/she will grow and develop. The theory organises the contexts of development into five levels of external influence, based on the belief that people encounter different environments throughout their lifespan that may influence their behaviour to varying degrees. These systems include the microsystem, the mesosystem, the exosystem, the macrosystem, and the chronosystem. The theory emphasises the relationship between the contextual factors and individual characteristics. The hypothesis is that the impact of contextual factors such as policy/protocol, training, environment and resources in planning a health promotion programme influence the individual's health outcome. Bronfenbrenner's multilevel systems environment links to the proposed multilevel interventions approach as the conceptual framework of this study.

In this study, the researcher adopted a multilevel interventions approach based on Bronfenbrenner's ecological systems theory, which looks at a child's development within the context of the systems environment and the relationships that form his or her environment, such as the school setting and the home environment. The researcher in this study planned and implemented hand hygiene health promotion programme by targeting various systems in schoolchildren's environment, including at the individual, group, community and organisation levels, to improve their

health outcomes. This includes formulating hand hygiene protocol, providing adequate training on proper handwashing technique, creating a supportive school environment to practise handwashing technique, and ensuring the availability of handwashing resources including manpower in planning and implementing the SBHHP for schoolchildren in primary schools in Malawi.

1.6 Organisation of the thesis

This thesis presents detailed findings of a cluster RCT conducted in primary schools in Malawi, sub-Saharan Africa, covering a period of one academic year (2016/2017). The study's aim was to evaluate the efficacy of a SBHHP using a multilevel interventions approach targeting schoolchildren, schools and their families in the intervention group versus the routine hand hygiene practice in the control group at four-time point (T₀, T₁, T₂ & T₃) for schoolchildren who participated in this study in Malawi, sub-Saharan Africa.

The thesis is structured and organised in six chapters. Chapter one provides the background to the problem being addressed in this study and gives an overview of the purpose and significance of the problem. This chapter helps readers to appreciate the milestones achieved and challenges facing hand hygiene practice from the point of view of Malawi and other developing countries. Chapter two presents a comprehensive literature review, including a published systematic review that was conducted to establish the existing gap in school-based hand hygiene and gather evidence for carrying

out this project. The following sub-sections are covered in this chapter; 1) multilevel interventions approach, 2) implementation of hand hygiene programmes across the globe, 3) factors influencing hand hygiene, 4) barriers and enablers to implementing hand hygiene programmes, 5) a whole school, WHO's health-promoting school framework, 6) World Health Organisation's 7-step handwashing technique, 7) a simplified 5-step handwashing technique, and 8) use Social Learning Theory to facilitate schoolchildren's learning of the proper handwashing technique. Finally, this section also presents information on rationale for using two theories in this study, theory of planned behaviour, Badura's Social Learning Theory, WHO's health-promoting school framework, research gaps, the study conceptual framework, and summary of chapter two. Chapter three describes the methodology used in this study. The rationale for using a cluster randomised controlled trial is justified. Focus group discussions were conducted to explore the perspectives of children, teachers, parents implemented the SBHHP using multilevel interventions approach targeted schoolchildren's hand hygiene behaviors to improve their health outcomes by reducing school absenteeism and improving school attendance. The study protocol, including the study tools, data collection methods, randomisation, blinding assessors, allocation concealment, outcome measures and the description of a SBHHP based on the whole-school approach, social learning theory, and the theory of planned behaviour, is explicitly presented following the guidelines in the Consolidated Standards of Reporting Trials (CONSORT) statement. The ethical considerations (code of ethics) are also presented in this chapter. Chapter four describes the process of analysing the data collected during the SBHHP implementation,

and the results, including the demographics of the participants and the school setting. Chapter five discusses the study results presented in chapter four and the related literature. Finally, chapter six draws conclusions and focuses on recommendations based on the findings of this study in order to guide upcoming research and policy implications. Limitations that were beyond the capacity of this SBHHP presented in chapter six.

CHAPTER TWO

LITERATURE REVIEW

2.0 Introduction

Hand hygiene is a general term applying to the use of soap or solution, which can be non-antimicrobial or have an antimicrobial effect and water, or a waterless antimicrobial agent, to the surface of the hands. Handwashing is defined as washing hands with plain or antimicrobial soap and water (World Health Organization (WHO), 2009). It is important to understand how hand hygiene programmes operate at the global, regional and national levels. As such, this chapter focuses on existing literature in hand hygiene. The following sub-sections are covered in this chapter; 1) multilevel interventions approach, 2) implementation of hand hygiene programmes across the globe, 3) factors influencing hand hygiene, 4) barriers and enablers to implementing hand hygiene programmes, 5) a whole school, WHO's health-promoting school framework, 6) World Health Organisation's 7-step handwashing technique, 7) a simplified 5-step handwashing technique, and 8) use Social Learning Theory to facilitate schoolchildren's learning of the proper handwashing technique. Finally, this section also presents information on rationale for using two theories in this study, theory of planned behaviour, Bandura's Social Learning Theory, WHO's health-promoting school framework, research gaps, the study conceptual framework, and summary of chapter two. Section 2.1 of this

chapter is presented next and provides literature on multilevel interventions approach.

2.1 Multilevel interventions approach

The term “multilevel intervention” refers to an intervention targeted to influence more than one contextual level (individual, group, community, and organisation) (Clauser, Taplin, Foster, Fagan, & Kaluzny, 2012). An intervention is multilevel if it addresses the individual client as well as at least two levels of contextual influence, such as organisations and providers, thereby targeting at least three different sources of influence (Edwards et al., 2012; Paskett, Thompston, Ammerman, Ortego, Marsteller, & Richardson 2016b; Taplin et al., 2012). While multilevel interventions in health care are less robust, it is believed that they influence interdependent interaction, thereby producing desirable outcomes (Edwards et al., 2012; Taplin et al., 2012). After recognising that multilevel intervention research was underrepresented as a clear focus in literature yet can enhance execution of studies, Clauser and his colleagues (2012) produced a monograph with the following aims; 1) to assess the added value of the multilevel interventions; 2) discuss lessons learnt to date about its challenges; and 3) identify specific ways to increase the scientific soundness, feasibility, policy, relevance, and research agenda of the multilevel interventions (Clauser et al., 2012).

The purpose of multilevel interventions is to affect the critical contextual issues and create a more efficient, effective, and coordinated public health

care delivery system that achieves relevant patient outcomes, including improved hand hygiene to prevent infectious disease outbreaks, health-related quality of life, and patient experience with care, at a reduced cost to all involved (Clauser et al., 2012).

Researchers agree that it is necessary to change negative social determinants to reduce health challenges. However, most disparities interventions focus on the individual, often ignoring the person's social and physical environments (Paskett et al., 2016b). Multilevel interventions are worth doing, because such interventions address multiple determinants of health at the same time within complex systems, they may have a broader public health impact compared to interventions that focus on only one or two levels (Paskett et al., 2016b). Multilevel interventions target the causes of health disparities by focusing on the following levels of influence that affect health: interpersonal, organizational, community, educational, occupational, environmental, and policy. These multilevel interventions must occur at a few levels simultaneously or in close succession (Paskett et al., 2016b). Multilevel interventions may address changes in behaviour, policy changes, changes in the delivery of health services, and environmental changes (Paskett et al., 2016b). The potential reach of multilevel interventions at the population level is much greater than that of individually targeted interventions. Studies have shown that effects at the population level are observed later and increase over time. For instance, in a study in North Karelia, Finland, tobacco use declined over ten years after a communitywide multilevel intervention to reduce cardiovascular disease was launched (Paskett et al., 2016b). There is need for policy-level changes

to ensure that multilevel interventions have strong impacts (Paskett et al., 2016b; Stange, Breslau, Dietrich, & Glasgow. 2012).

The Center for Population Health and Health Disparities at Ohio State University conducted a study to test a multilevel intervention to address the problem of low uptake of the human papillomavirus (HPV) vaccine among girls in the region. (Paskett, Krok-Schoen, Pennell, Tatum, Reiter, Bernardo,..... & Katz. 2016a). In their study, they used a group-randomized trial in twelve counties in Appalachian Ohio. Six counties were assigned to the intervention condition (uptake of the HPV vaccine) and six counties assigned to the comparison condition (uptake of the influenza vaccine). Paskett and colleagues (2016a) implemented their study at three different levels. The first level targeted the health system and included posters and brochures about the HPV vaccine, vaccination reminder cards to be mailed to patients, and buttons about HPV for providers to wear on their lab coats. The second level included a PowerPoint presentation on HPV and how to talk to patients about the vaccine, relevant articles on cervical cancer and HPV, and regional HPV statistics which were delivered to providers at regular staff meet. The third level focused on parents with daughters needing HPV vaccination and included completed surveys, and were mailed a specially designed DVD about HPV and the HPV vaccine (in the six intervention counties) or a DVD about influenza and the influenza vaccine (in the six comparison counties), a complementary brochure that reinforced the information in the DVD, and a medical record release form to sign and return to the study office (Paskett et al., 2016a). Their results indicated that the intervention successfully increased the percentage of daughters who

received the first shot of the HPV vaccine within three months of receiving the intervention (7.7 percent in the intervention group versus 3.2 percent in the comparison group; $p = 0.06$). However, the absolute number of girls who received the vaccine, as verified by a review of medical records, remained very low (ten in the intervention group versus four in the comparison group). They also found that providers' knowledge about HPV and the HPV vaccine increased significantly. (Paskett et al., 2016a). Although their study focused on three levels (patient, provider, and clinic), the effect of the intervention, as measured by uptake of the HPV vaccine among daughters of enrolled parents, was weak, owing to lack of public policy mandate for receiving the HPV vaccine (Paskett et al., 2016a).

The Proyecto MercadoFRESCO (fresh market project), was a multilevel, community-engaged food environment intervention that was intended to improve access to healthy food in the two neighborhoods, both of which were food swamps in East Los Angeles and Boyle Heights (Ortega, Albert, Sharif, Langellier, Garcia, Glik,.... Prelip. 2015). The project involved multiple stakeholders and intervention targets, including neighbourhood residents, business owners, local politicians, high school students, community clinics, community-based organizations, and law enforcement officials. They also reorganized stores so that healthy foods were featured at the front and unhealthy foods at the back. The multilevel intervention in their study also included communitywide social marketing that emphasized healthy eating and the benefits of shopping locally and learning to eat healthy foods, as well as cooking demonstrations and other community events held at the stores (Ortega et al., 2015). The primary outcomes were

changes in the purchasing and consumption of fresh fruit and vegetables at both the individual and community levels. The results of their study found that at the community level, perceptions of food availability and the corner stores improved over time, but changes in patronage of the stores and consumption of healthy food were not significant. On average, store owners reported a 20 percent increase in sales and high levels of satisfaction with the store transformations (Ortega et al., 2015). Although the findings of this multilevel intervention study were also weak, the public generally was more positively oriented to healthy eating owing to support by local politicians from the start and that gained community support. (Paskett et al., 2016b; Ortega et al., 2015).

A systematic review on hand hygiene intervention strategies to reduce diarrhoea and respiratory infections among schoolchildren in developing countries, indicated that few interventional studies have used multilevel approach to evaluate the impact of hand hygiene programmes implemented in school settings in developing countries; there were none from Malawi (Mbakaya et al., 2017). This systematic review identified and grouped the activities in the selected articles under preparation on multilevel interventions strategies that were recommended in the implementation of handwashing interventions in future studies especially in developing countries. The identified multilevel intervention strategies from this review were policy, training/education, environment, and funding/resources. The multilevel intervention strategies include formulating hand hygiene policy, providing proper handwashing technique training, creating a supportive school environment to practice hand hygiene and making resources

available would provide a guide for the researcher to plan, implement and evaluate the impact of the SBHHP for schoolchildren in Malawi, Southern Africa.

2.1.1 Policy/ Protocol

The first component of the hand hygiene multilevel interventions approach is the formulation of protocol in the school setting for the implementation of hand hygiene programmes targeting schoolchildren in developing country to reduce the outbreak of infectious diseases. Policy can also be implemented in two other ways namely, first by creating an institutional safety climate, and second by putting reminders in strategic places in the school environment.

The institutional safety climate refers to creating an environment and perceptions that facilitate awareness-raising and consideration of handwashing improvement as a high priority at all levels, including active participation at both the institutional and individual levels, as well as awareness of individual and institutional capacity to change and improve self-efficacy (WHO, 2009).

Reminders in the school setting are key tools for prompting and reminding children about the importance of handwashing, as well as about the appropriate indications and procedures for performing it (WHO, 2009).

2.1.2 Training

The second component of the multilevel interventions approach is to provide adequate training for the implementation of hand hygiene programme in developing countries to reduce the outbreak of infectious diseases. Training is a critical success factor and represents one of the cornerstones for improvement of hand hygiene practices (WHO, 2009). Schoolchildren require training on the importance of hand hygiene and the correct procedures for handwashing and hand rubbing. Clear education messages on handwashing help to induce behavioural and cultural change and ensure that competence is deep-rooted and maintained among all children in relation to handwashing hygiene. While all studies included in a systematic review by Mbakaya and colleagues (2017) had training components, no single study that used handwashing in its intervention described the handwashing technique used in children's training, that is, whether they had used the conventional 7-step handwashing technique based on the WHO, or the simplified 5-step handwashing technique, which has been tested and found to be effective in a study performed in Hong Kong (Lee et al., 2015; Lee et al., 2014). Training is an important strategy that can be easily integrated with all other essential strategy components (WHO, 2009).

2.1.3 Environment/ Setting

The environment in which hand hygiene programmes take place is described by WHO as an institutional safety climate and system change (WHO, 2009). A conducive environment or setting is important in a

successful implementation of hand hygiene programmes. Institutional safety climate can be achieved through creating an environment and perceptions that facilitate awareness-raising safety issues while guaranteeing consideration of hand hygiene improvement as a high priority at all levels (WHO, 2009). For example, involvement of children in the hand hygiene programmes, establish behaviour rules, hand hygiene training, involvement of teachers, and formation of hand hygiene clubs/groups. On the other hands, system change ensures that necessary infrastructure is in place to allow schoolchildren to practice proper hand hygiene. For example, provision of handwashing resources such as soap and water, and handwashing stations. In addition, these resources should be made accessible to students all the time to promote hand hygiene compliance. The hand hygiene practices and infrastructure should be continuously monitored and evaluated (WHO, 2009).

2.1.4 Resources

Funding ensures that schools have the necessary infrastructure in place to allow students to perform handwashing (WHO, 2009). Compliance with handwashing among children is only possible if schools ensure that infrastructure and a reliable and permanent supply of hand hygiene products are available at the right times and in the right locations (WHO, 2009).

The findings of the literature review suggested that the adoption of multilevel intervention strategies had a bigger impact than adopting a

single-level intervention in implementing school-based hand hygiene programmes in developing countries.

The determinants of health disparities are complex as such, cannot easily be addressed. Health among disadvantaged population is influenced by a combination of a broad range of biological, interpersonal, organizational, community, environmental, and policy-related which calls for research on multilevel interventions (Paskett, Thompson, Ammerman, Ortega, Marsteller, & Richardson 2016). Although intervention research directed at specific individual levels has been conducted for decades, more recent research efforts have attempted to address multiple levels simultaneously to address a single health-related problem or behavior (Paskett et al. 2016). However, implementation of multilevel approach faces several challenges as discussed below.

2.1.5 Challenges in implementation of multilevel interventions approach

There are many challenges facing the implementation of multilevel intervention. Firstly, measuring the effects of multilevel interventions is challenging, because they allow for interaction among levels, and the impact of each intervention must be assessed and translated into practice (Paskett et al., 2016). Secondly, selecting who or what will be randomized in an RCT (the gold-standard) is a key decision, and yet has implications for sample size, recruitment strategies, mode of data collection, analysis, and how the results and effective interventions are disseminated (Paskett et al., 2016). Thirdly, sufficient sample size is also required to allow studies of multilevel

interventions to detect and assess possible synergistic effects between and within levels and requires many years of follow-up and data collection to see population-level effects (Paskett et al., 2016). Fourthly, existing statistical methods and techniques, such as multivariable logistic regression models, make it possible to assess multilevel interventions in the presence of such potentially complex interactions. However, because the existence and nature of such interactions are often unclear, determining the necessary sample size for studies of multilevel interventions can be a challenge (Paskett et al., 2016). Lastly, it is challenging to design a study and measurement strategies that assess the interaction between multiple levels of influence, but doing so is critical (Paskett et al., 2016b). Conducting multilevel interventions designed to address health disparities is often complex and the interventions are less likely than individual randomized controlled trials to show strong effects on individuals (Paskett et al., 2016b).

Stange and colleagues (2012) conducted a systematic review on the state-of-the-art and future directions in multilevel interventions across the cancer control continuum. They found that research methodology of multilevel interventions studies is underdeveloped. They also found that most multilevel interventions address issues in just one setting without reporting a complete context, nor the details of how the interventions were implemented (Stange et al., 2012). Most interventions address fewer than three levels, and descriptions of the interventions and measures at the various levels are limited or lacking (Stange et al., 2012)

2.2 Implementation of hand hygiene programmes across the globe

2.2.1 Developed countries

Previous studies have stated that effective hand hygiene intervention strategies are well established in developed countries as documented in a report released by UNICEF (2015), which indicates that school water and sanitation coverage is at 89% in developed countries.

Azor-Martinez and colleagues (2014) conducted a study in Almenia, Spain, whose aim was to assess the impact of infections on primary school absenteeism and their reduction with a handwashing programme using hand sanitiser. In their study, the experimental group washed their hands with soap and water, complemented with the use of hand sanitiser, and the control group followed the usual handwashing procedure in an 8-month-long randomised controlled open study. Azor-Martinez and colleagues (2014) found that the incidence of total absent episodes and percentage of missed days, including those missed because of upper respiratory or gastrointestinal infections, were significantly lower in the experimental group than in the control group ($p < .001$), and this was maintained through the influenza pandemic period (Azor-Martinez et al., 2014). In their study, they offered training, provided a conducive environment by providing support systems and installation of dispensers of hand sanitizer in classroom, and provided resources to primary school children aged 4 to 12 years attending state schools (multilevel). Azor-Martinez and colleagues (2014) implemented their study at three contextual levels, thus individual, group and institution.

Rosen and colleagues (2005) conducted a study in preschools in Jerusalem in 2005 with an aim to determine whether a hygiene programme can promote handwashing and thereby reduce illness absenteeism. In their study, they included 40 preschools in a cluster randomised trial with 1,029 children. The intervention included an educational programme, environmental changes and resources. A simultaneous sub-trial was run to test a home component. Rosen and colleagues (2005) in their study, found that the intervention programme produced sustained behavioural and environmental changes over a 6-month study period/duration. However, the preschool intervention programme did not reduce illness absenteeism or overall absenteeism (Rosen et al., 2005). Authors of this article suggested the need for enhanced approaches for reducing illness absenteeism (Rosen et al., 2005). In this study, their intervention focussed on the training/education, environmental changes and resources. In addition, they managed to implement the intervention by targeting three contextual levels of the individual students, school and home. The non-significant reduction in illness absenteeism was explained by seasonal low rates of diarrhoea in Jerusalem during the study period. A higher base rate of gastrointestinal disease may have led to a stronger programme effect on illness absenteeism (Rosen et al., 2006).

Nandrup-Bus (2009) conducted a study in elementary schools in Denmark to determine the effect of mandatory, scheduled handwashing on actual absenteeism due to infectious illness. He conducted a three-month pilot intervention study, randomized between two schools on 652 pupils aged 5 to 15 years. The pupils at the intervention school were required to wash their

hands before the first lesson, before lunch, and before going home, while those at the control school continued their usual handwashing practices. The results demonstrated a significantly reduced rate of absenteeism for the intervention school compared with the control school ($p=.002$). Nandrup-Bus's study suggests that handwashing could be an effective tool to reduce absences due to infectious illness in elementary school pupils. A school policy regarding hand hygiene and teaching of hand hygiene is warranted. In his study, Nandrup-Bus (2009) provided training/education, sanitary provision (handwashing soap, disposable paper towel), and put stickers and posters at the handwashing area to act as reminder for students (environmental changes). He implemented his intervention at individual level as well as organization level.

A study was conducted in Netherlands by Zomer and colleagues (2016) in which they developed an intervention to increase hand hygiene (HH) compliance and reduce infections in daycare centres (DCCs) (Zomer, Erasmus, Looman, Van Beeck, Tjon-A-Tsien, Richardus, & Voeten 2016). The objective of their paper was to evaluate the effectiveness of this intervention on HH compliance. The intervention was evaluated in a two-arm cluster randomized controlled trial in 71 DCCs. Thirty-six DCCs received the intervention including: (1) HH products; (2) training about HH guidelines; (3) two team training sessions aimed at goal setting and formulating HH improvement activities; and (4) reminders and cues for action (posters/ stickers). Thirty-five DCCs in the control group continued with their usual practice. HH compliance of caregivers and children was observed at baseline and at 1, 3 and 6 months' follow-up. Of 795 caregivers,

Zomer and colleagues (2016) managed to observe 5042 HH opportunities for caregivers and 5606 opportunities for supervising children's HH. The results revealed that at 1-month follow-up caregivers' compliance in intervention DCCs was 66% vs. 43% in control DCCs (OR 6.33, 95% CI 3.71–10.80), and at 6 months 59% vs. 44% (OR 4.13, 95% CI 2.33–7.32). No effect of the intervention was found on supervising children's HH (36% vs. 32%; OR 0.64, 95% CI 0.18–2.33). They concluded that HH compliance of caregivers increased due to the intervention (Zomer et al., 2016). A critical analysis of their study show that they applied multilevel interventions approach as evidenced by implementation of their intervention through training, environment, and provision of resources targeting the children, caregivers and the institution.

Lee and her colleagues considered different levels of handwashing-promoting practices that required multidimensional aspects such as institutional support and capacity building in the implementation of the hand hygiene programme to enhance the compliance of schoolchildren in proper handwashing behaviours in special and ordinary school communities in Hong Kong (Lee, Leung, Tong, Chen, & Lee, 2015). In their study, Lee and her colleagues targeted several contextual level such as individual students, group, community and institution. They managed to provide training on handwashing, provided necessary resources, provided conducive environment and also involved school principals/authority. The results of their study showed that intervention group experienced a significant increase in the rating of their handwashing quality in both hands from pre- to post-test: left dorsum (+1.05, $P < .001$); right dorsum (+1.00, $P < .001$);

left palm (+0.98, $P < .001$); and right palm (+1.09, $P < .001$). The pre- to post-test difference in the intervention group (+1.03, $p < .001$) was significantly greater than the difference in the control group (+0.34, $p = .001$). The intervention school experienced a significantly lower absenteeism rate (0.0167) than the control group in the same year (0.028, $p = .04$). Students in this study showed better performance in simplified handwashing techniques and experienced lower absenteeism than those using usual practice in special education school settings.

From the review of studies conducted in developed countries, results show that authors implemented their studies using a multilevel approach by targeting two or more levels of intervention (policy, training, environment and resources) and implemented at more than one contextual levels of individual, group, community and organisation. Their study findings were associated with significant impact except one study (Rosen et al., 2006), in which non-significant reduction in illness absenteeism was explained by seasonal low rates of diarrhoea in Jerusalem during the study period. However, their study findings show that the intervention programme produced sustained behavioural and environmental changes over a 6-month study period/duration. All the studies reviewed above, used rigorous interventional designs such as RCT, cluster RCT and Quasi-experimental studies which provide scientific evidence that their study findings can be relied upon to inform policy, training and education. This could also warrant the replication of the strategies (multilevel) in other settings like developing countries.

Having presented literature on hand hygiene in developed countries, the next section examined the implementation of hand hygiene programme in developing countries.

2.2.2 Developing countries

More than 2.5 billion people worldwide lack access to improved sanitation facilities, and the majority of these live-in developing countries (WHO & UNICEF, 2010). In 2008, only 37% of schools in UNICEF-priority countries were reported as having adequate sanitation coverage (UNICEF, 2009).

In a study done in Egypt, elementary schoolchildren in the intervention schools were asked to wash their hands twice a day, and health messages were delivered through entertainment activities. The results revealed that in the intervention group, overall absences caused by influenza-like illnesses decreased (reduced 40%, $p < 0.0001$), as did those caused by diarrhoea (reduced 30%, $p < 0.0001$), conjunctivitis (reduced 67%, $p < 0.0001$), and laboratory-confirmed influenza (reduced 50%, $p < 0.0001$). It was concluded that an intensive handwashing campaign was effective in reducing absenteeism caused by these illnesses (Talaat, Afifi, Dueger, El-Ashry, Marfin, Kandeel, & El-Sayed, 2011). Much as Talaat and colleagues used a rigorous design (RCT) in their study, their intervention targeted only one contextual level of a student and provided training only and not the other multilevel components such as policy, environment and resources.

A study conducted in Kenya by Saboori, Moe, Freeman, Caruso, Akoko, and Rheingans (2013) assessed whether supplying soap to primary schools on a regular basis increased pupils' handwashing and decreased *Escherichia coli* hand contamination. Multiple rounds of structured observations of handwashing events after latrine use were conducted in 60 Kenyan schools, and hand rinse samples were collected once in a subset of schools. The proportion of pupils observed to practise handwashing with soap was significantly higher in schools that received a soap provision intervention (32%) and schools that received soap and latrine cleaning materials (38%) compared with controls (3%). Girls and boys had similar handwashing rates. They concluded that removing barriers to soap procurement can significantly increase the availability of soap and improve handwashing among pupils (Saboori et al., 2013). Despite using a cluster RCT study design, Saboori and colleagues (2013) used a single level approach in their study by providing resources to primary school students and targeting the student's contextual level only.

School-based hygiene and water treatment programmes increased student knowledge, improved hygiene, and decreased absenteeism in a study conducted among 42 Kenyan schools (Patel, Harris, Juliao, Nygren, Were, Kola, & Quick, 2012). In their study, a curriculum on safe water and hand hygiene was instituted in the intervention schools, and water stations were installed. Patel and colleagues found that there was an improvement in proper handwashing techniques after the school programme was introduced. They also observed a decrease in the median percentage of students with acute respiratory illness among those exposed to the programme. Students in

this school programme exhibited sustained improvement in hygiene knowledge and a decreased risk of respiratory infection after the intervention (Patel et al., 2012). The study intervention by Patel and colleagues imply that they implemented their intervention targeting training, and resources delivered at individual contextual level of a student only.

In a study conducted in Kenya by Greene and colleagues (2012) aimed at assessing the effect of a school-based water sanitation and hygiene (WASH) intervention on reducing fecal contamination on hands (Greene, Freeman, Akoko, Saboori, Moe, & Rheingans, 2012). Their trial examined whether a school-based WASH intervention reduced *Escherichia coli* contamination on pupils' hands in western Kenya. Greene and colleagues (2012) found that a hygiene promotion and water treatment intervention did not reduce risk of *E. coli* presence (relative risk [RR] = 0.92, 95% confidence interval [CI] = 0.54–1.56); the addition of new latrines to intervention schools significantly increased risk among girls (RR = 2.63, 95% CI = 1.29–5.34), with a non-significant increase among boys (RR = 1.36, 95% CI = 0.74–2.49). In their study, they used a cluster RCT in Kenyan primary school and implemented their study by targeting students as single contextual level. Greene and colleagues managed to offer training, and resources for students to practice hygiene. Greene and colleagues (2012) attributed failure to reduce risk of *E. coli* presence to lack of sufficient hand hygiene behaviour change among students.

Zhang and colleagues (2013) conducted a study to measure the efficacy of a tippy-tap-based handwashing programme in promoting handwashing rates

in elementary schools in rural Uganda (Zhang, Mosa, Hayward, & Matthews, 2013). They fielded pre-/post intervention surveys in eight schools (398 students, ages 7–13 years). Four intervention schools were given tippy-taps, soap and educational materials, while four control schools initially received only educational materials. Zhang and colleagues found that after 1 month, the intervention schools reported a large increase in daily handwashing rates and absence of stomach pain episodes compared with the control schools. After receiving the intervention, the control schools attained similar handwashing and stomach pain rates. Zhang and colleagues (2013) targeted the individual contextual level and delivering their intervention at two levels (training and resources).

Pickering and colleagues (2013) conducted a cluster RCT study in primary schools within urban Kibera, Kenya. They investigated the impact of providing waterless hand sanitizer on student hand hygiene behaviour. Two schools received a waterless hand sanitizer intervention, two schools received a handwashing with soap intervention, and two schools received no intervention. Hand cleaning behavior after toilet use was monitored for 2 months using structured observation. In their study, they found that hand cleaning after toileting was 82% at sanitizer schools (N = 2,507 toileting events), 38% at soap schools (N = 3,429), and 37% at control schools (N = 2,797). Students at sanitizer schools were 23% less likely to have observed rhinorrhea than control students ($p = 0.02$); reductions in student-reported gastrointestinal and respiratory illness symptoms were not statistically significant. Providing waterless hand sanitizer markedly increased student hand cleaning after toilet use, whereas the soap intervention did not

(Pickering, Davis, Blum, Scalmanini, Oyier, Okoth, Breiman, & Ram, 2013). Pickering and colleagues (20113) managed to deliver their study at two levels by providing resources and training of students and teachers.

A cluster randomized controlled trial of 36 low- income neighbourhoods in urban squatter settlements in Karachi, Pakistan was conducted with an aim to evaluate the effect of promoting household handwashing with soap among children at the highest risk of death from diarrhea (Luby, Agboatwalla, Painter, Altaf, Billhimer & Hoekstra, 2004). Field workers visited participating households at least weekly from April 15, 2002, to April 5, 2003. Eligible households located in the study area had at least 2 children younger than 15 years, at least 1 of whom was younger than 5 years. Weekly visits were scheduled in 25 neighbourhoods to promote handwashing with soap after defecation and before preparing food, eating, and feeding a child. Within intervention neighbourhoods, 300 households (1523 children) received a regular supply of antibacterial soap and 300 households (1640 children) received plain soap. Eleven neighbourhoods (306 households and 1528 children) comprised the control group. Their study found that children younger than 15 years living in households that received handwashing promotion and plain soap had a 53% lower incidence of diarrhoea (95% CI, -65% to -41%) compared with children living in control neighbourhoods. Infants living in households that received handwashing promotion and plain soap had 39% fewer days with diarrhoea (95% CI, -61% to -16%) versus infants living in control neighbourhoods (Luby et al., 2004). In this trial, Luby and colleagues (2004) managed to deliver their intervention at one level by providing resources. It is not clear

how field workers promoted handwashing during follow-ups in the community. The intervention targeted two contextual levels of a child and family/group.

Luby and colleagues (2005) undertook a randomised controlled trial to assess the effect of handwashing promotion with soap on the incidence of acute respiratory infection, impetigo, and diarrhea in Karachi, Pakistan (Luby, Agboatwalla, Feikin, Painter, Billhimer, Altaf, & Hoekstra 2005). They randomly assigned 25 neighbourhoods to handwashing promotion, and 11 neighbourhoods to control group. In the intervention group, 300 households were assigned to antibacterial soap containing 1.2% triclocarban and to plain soap. Fieldworkers visited households weekly for 1 year to encourage handwashing by residents in soap households and to record symptoms in all households. Luby and colleagues (2005) found that children younger than 5 years in households that received plain soap and handwashing promotion had a 50% lower incidence of pneumonia than controls (95% CI -65% to -34%). Also compared with controls, children younger than 15 years in households with plain soap had a 53% lower incidence of diarrhoea (-65% to -41%) and a 34% lower incidence of impetigo (-52% to -16%). Incidence of disease did not differ significantly between households given plain soap compared with those given antibacterial soap. In this trial, Luby and colleagues (2004) managed to deliver their intervention at one level by providing resources. It is not clear how field workers promoted handwashing promotion during follow-ups in the community. The intervention targeted two contextual levels surrounding a child which were the school and family.

Kalenga (2012) conducted a study in Blantyre, Malawi with the aim of assessing WASH in primary schools. The research had two components namely literature review and field survey. The findings of his literature review indicated that there were inadequate toilets, lack of adequate handwashing facilities, inadequate hygiene promotion and low sanitation coverage, which was confirmed by the information from the survey. Each of the 11 schools that were sampled had water supply either in form of tap water or boreholes. Some schools had both sources. The research found that the water sources are conveniently positioned to classrooms having a distance of 5-20 metres. Further, the research found that water sources in nine of the ten sampled schools are reliable but in the two schools there is an intermittent water supply due to low pressure. According to school records, no incidence of water related diseases was registered at the sampled schools. The problems related with water supply are disconnection of tap water due to the failure of the school management to pay for water bills and stagnation of water at some water points. In terms of sanitation, the main problem that was experienced is lack of adequate toilets with toilet/pupil ratios as high as 1:444. None of the schools that were sampled had soap for hand washing, two schools had hand washing facilities and none had sanitation club although few schools had sanitation committees that are dominated by members of staff. The research also found that little is done on hygiene promotion so that hygiene messages are relayed to pupils although some schools remind pupils about personal hygiene during morning assembly time. Generally, the findings proved that there is little progress in primary school WASH and additional commitment will be required if Malawi is to improve on water and sanitation. Kalenga (2012) recommended that

primary school WASH needs collaborative effort among various stakeholders like pupils, teachers, government, NGOs, water utility companies and local councils (multilevel and multisectoral approach). Failure to address WASH challenges in Malawi Primary Schools can retard pupil's school performance (Kalenga, 2012).

A study was undertaken to determine the efficacy of hygiene practices in 2 primary schools in Malawi (Grimason, Masangwi, Morse, Jabu, Beattie, Taulo, & Lungu, 2014). The study determined: (1) presence of *Escherichia coli* on the hands of primary school pupils, (2) knowledge, awareness and hygiene practices amongst pupils and teachers and (3) the school environment through observation. They found that pupil appreciation of hygiene issues was reasonable. However, the high percentage presence of *E. coli* on hands (71%) and the evidence of large-scale open defaecation in school grounds revealed that apparent knowledge was not put into practice. The standard of facilities for sanitation and hygiene did not significantly impact on the level of knowledge or percentage of school children's hands harbouring faecal bacteria. Evidence from pupils and teachers indicated a poor understanding of principles of disease transmission. In this study by Grimason and colleague (2014) identifies the need for a multidisciplinary approach to improve sanitation and hygiene practices within schools. In their study, they targeted students with hand hygiene lesson without adopting multilevel approach. They used existing handwashing resources.

The current hygiene situation in Malawi is that the percentage of households with an improved toilet facility is at 8%. Studies conducted in rural areas in

Malawi suggest that the real practice of handwashing with soap at critical times is occurring between 3% and 18% of the time (MMoH, 2011). In addition, the percentages of the population that have handwashing facilities with soap and water at home are 7% and 2% in urban and rural Malawi respectively (UNICEF, 2015).

The Malawi government, in collaboration with the World Food Programme (WFP), developed school health and nutrition guidelines in 2010. The guidelines provide the first overall framework for sustainable, coordinated and comprehensive health and nutrition programmes in Malawi's schools. The guidelines seek to provide quality education while promoting health and nutrition in schools (Malawi Government, 2010). However, the guidelines put much emphasis on the feeding programme to retain children in school. Many other aspects of the multilevel interventions approach and the WHO's HPS framework using the whole school approach, such as hand hygiene just to mention one, have not been scaled down to the implementation level in schools and communities in general. For example, many schools still do not have clean and safe running water available within the school. Many have no handwashing facilities, and soap for handwashing is not available. The Ministry of Education and Health has not streamlined the WHO's HPS framework (1987) and the whole school approach. The clear link of collaboration between ministry of health and ministry of education is not defined. This is evident in the findings of many studies and reports (Kalenga, 2012; MMoH, 2011; UNICEF, 2015; 2014; 2010; 2009; 2008).

Literature presented above from developing countries, show that many studies implemented their intervention at a single level or 2 levels and targeted schoolchildren only (one contextual level). Most studies used education/training only and targeted a schoolchild. Some studies used rigorous study designs like RCT while others did not. However, even those that used rigorous design, had methodological flaws and make their results questionable according to a systematic review report conducted by Mbakaya and colleagues (2017). For example, the review which included most of the studies (Greene et al., 2012; Luby et al., 2005; Luby et al., 2004; Patel et al., 2012; Pickering et al., 2013; Saboori et al., 2013; Talaat et al., 2011; Zhang et al., 2013) used in this section, found that after applying the Jadad scale to all the eight included studies, 75% (6/8) were found to be of low quality and only 25% (2/8) were of high quality. The highest score was four out of five (Luby et al., 2005; Luby et al., 2004) and the lowest was one out of five (Saboori et al., 2013). Most of the hand hygiene programmes that used a single-level approach did not evaluate specific outcome measures. Applying the components of hand hygiene multilevel interventions approach which include formulating hand hygiene protocol, delivering proper handwashing technique training, creating supportive environments in practicing proper handwashing technique and ensuring resources are available is an important approach to support hand hygiene programmes especially in developing countries.

Very few robust studies using the HPS framework for advancing hand hygiene practice in the school setting using the whole school approach have

been conducted in developing countries compared to developed countries like Hong Kong (Langford et al., 2014; Lee et al., 2005; WHO, 1996).

2.3 Factors influencing hand hygiene

According to Dreibelbis, Winch, Leontsini, Hulland, Ram, Unicomb, & Luby (2013), contextual, psychosocial and technological factors influence handwashing at five different aggregate levels: habitual, individual, interpersonal, community and societal (Dreibelbis et al., 2014). According to Dreibelbis, contextual factors involve determinants related to the individual, setting, and/or environment that can influence behaviour change and the adoption of new technologies; psychosocial factors comprise the behavioural, social, or psychological determinants that influence behavioural outcomes and technology adoption; and technological factors comprise attributes of a technology, product, or device that influence its adoption and sustained use (Dreibelbis et al., 2014; Hulland, Leontsini, Dreibelbis, Unicomb, Afroz, Dutta... & Winch (2013). Dreibelbis and colleagues (2014) further state that these factors influence handwashing at five different aggregate levels: habitual, individual, interpersonal, community, and societal. According to them, the societal/structural level refers to the organisational, institutional or cultural factors that influence behaviours, such as laws, policies, climate, geography, and distribution of products; the community level includes the physical and social environment in which individuals are nested, as well as the formal and informal institutions that shape individual experiences; the interpersonal/household level represents interactions between individuals and the people they

associate with, such as norms, aspirations, shame, sharing access to a product, and behavioural modelling; the individual level includes socio-demographic factors such as age and gender, individual cognitive factors, and attitudes toward the product, hardware, or behaviour; and the habitual level reflects the fact that the opportunity and necessity for handwashing behaviours are repeated over the course of the day, and that there are multiple processes or events that can result in the specific behavioural outcomes (Dreibelbis et al., 2014; Hulland et al., 2013).

Addressing challenges that affect handwashing among schoolchildren can be vital in promoting health and reducing school absenteeism due to infectious diseases. While studies in the review by Mbakaya and colleagues (2017) addressed some of these factors in their implementation, contextual and psychosocial factors were seldom used. They further recommended that future studies need to consider using all three types of factor and delivering interventions at all five levels to maximise their impact on behaviour change and increase the uptake of handwashing among schoolchildren (Mbakaya et al., 2017).

2.4 Barriers and enablers to implementing hand hygiene programmes

A systematic review of literature was conducted by Mbakaya and his colleagues in 2017 to identify intervention strategies including both barriers and enablers to implement hand hygiene programmes for schoolchildren in developing countries. It reported that most of the studies using a single level intervention without evaluating the outcomes properly. Inadequate resources

such as water and soap, were identified as major barriers to hand hygiene practice, while proper training, policy and availability of resources were found to enable hand hygiene practice. Many studies included in the systematic review by Mbakaya and colleagues in 2017 used either training only or combined training with resources. However, the commonly used and most prioritized strategy was training, followed by funding and policy delivered at individual level. Rarely the three enabling strategies were combined (Mbakaya et al., 2017). See details in sections 2.5.1 and 2.5.2 below.

2.4.1 Barriers to implementing hand hygiene programmes

Promoting hand hygiene programmes remains a big challenge due to hindrances in transforming knowledge into behaviour change and ensuring accessibility of supplies and infrastructure (Zhang et al., 2013). Poor hygiene practices and insufficient sanitary conditions play greater roles in the increased prevalence and incidence of communicable diseases in developing countries (Vivas et al., 2010). Appropriate and effective hand hygiene practice for schoolchildren is important in preventing infectious diseases such as diarrhoeal and respiratory infection, which are the two most common causes of death among children in developing countries (Cairncross et al., 2010; Talaat et al., 2011).

Inadequate resources such as water, soap, hand rubs and hand hygiene facilities have been highlighted in studies by Oswald, Hunter, Lescano, Cabrera, Leontsini... & Pan (2008) and O'Loughlin (2006) as some of the

barriers to children's hand hygiene practice. In addition, hand hygiene among students was largely influenced by their knowledge about and attitude to hand hygiene (Oswald et al., 2008; O'Loughlin, 2006).

Untreated water and unhygienic conditions have an impact on the health, school attendance and learning capacities of school-age children due to illnesses that occur because of infectious diseases (Lee & Lee, 2014; UNICEF, 2006). It is reported that most people who live in low- and middle-income countries live in rural areas, 19% lack improved sanitation, and 35% lack water and soap for handwashing (WHO, 2017). In situations where water and water stations are not readily available, people may not treat handwashing as a priority, affecting hand hygiene practice. Failure to prioritise washing hands, especially after visiting the toilet; before eating or feeding a child; before, during and after preparing food; and after changing and cleaning up a child who has used a toilet increase the chances of contracting or spreading diarrhoeal and respiratory-related diseases (CDC, 2016; UNICEF, 2017).

A Water and Sanitation Programme report (2009), found that many different reasons were given by students in Senegal for not washing their hands. Among these reasons were not wanting to listen to what adults say, laziness, rushing to go for a break, loss of playtime, and the dirty and smelly toilets.

Schmidt and colleagues in 2009 conducted a pilot study in four primary schools in East London to establish the need for enhanced hand hygiene interventions, identify barriers to their implementation, and test their

acceptability and feasibility (Schmidt, Wloch, Biran, Curtis, & Mangtani, 2009). The pilot study included key informant interviews with teachers and school nurses, interviews, group discussions and essay questions with the children, and testing of organised classroom hand hygiene activities. Schmidt and colleagues found that basic issues of personal hygiene were taught in all schools, especially in the younger age groups (Schmidt et al., 2009). However, they identified many barriers to implementing intensive hygiene interventions, time constraints and competing health issues. Teachers' motivation to teach hygiene and enforce hygienic behaviour was primarily educational rather than immediate infection control (Schmidt et al., 2009). Children of all age groups had good knowledge of hygiene practices and germ transmission. In many settings there may be logistical issues in providing all schools with an adequate supply (Schmidt et al., 2009).

Lopez-Quintero and colleagues conducted a study in Bogotá, Colombia to assess handwashing behaviours and intentions among schoolchildren to help identify and overcome barriers to proper hygiene practices (Lopez-Quintero, Freeman, & Neumark, 2009). They collected data on handwashing behaviour and intentions and individual and contextual factors from students in 25 schools via anonymous questionnaires. A member of the school administration or teaching staff completed a questionnaire about the school environment. They also conducted an inspection of bathroom facilities. Lopez-Quintero and colleagues found that only 33.6% of the sample reported always or very often washing hands with soap and clean water before eating and after using the toilet (Lopez-Quintero et al., 2009).

About 7% of students reported regular access to soap and clean water at school. A high level of perceived control was the strongest predictor of positive handwashing intentions (adjusted odds ratio [AOR] = 6.0; 95% confidence interval [CI] = 4.8, 7.5). Students with proper handwashing behaviour were less likely to report previous-month gastrointestinal symptoms (OR = 0.8; 95% CI = 0.6, 0.9) or previous-year school absenteeism (OR = 0.7; 95% CI = 0.6, 0.9). It was concluded that the scarcity of adequate facilities in most schools in Bogotá prevents children from adopting proper hygienic behaviour and thwarts health promotion efforts (Lopez-Quintero et al., 2009).

2.4.2 Enablers to implementing hand hygiene programmes

Enabling factors for proper hand washing, according to a study done in sub-Saharan Africa, were avoidance of disgust, such as dirt and smelly faeces; nurturing, such as teaching children to wash hands so as to avoid ill health; status, whereby clean people seem to be more accepted; association of cleanliness with better socioeconomic status; looking more attractive due to cleanliness; the comfort from feeling and smelling fresh hands; and fear of catching diseases (Scott, Curtis, Rabie, & N G-A, 2007). In addition, students indicated that they washed their hands because they did not want to get ill and experience the double loss of classes and chatting with friends. Some students thought having clean hands would help them to keep their books clean and in return get better grades (Water & Sanitation Programme, 2009). A combination of education, enhanced perception of the health threat, self-efficacy, and perceived social pressure could improve hand

hygiene compliance (Pittet, 2001). Interventions aimed to promote hand hygiene could save millions of lives (Curtis et al., 2009; Cairncross et al., 2010).

In a study done by Zhang et al. (2013), after a HWP intervention, schoolchildren reported a large increase in daily handwashing rates. The HWP comprised three main components: handwashing education, the construction of tippy-tap handwashing stations, and the provision of soap (Zhang et al., 2013). In another study, it was found that the proportion of pupils observed practising handwashing with soap was significantly higher in schools that received training and handwashing supplies (Saboori et al., 2013). Training/education, policy and provision of resources/funding have proven to be effective strategies in successfully implementing hand hygiene programmes (WHO, 2009).

More scientifically sound, evidence-based studies need to be carried out in developing countries, since there has been limited evaluation of the effectiveness of intervention strategies with a multilevel approach when addressing factors that affect handwashing to scale up and improve handwashing practice among schoolchildren in the context of the whole school approach.

2.5 A whole school, WHO's health promotion school

The concept of health-promoting schools (HPS), defined as schools that are constantly strengthening their capacity as a healthy setting for living,

learning and working, has existed internationally for more than 15 years (WHO, 1996). The WHO's HPS Framework is a holistic, settings-based approach to promoting health and educational attainment in school. It focuses on three areas of intervention within schools and its local community.

A whole school approach distinguishes that all aspects of the school community can positively impact upon student's health safety and wellbeing (WHO, 1996). A whole school, health promoting school framework brings together school principals and school councils to health promotion in the school setting. They can support a whole school approach to hand hygiene by providing leadership and support to implement the SBHHP with the hand hygiene policy and curricular integration (Langford et al., 2014).

The growing number of epidemics of emerging infectious diseases and sedentary behaviours has raised the importance of a settings approach and including the HPS framework to promote better health and hygiene (Lee et al., 2008). Schools are places where children and adolescents spend a huge proportion of their lives and are nurtured during different developmental stages, thus schools have the potential to be a powerful domain of influence on children's health (Langford et al., 2014). Recognition of this has led to an interest in using schools as a means of promoting healthy behaviours in children and young people (Langford et al., 2014). It is important to make schools as healthy as possible using a public health perspective (Lee et al., 2008; 2006; 2005).

Attitude, beliefs and behaviours learned during the early years have shown a strong tendency to continue into adulthood (State Government of Victoria, Australia, 2017). Thus, it is important to establish healthy living habits during the early years for formative learning. This is a key public health priority for health promotion during early childhood as a strategy to reduce morbidity and mortality rates in the global public health agenda (WHO, 2009).

Traditional health education approaches focused on promoting health messages such as “do not smoke” and “eat healthily” through the school curriculum and were not found satisfactory based on health outcome measures. In the late 1980s, a new holistic approach to school health promotion was found, which focused on promoting health through the whole school environment embraced in the new WHO’s HPS framework’ (1996). The focus of the HPS required action in three areas of interventions within schools and its local community: 1) school curriculum, teaching and learning to help students develop the knowledge, attitudes and skills needed for healthy choices, 2) school ethos, environment and organisation to promote the health and wellbeing of students and staff in the informal curriculum, consisting of values and attitudes promoted within the school and the physical environment and setting of the school, such as providing hand hygiene resources to promote proper handwashing technique, and 3) school community participation and services to engage families, non-governmental organisations (NGOs) and community stakeholders in promoting child health in the school communities, such as extending the

school-based health programme to the home setting via mobile apps to deliver health messages. This is depicted in figure 1 below.



Figure 1 World Health Organisation's Health-Promoting School Framework

Government of Western Australia Department of Health (2018). Accessed from www.gdhr.wa.gov.au/

The HPS framework developed by the WHO encourages a whole school approach to support health issues (Langford et al., 2014; Lee et al., 2005; WHO, 1996). Mitchell Ollis and her colleagues reported that a whole-school approach was more than just the implementation of a formal curriculum (Ollis et al., 2000). School health policy and guidelines are essential to form the backbones to support and monitor the students' health outcomes. School-based health programmes should be integrated within a formal student

welfare support structure and link students with relevant community agencies for support and assistance when needed (Ollis et al., 2000).

In a study conducted in Hong Kong by Lee and colleagues in 2008, they found that students in schools that had adopted the HPS framework had a more positive health behaviour profile than those in non-HPS. Although they did not establish a causal relationship, the HPS appears to be a viable approach for addressing communicable diseases (Lee et al., 2008). In yet another study, conducted in Hong Kong, the results suggest that comprehensive implementation of HPS would contribute to differences in certain behaviours and self-reported health and academic status (Lee et al., 2006). It is therefore important to implement the hand hygiene programme in school settings using the HPS framework to achieve better results.

Langford and her colleagues conducted a Cochrane systematic review of the WHO's HPS framework to identify the 'gold standard' method by reviewing those studies to evaluate the intervention effectiveness using cluster randomized controlled trials; they also adopted the HPS approach (Langford et al., 2014). After identifying and reviewing 67 trials that met the inclusion criteria, the review concluded that there were few studies, especially in sexual health, handwashing, eating disorders and others, that measured the impact of the intervention on students' attendance or academic achievement. This systematic review identified a gap in the evaluation of intervention effectiveness in handwashing using the HPS approach (Langford et al., 2014). More research in this area is justified in low- and middle-income countries. High-quality RCTs using the HPS approach are

also urgently needed. In addition, such trials should include post-intervention follow-up measures to determine the sustainability of the HPS approach (Langford et al., 2014).

2.6 World Health Organisation's 7-step handwashing technique

WHO has long advocated for the use of a 7-step technique for handwashing. This has been incorporated in formal training in developed and in some developing countries as part of healthcare training (WHO, 2009). However, the incidence and prevalence of infections due to poor hand hygiene practices is still on the increase, especially in developing countries. Many studies have shown low compliance with the 7-step handwashing technique among health workers globally (Kalata, Kamange, & Muula, 2013; Regidor, Dioso, Samporna, Eden, & Sha, 2012; Voss & Widmer, 1997). For example, a study conducted in Malawi found that adherence to hand hygiene practice using the WHO recommended protocol was found to be as low as 23% (Kalata et al., 2012). In the same study, participants cited forgetfulness, lack of hand hygiene resources and negligence as reasons for non-compliance (Kalata et al., 2012). In yet another study it is reported that compliance for handwashing using the 7-step handwashing technique rarely exceeded 40% under study conditions (Voss & Widmer, 1997).

Pittet in his review found that compliance with recommended instructions on handwashing often is poor among healthcare workers (Pittet, 2015). He further stated that although some previous interventions to improve compliance have been successful, none has achieved lasting improvement.

The hand hygiene promotion and compliance level does not rely on individual factors alone. The complexity of the process of change results in failure of solo interventions, which in turn calls for the use of multimodal and multidisciplinary strategies (Pittet, 2015).

2.7 A simplified 5-step handwashing technique

While there are many factors that affect handwashing, as presented in chapter two of this study, it is possible that the complexity of the 7-step procedure also contributes greatly to non-compliance, especially among young school-aged children (Lee et al., 2015; Lee et al., 2014). This is more pronounced in young schoolchildren, who learn better through simple and shorter instructions rather than complex procedures (Lee et al., 2015; Lee et al., 2014). Since children's cognitive and motor skills are not fully developed, it is very easy for them to get their long sleeves wet as they practise washing their hands and wrists using the 7-step handwashing technique (Lee et al., 2015; Lee et al., 2014). Wet sleeves create an environment that is conducive to microorganisms living and multiplying, thereafter being transferred through direct contact to the hand, then to the mouth or eyes, completing the epidemiological triad of the infectious disease transmission cycle (hand-to-mouth or hand-to-eye). Although WHO advocates for a 7-step handwashing technique, a simplified 5-step handwashing technique has been developed and proven effective compared to the conventional 7-step handwashing technique (Lee & Lee, 2014).

2.8 Use Social Learning Theory to facilitate schoolchildren's learning of the proper handwashing technique

The simplified 5-step handwashing technique was developed because of reducing the number of steps in the WHO's 7-step handwashing technique and validated in a pilot study by Lee & Lee (2014). The simplified 5-step handwashing technique is simpler and easier to master/memorise than the 7-step handwashing technique for children whose cognitive and motor abilities are not fully developed. Children at the elementary stage are still young and immature socially, physiologically, psychologically and intellectually. This means they take longer to follow instructions and master complicated procedures, being at the same time more vulnerable to infections. Therefore, a simplified 5-step handwashing technique is a better way of teaching the skill than using the 7-step handwashing technique, which are longer and somehow more complex for children by comparison.

While any handwashing is highly recommended, this simplified 5-step handwashing technique has proven to be more effective in reducing the spread of infectious diseases compared to the WHO's 7-step handwashing technique (Lee et al., 2015). This was evident in a comparative efficacy study of a simplified handwashing programme for improvement in hand hygiene and reduction of school absenteeism among children with intellectual disability, conducted in Hong Kong (Lee et al., 2015). Lee and colleagues used Bandura's social learning theory (1997) in their study and produced significant results in all the outcome measures (proper hand washing, reduction of infection and reduction of school absenteeism (Lee et

al., 2015). This justifies the use of a simplified 5-step handwashing technique in preference to the 7-step one, especially in the community and school setting, due to its validity, simplicity and effectiveness. Much as a correct handwashing procedure is critical for effective proper handwashing (cleanliness of the hands), complex procedures do little to promote efficient learning in children.

Handwashing is acknowledged and recommended by the WHO and CDC as an important public health intervention to reduce infectious diseases (CDC, 2011; WHO, 2009). Proper handwashing is the single most effective action and the primary measure a person can perform to reduce the spread of infectious diseases such as diarrhoea, influenza and other respiratory illnesses (Lee & Lee, 2014). In addition, Lee and Lee (2014) proved in their study that a simplified proper handwashing technique with mass media and using social learning theory could reduce the absenteeism rate for children with special needs. Handwashing is regarded as a cornerstone of public health because it breaks the transmission cycle of many infectious diseases (Malawi Ministry of Health [MMoH], 2011).

Langford and colleagues conducted a systematic review in which the aim was to assess the effectiveness of the HPS framework in improving the health and well-being of students and their academic achievement. Out of the 65 articles included in their review, they found that the most commonly cited theory (20 studies) was the social learning theory (Langford et al., 2014). Social learning theory is preferred in behavioural studies dealing with children because of its emphasis on self-efficacy and observational

learning, since children learn better by observation (Bandura, 1977).

2.9 Rationale for using two theories in this study (SBHHP)

To plan and implement the SBHHP using the multilevel intervention strategies, two major components must be fully addressed. First is the learning process, which involves teaching demonstrations and return demonstrations by primary school students (learners). For successful learning to take place in children, Bandura (1997) proposed a social learning theory that suits this age group. Children learn better through observation in an appropriate environment, with role models as described below. The second is practising what they have learnt (behaviour change). Hence the use of the theory of planned behaviour by Ajzen (1988) to help them change their hand hygiene behaviour as described below. In addition, for both learning and behaviour change to take place, students need a support system that embraces the multi-sectoral approach, hence use of the HPS framework using the whole school approach.

2.10 Theory of Planned Behaviour

The theory of planned behaviour (TPB) was developed in 1988 by Ice Ajzen. The TPB has been more successfully and widely used in public health than other theories such as the health belief model to predict and explain different types of health behaviour (Knabe, 2012). The main element to TPB is behavioural intent, whereby behavioural intentions are influenced by attitudes about the probability that the behaviour will have the

expected outcome, and the subjective evaluation of the risks and benefits of that outcome (Ajzen, 1988). TPB uses attitudes, subjective norms and perceived behavioural control to predict behavioural intention. Subjective norm is the social pressure schoolchildren perceive from significant others (normative referent) who desire or expect hand hygiene compliance. Schoolchildren's perceived hand hygiene control is their unconstrained opportunity to perform or not perform hand hygiene. According to TPB, motivation (intention) and ability (behaviour control) are determinants for a person to achieve a desired behaviour, as shown in figure 2 below.

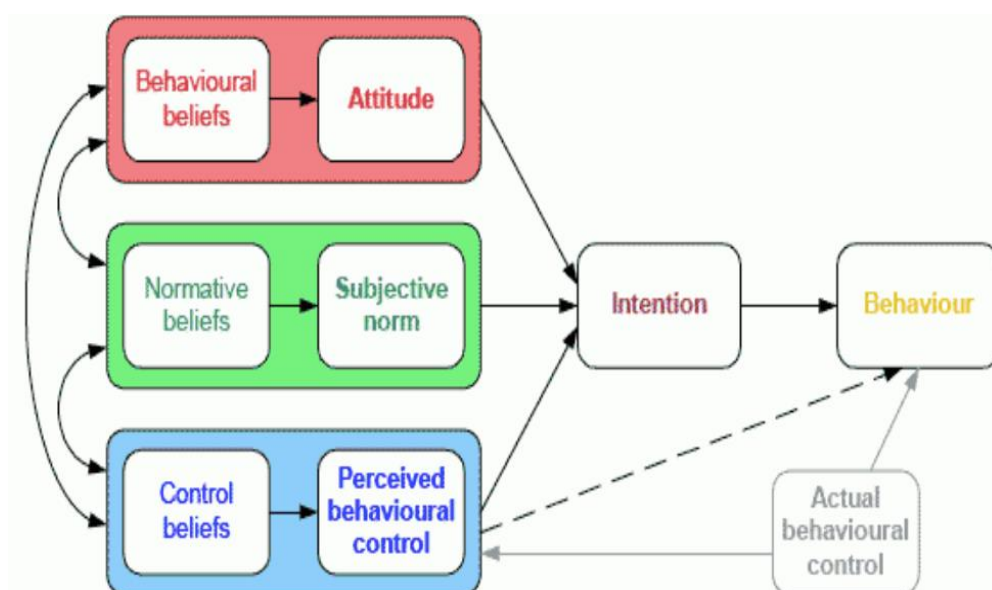


Figure 2 Theory of Planned Behaviour

Source: Ajzen, I. (2000). TPB Diagram. The theory of planned behaviour. Retrieved March 31, 2018 from <https://www.cleverism.com/theory-of-planned-behavior/>

2.11 Bandura's Social Learning Theory

The social cognitive theory (SCT) was developed by Bandura (1963) as a theory of social learning with the principles of observational learning and mediated reinforcement. It is a learning theory that describes how behaviours are learned, as shown in figure 3 below. Bandura (1977) introduced the concept of self-efficacy, which is a person's beliefs in his/her ability to produce a given attainment (Bandura, 1997, quoted in Bandura, 2006, p.307). Three factors (environment, people and behaviour) are constantly influencing each other. Observational learning occurs when a person watches the actions of another person and the reinforcements that the person receives (Bandura, 1997). Bandura further emphasised that children learn much more simply by observing other people.

Below is the diagram depicting the framework for Bandura's Social Learning Theory, describing how behaviour, environment and personal/cognitive factors interact to influence learning and consequently change behaviour.

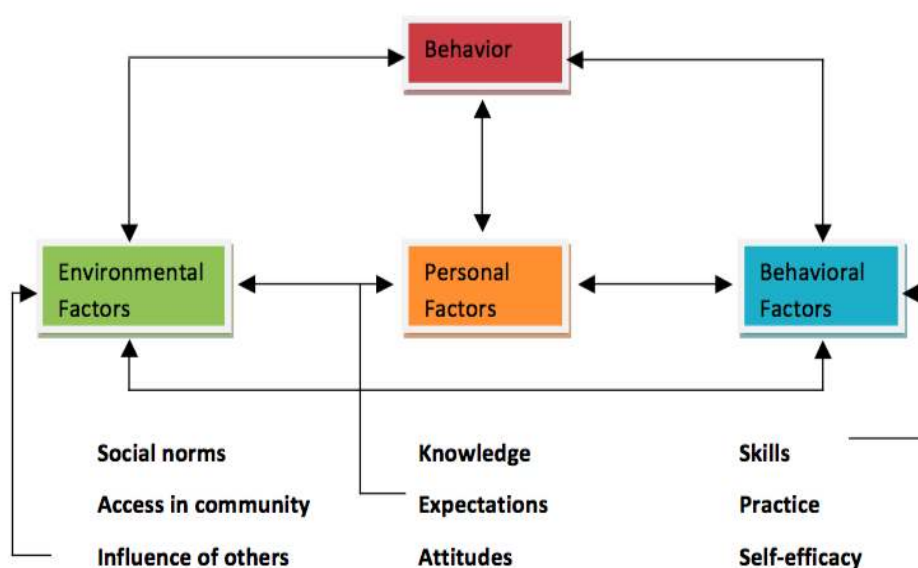


Figure 3 Bandura's Social Learning Theory

Source: Pajares (2002). *Overview of social cognitive theory and of self-efficacy*. Retrieved Dec. 31, 2016 from <http://www.emory.edu/EDUCATION/mfp/eff.html>.

2.12 WHO's Health Promoting School Framework.

A health promoting school framework is a multifaceted approach that support health behaviors (WHO, 1996) with the support of the systematic review of the literature to identify what types of intervention that work best for whom, in what circumstance to create heathier schools and children. It is important that staff in health and education agreed to the frameworks and work collaboratively to support best health and education outcomes for children in schools.

Schools are unique settings to foster the younger generations' participation in furthering their own health and sustainability. The health promoting school's framework and supporting resources guide the school through a

whole-school approach to promoting the health, wellbeing and engagement of its students, including hand hygiene practices. There are three areas of intervention that are inter-connected in the HPS: 1) school curriculum, teaching and learning, 2) school ethos, environment and organization, 3) school community partnership and services. These three key areas of intervention are summarized in the table 1 below. The three areas of intervention described below recognise different levels of influence on health, moving from the individual to the school environment to the wider community context, and emphasising the need to act on all three levels to successfully influence health.

Table 1 WHO's Health Promoting School Framework

Area of intervention	Description
School curriculum, teaching & learning	Health education topic are promoted through formal school curriculum
School ethos, environment & organisation	Health and wellbeing of students are promoted through the hidden or informal curriculum which encompasses values and attitude promoted within the school and physical environment and setting of the school
School community participation & services	School seek to engage with families, outside agency and wider community in recognition of the importance of these other spheres of influence on children's health

2.12.1 School curriculum, teaching and learning

In this study, schoolchildren were taught about proper hand hygiene with an emphasis on using soap and clean water and following the 5-step technique of handwashing. This was done once a week for 6 months, with teachers reminding students twice a day during break and lunch, and during the morning assembly, for a period of 9 months. The education content covered the why, how and when to wash hands. This helped to increase students' self-confidence and self-efficacy.

2.12.2 School ethos, environment and organization

This domain was achieved through promotion of health messages beyond the classroom in the wider school environment, for example, via posters, information displays, and school assemblies, teachers were trained on the SBHHP. The researcher also used peer-lead activism among students. In this study, changes to the physical environment of the school were also implemented, for example the researcher provided handwashing soap to schools for the entire academic year, constructed water pipes, constructed handwashing sinks, and paid water bills in some situations to facilitate hand washing.

2.12.3 School community partnership and services

On this domain, the researcher reached out to parents through schoolchildren by giving them a take-home package that contained the same

information that was given to students at school and displayed on posters. An information sheet was also given to parents, with detailed information to read and understand before consenting to their child's participation in the SBHHP. Parents were also involved in the focus group discussion to hear their views, opinions and suggestions regarding the SBHHP. Meeting with the representatives of the Independent School Association of Malawi (ISAMA) was also organised to discuss the SBHHP implementation.

2.13 Study Conceptual Framework

In this study, the conceptual framework was developed as shown in figure 4. The findings of the literature review suggested that the adoption of multilevel intervention strategies had a bigger impact than adopting a single-level intervention in implementing hand hygiene programmes in developing countries (Mbakaya et al., 2017). Hence the intent to use the multilevel interventions approach to address hand hygiene issues among Malawian schoolchildren underpinned by Bronfenbrenner's Ecological Framework, and WHO's HPS framework and how it eventually impacts schoolchildren's ecological outcomes in terms of improved hand hygiene compliance, improved school attendance, reduced school absenteeism (sick leave days), hand hygiene protocol integration into the school curriculum, creating supportive environment for the student's hand hygiene behaviour, making resources available, and the linkage to the community or family (see Figure 4).

This is important because the complexity of the process of change results in failure of single-level interventions approach, which in turn calls for the use of multimodal and multidisciplinary strategies (Pittet, 2015). By applying the multilevel framework, it rectifies the limitations of the previous interventional approaches targeting single domain framework in the area of hand hygiene especially in developing countries. Bronfenbrenner's ecological systems theory (1987) stresses on the quality and context of the child's surroundings and it explains the five levels of external influence on the hand hygiene behaviour among schoolchildren in varying degrees (Bronfenbrenner, 1979). These systems include the microsystem, the mesosystem, the exosystem, the macrosystem, and the chronosystem. The impact of contextual factors such as policy/protocol, training, environment and resources in planning a health promotion programme influence the schoolchildren's ecological outcomes such as improved hand hygiene compliance, improved school attendance, reduced school absenteeism (sick leave days), hand hygiene protocol integration into the school curriculum, creating supportive environment for the student's hand hygiene behaviour, making resources available, and the linkage to the community or family (see Figure 4). The researcher in this study plans and implements hand hygiene health promotion programmes by targeting schoolchildren's various systems (immediate environment with family members, the school environment with peers, the organization environment with school) in their environments to improve their ecological outcomes. The strategies of the multilevel interventions approach include policy/protocol, training, environment and resources target more than one contextual factor (family members and peers) across the five systems of environmental influences as

suggested by Bronfenbrenner's Ecological Systems Theory (1979) (See Figure 4).

2.13.1 Synthesis of identified theoretical underpinnings with study variables

2.13.1.1 Microsystem

Microsystem is the smallest and most immediate environment in which the child lives. As such, the microsystem in this study comprises of the school in which students spend much of their time interacting with others and being exposed to different types of infectious diseases (immediate setting) that allow the students to interact (Bronfenbrenner, 1979). The handwashing resources included the construction of water pipes, building handwashing sinks/stations and the availability of the handwashing soap. In this setting,

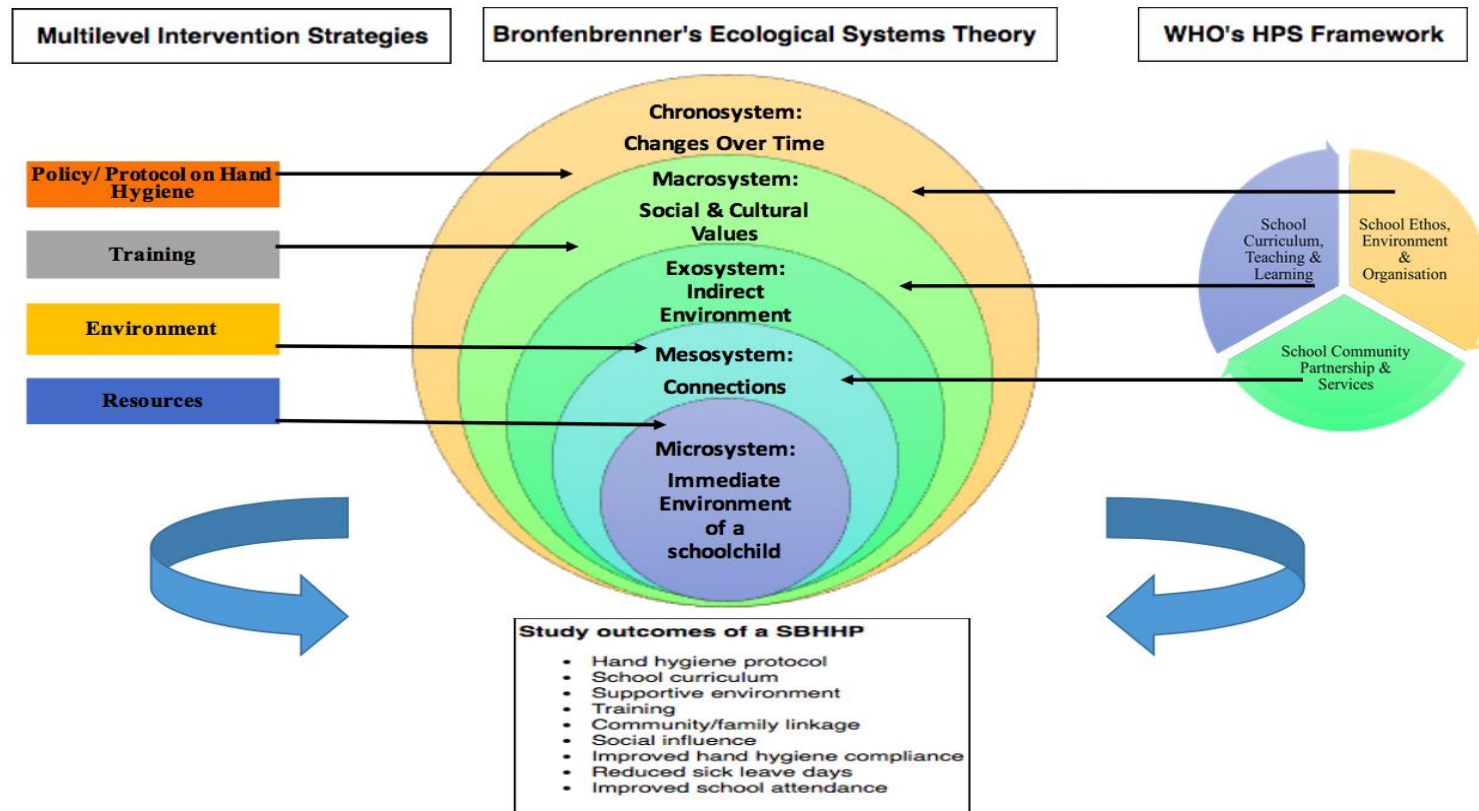


Figure 4 Study conceptual framework

Source: Bronfenbrenner, 1979; Mbakaya et al., 2017; WHO, 1996

the schoolchildren learn hand hygiene practice from fellow students (peer), research team and teachers who also acts as role models. This level is synonymous to the individual and group contextual levels in the multilevel interventions approach (Mbakaya et al., 2017), where it is expected that a group could be a source of influence to student's hand hygiene behaviour. At the same time, it is also equivalent to the first area of intervention of the WHO's HPS framework in which students are exposed to the school curriculum, teaching and learning regarding hand hygiene. Distribution of leaflets to schoolchildren containing information on how, why and when to wash hand forms part of microsystem. In addition, delivery of lessons on hand hygiene including the demonstrations and return demonstrations to schoolchildren form part of this system.

2.13.1.2 Mesosystem

The mesosystem encompasses the interaction of different microsystems which the developing child finds himself in (Bronfenbrenner, 1979). It is a system of microsystems and as such, involves linkages between home and school, between peer group and family (Bronfenbrenner, 1979). In this study families of schoolchildren access leaflets containing information on why, how and when to wash hands to reinforce student's hand hygiene practice in the home, thereby linking the school and home. In addition, focus group discussion with parents to explore their opinions regarding the acceptability and sustainability of the SBHHP forms part of mesosystem. Parents access leaflets containing information on hand hygiene

through their children. The students working in groups to practice the 5-step of handwashing at the sink where they had the handwashing technique demonstrations and return demonstrations thereby peer led activism forming an important part of the mesosystem. There was also a school link with other resources to children's home for the parents.

2.13.1.3 Exosystem

The exosystem layer defines the larger social system in which the child does not function directly (Bronfenbrenner, 1979). Children do not participate in the protocol development on hand hygiene, timings when to deliver hand hygiene content which is exosystem to student but influenced their hand hygiene practice. The structure in this layer impact the child's development by interacting with some structure in her microsystem (Bronfenbrenner, 1979). The home setting and the neighbourhood of the child play a crucial role in this study. For example, the inclusion criteria ensure that all participants were coming from within Mzuzu City with similar social demographic characteristics to ensure similarity in the availability of resources such as water.

2.13.1.4 Macrosystem

The macrosystem is the largest and most distant collection of people and places to the child that still exercises significant influence on the child. It is composed of the child's cultural patterns and values, specifically the child's

dominant beliefs and ideas, as well as political and economic systems (Bronfenbrenner, 1979). In this study, the macrosystem comprise of involving the ministry of education through the District Education Manager (DEM), the school directors, and also the involvement of the president of the Independent Schools Association of Malawi (ISAMA). Their involvement helps to lobby for the hand hygiene protocol to be established in the private primary schools within Mzuzu city, and to make sure that resources such as clean water are always available in order to reinforce the hand hygiene practice among students. This level corresponds to the multilevel hand hygiene strategies (Mbakaya et al., 2017) which advocates for policy and resources besides training and environment. These would in turn help to improve hand hygiene compliance, reduce infectious diseases and consequently reduce school absenteeism (sick leave days), and improve school attendance. In addition, this would also help to integrate hand hygiene protocol into the school curriculum, creating a supportive environment for schoolchildren to practice hand hygiene behaviour, help to mobilise hand hygiene resources and helps to form a strong linkage with the community and family. Behavioural rules were established regarding hand hygiene such as everyone should wash hands before and after eating, after visiting the toilet, after playing.

2.13.1.5 Chronosystem

The chronosystem adds the useful dimension of time, which demonstrates the influence of both change and constancy in the child's environment (Bronfenbrenner, 1979). The chronosystem may thus include a change in

the hand hygiene practice of schoolchildren, assessed at 3rd month after they participated in the programme, at 6th month to assess their compliance to handwashing and at 9th month to assess the sustainability. Conducting meetings with the parents and teachers through parent teacher association (PTA) on how to sustain the student's hand hygiene practice so as to have a fully established system in the student's environment for sustainability of the hand hygiene behaviour. Policy changes to incorporate hand hygiene protocol in the school extra-curricular, parent reinforcement of hand hygiene at home are also advocated in this study and forms part of chronosystem. In this study, schoolchildren have three sources of influence to change their hand hygiene behaviour such influence as from the students, research team and the organisation (school), the daily home, school, peer group or community environment of the child. The chronosystem specifically is consistent with the third area of intervention of HPS (school community participation & service).

Changes across time such as the radio programme on hand hygiene across the nation and also mass campaign on WASH during the cholera outbreaks in Malawi which may positively influence hand hygiene behaviour for students which is a critical part of the chronosystem.

2.14 Research gaps

Despite investment in community-based disease control and surveillance in infectious disease, published evidence evaluating interventions is limited in quantity and quality in terms of hand hygiene programmes focusing on the

multilevel interventions with specific outcome measures on the targeting population using rigorous study designs such as RCT. Several research gaps were identified through the literature review: 1) There is a lack of a structured school-based handwashing programme for children in primary schools in Malawi and other developing countries, especially in sub-Saharan Africa; 2) The uptake of and compliance with hand hygiene practice was very low among primary school students; 3) Very limited studies in developing countries applied all the hand hygiene intervention strategies (policy, training, environment and funding/resources) of the multilevel interventions approach, and 4) There is a gap in the evaluation of intervention effectiveness in handwashing using the HPS framework.

2.15 Summary of chapter two

The literature review revealed that there is insufficient evidence on the application of the HPS framework using a whole school approach, especially in hand hygiene. The HPS should be more than just a formal school curriculum on health education and health promotion using a whole school approach. In addition, literature revealed that there is low uptake of handwashing practice/poor adoption among schoolchildren and the general population in developing countries. It was also found that there was limited synthesised knowledge on the broader multilevel strategies that could impact local implementation barriers in the community and support uptake of the multilevel implementation strategies approach in developing countries. Single interventions often fail because of the complexity of the process involved in behaviour change. Therefore, use of a multilevel,

multidisciplinary and multidimensional strategy is necessary to achieve compliance in hand hygiene practices (Pittet, 2001). Use of multilevel intervention strategies is associated with better outcomes, such as reductions in diarrhoea, respiratory infections and school absenteeism (Taplin et al., 2012).

The results of the review also found that none of the studies that used handwashing as an intervention specified or described the handwashing technique used that is whether they used a conventional 7-step handwashing technique according to the WHO, or a simplified 5-step handwashing technique according to Lee et al (2015), or any standardised handwashing technique/procedure. This chapter also presented the two theories used in this study, namely the social learning theory according to Bandura (1977), and Ajzen's theory of planned behaviour (Ajzen, 1988). The study conceptual framework is also presented.

CHAPTER THREE

METHODOLOGY

3.1 Introduction

This chapter discusses the use of the cluster randomised controlled trial (RCT) and focus group discussions to evaluate the multilevel impacts and efficacy of a SBHHP for schoolchildren in Malawi, sub-Saharan Africa, including the feasibility, acceptability and sustainability of the study using the whole-school approach to develop health-promoting schools. The theory of planned behaviour used in this study explains that one's intention to perform a behaviour is determined by one's attitude concerning the likelihood that the behaviour will have the expected outcome, and one's subjective evaluation of the risks and benefits of that outcome (Ajzen, 1991). The following areas have been clearly outlined: study designs, study setting, study sample, sample size calculation, randomisation procedure, SBHHP (intervention), treatment fidelity, developing school health policy and hand hygiene protocol in implementation of the SBHHP, measurements, procedure for data collection, pre- and post-test of the hand hygiene knowledge quiz, procedure for data analysis, focus group discussions nested in a cluster RCT, and ethical considerations. Lastly, the summary of chapter three is provided. The key findings of the study have provided new evidence in the implementation of a SBHHP for both educational and health policy makers, so as to provide adequate resources in planning hand hygiene training, developing school health policy and integrating hand hygiene protocol into the school curricula.

3.2 Study design

A cluster RCT was chosen as the major design for this study because it allows a researcher to implement and evaluate intervention programmes at the community level and produce an impact. Settings such as schools require interventions to be delivered using a cluster RCT design in order to be effective and reduce contamination of the intervention. The qualitative aspect nested in the cluster RCT is important in order to get detailed views and opinions of schoolchildren, parents, school principals/heads, and teachers on the acceptability and sustainability of the SBHHP. The main aim of this study was to evaluate the efficacy of a SBHHP using a multilevel interventions approach targeting schoolchildren, schools and their families in the intervention group versus the routine hand hygiene practice in the control group at four-time point (T₀, T₁, T₂ & T₃) for schoolchildren who participated in this study in Malawi, sub-Saharan Africa. As such, a cluster RCT was used and a comparison made between the intervention group, in which a SBHHP was implemented, and the control group, in which participants were not given any intervention and left to continue with their usual hand hygiene practices in which they were expected to follow the WHO 7-step handwashing technique. A cluster RCT design with four-time point measure (T₀, T₁, T₂ & T₃) was used. Clusters (schools) were randomised into the intervention and control groups. It was envisaged that the results from this study could help to improve knowledge and skills regarding proper handwashing among primary school students, and in turn increase the uptake/adoption of handwashing practice/behaviour among schoolchildren, especially in developing countries.

3.2.1 Cluster Randomised Controlled Trial

The randomised controlled trial (RCT) remains one of the most reliable methods for evaluating the efficacy of therapies (Atkinson & Biswas, 2013). Randomised controlled trials are accepted as a gold standard for the evaluation of new health interventions (Hayes & Bennett, 1999). In this study, the design was appropriate because it aimed to design, implement and evaluate a SBHHP for children in Malawi. Matching was done in terms of age range, class/grade, sex, geographical location and type of school (private primary schools only), in order to reduce the chances of baseline imbalance among randomised clusters. In turn, this reduce the chances of producing biased estimates of the intervention effect. A balance of covariates between intervention and control clusters increases statistical power and precision (Beaty & Dickinson, 2014).

This was a two-armed cluster RCT design, with one intervention group and one control group. The intervention group received the SBHHP consisted of integrating handwashing practice in the school health protocol, setting up proper handwashing facilities, training school teachers, delivering health talks to schoolchildren, developing reminders and posters of the simplified 5-step handwashing technique, peer briefing sessions, demonstrations and return demonstrations. Parents were reached through a take-home package, which comprised a simplified 5-step handwashing poster, leaflets/pamphlets and a commitment letter. Parents were also given details of the programme through an information sheet. The control group was not given the SBHHP

intervention apart from providing them with handwashing resources but could continue with their usual practice, which advocates for the WHO's 7-step technique of handwashing, countrywide. This helped to compare the effect of the intervention on the outcomes, which were the primary school students' handwashing compliance (knowledge, skills/technique and cleanliness) at four-time point (i.e. knowledge refers to the scores of handwashing quiz; skills/technique refer to the scores of handwashing observational checklist; and hand cleanliness refers to the scores of the fluorescent stain test on both hands) as the primary outcome. The secondary outcomes were the school absenteeism (sick leave days) and the focus group discussions on the acceptability of the SBHHP.

This study also met the three criteria that are needed to support the claim of an influence of the independent variable on the dependent variable (cause-effect). These are randomisation, manipulation and control group. This altogether helps to maximise the internal validity. The researcher ensured that allocation concealment was properly done by using an independent person who was not involved in the study to allocate the randomly selected clusters into intervention and control groups. The researcher also blinded the outcome assessors. The intervention and control groups had three schools each. Refer to the study flow chart below (Figure 5).

It is always important in cluster RCTs to maximise concealment of the allocation of participants and thereby ensure that selection bias and confounding of unknown variables are minimised. Cluster RCTs are also feasible for application at a community or group level and are regarded as

the ideal ones to use when conducting studies on a large group of people (Hayes & Bennett, 1999; Isaakidis & Ioannidis, 2003). A cluster RCT design is also ideal because of its logistical convenience, the ability to capture the mass effect of the intervention, and its applicability to measure the effectiveness on community-wide basis (Hayes & Bennett, 1999). In addition, a systematic review of literature conducted by Mbakaya and his team (2017) found that all eight studies on hand hygiene in elementary schools had used cluster RCT. However, most of them had methodological flaws. As such, they recommended that more rigorous study designs be conducted in developing countries in order to produce reliable results to inform policy, practice and education. In addition, the review found that most studies included in the systematic review used only two or single level to implement their intervention, and mainly targeted one contextual level of a student.

This trial design could be of great importance in developing countries, where infectious diseases are the main cause of illnesses and interventions are required at the group/community level more than at the individual level (Hayes & Bennett, 1999). Based on evidence from the literature, it was therefore important to use a cluster RCT in this study, where the aim was to evaluate the efficacy of a SBHHP using a multilevel interventions approach targeting schoolchildren, schools and their families in the intervention group versus the routine hand hygiene practice in the control group at four-time point (T₀, T₁, T₂ & T₃) for schoolchildren who participated in this study in Malawi.

3.3 Study setting

Malawi is one of the countries in sub-Saharan Africa whose health indicators have generally remained poor across the board, yet two years have passed beyond the 2015 deadline to achieve the Millennium Development Goals (MDG). Malawi is located south of the equator and bordered by Tanzania to the north and northeast, Mozambique to the south and southwest, and Zambia in the northwest. It has a total area of 118,484 square kilometres, of which 94,080 are covered by land and 24,404 by water. Malawi's population is estimated at 19,107,706 (<http://worldpopulationreview.com/countries/>). The country is divided into three administrative regions: the south, central and northern regions. In Malawi, healthcare services are delivered at three levels. At the primary level, services are mainly preventive, promotive and rehabilitative, and are mostly community based. This project falls into this level of care service and setting (school). The other levels are the secondary (district and mission hospitals) and tertiary levels (specialised services).

Mzuzu, in which this study was conducted, is in the northern administrative region. It is the third largest city in Malawi after Blantyre (commercial) and Lilongwe (the new capital). Mzuzu is located 367 kilometres north of Lilongwe, the capital city. It has total land of 26,931 square kilometres and a total population of 175,345 people. Mzuzu was chosen because it is relatively smaller than the other two cities in terms of size (square kilometers) and population. As such, it was expected that it would be less demographically diverse. The city has a total of 55 elementary/primary

schools, of which 41 are government owned with a total of around 51,729 students, while 14 are private schools with a total of around 7,673 students. This study took place in six private primary schools in Mzuzu in the academic year from September 2016 to July 2017.

3.4 Study sample

Table 2 below presents the detailed demographic characteristics of the six private primary schools involved in this study, three of which were in the intervention group and the other three the control group. The shortest distance between schools involved in this study was approximately one kilometre, while the greatest distance between schools was approximately eight kilometres. It is good to know the distance between schools to make sure there is minimal interaction among students

Table 2 Characteristics of the six schools included in the study

Item	Intervention schools			Control schools		
	School 1 Wongani (<i>n</i> ₁ = 473)	School 2 Hilltop (<i>n</i> ₂ = 851)	School 3 Royal (<i>n</i> ₃ = 424)	School 4 Trust (<i>n</i> ₄ = 560)	School 5 Katawa (<i>n</i> ₅ = 639)	School 6 SOS (<i>n</i> ₆ = 342)
Total no. of students by gender						
Male	245	437	206	276	282	180
Female	228	414	218	284	357	162
Number of teachers	14	19	16	16	20	11
Water source						
Pipe/tap	1	1	1	1	1	1
Borehole	0	0	0	1	0	0
Location of water source at school						
Classroom (0=no, 1=ys)	1	0	0	1	0	1
Near toilet (0=no, 1=ys)	1	0	0	1	0	1
Central	0	1	1	0	1	0

**point (0=no,
1=ys)**

**Eating area
(0=no,
1=ys)**

Distance to
& from
water source

Water
accessibility

Functional
latrines for
students

Male

Female

1	0	0	1	0	0
Within 10 metres	Within 10 metres	Within 10metres	Within 10 metres	Within 10 metres	Within 10metres
Full access	Full access	Full access	Full access	Full Access	Full access
8	6	8	6	8	5
6	8	8	6	8	5

3.4.1 Inclusion criteria

At the cluster level, criteria for inclusion were: (1) Schools that had treated, clean and safe running water sources situated in Mzuzu, and (2) Private primary schools. At the student level, the criteria were: (1) Schoolchildren without visual, hearing or intellectual problems, (2) Schoolchildren in elementary (grades) one or six, and (3) Schoolchildren who were able to read and write.

3.4.2 Exclusion criteria

At the cluster level, exclusion criteria were: (1) Schools with less than 30 students per class in grades one and six, and (2) Government-subsidised primary schools, while at the student level they were: (1) Absence of parental consent to allow their child to participate in the study, (2) Schoolchildren with chronic diarrhoea and respiratory conditions, and (3) Children who are not able to follow instructions and cooperate with the study protocol, and (4) Schoolchildren who were planning to transfer to another school within the same academic year (2016/2017).

Private primary schools have better hygiene and sanitation facilities than government elementary schools in the city. For example, each private school at least had separate toilets for boys and girls, as well as treated, safe, clean running water provided by The Northern Region Water Board. Children attending private primary schools pay school fees, unlike those in

government-subsidised primary schools, who can attend for free. As such, these children come from the middle class and have relatively stable finances and better homes, where it was assumed that with proper and intensive training on SBHHP, they could continue to practise handwashing for sustainability and behaviour change. Children attending private primary schools can afford shoes and prevent infections that could be contracted through cuts, thorns and other forms of infection due to walking barefoot, as is the case for many schoolchildren attending government schools in the country. In return, this could affect the outcome of the study.

In addition, in government-subsidised primary schools, the sanitation is poor. For example, some schools have no source of water; they use dirty pit latrines that have no covers and lots of flies. Some children go barefoot, and even their personal hygiene is not up to standard among the majority. This is because of their poor financial status. The government declared that public schools should be free to accommodate children of low/poor economic status. It was therefore important to conduct this study in private schools, where treated, safe and clean running water, which could be used for hand washing, was available. Besides that, hygiene and general sanitation is better, so that we start with the best practice and set standards that can later be applied to government schools. The availability of resources and better hygiene standards in private schools could help to make the programme more feasible and acceptable. It would also help to control confounders, which would affect the results of the outcome.

3.3.1 Feasibility assessment of the study site

This process was performed to evaluate the possibility of conducting a trial project at a potential study site, and to assess whether the proposed sites had the potential to be part of the study. The assessment looked at the following areas: 1) the inclusion and exclusion criteria of this study, 2) the availability of participants/subjects, 3) the financial feasibility, and 4) regulatory compliance. The process also helped to highlight challenges beforehand and helped in taking corrective measures to work efficiently. The feasibility assessment of the study sites was conducted in all six randomly selected private schools in Mzuzu. One of the challenges that arose out of the feasibility assessment was the inadequate handwashing facilities (water pipes and sinks) in some schools. However, the strength was the availability of a tap with clean and safe running water, supplied by the Northern Region Water Board to all the private primary schools, which was one of the inclusion criteria. This prompted the researcher to construct more water pipes and at least two handwashing sinks for each of the six schools that were recruited in the study, for homogeneity and to minimise baseline discrepancies.

3.5 Sample size calculation

The cluster RCT sample size was calculated by assuming individual randomisation and inflating it by a design effect to account for randomisation by cluster (Rutterford, Copas, & Eldridge, 2015). Since the design of the study was a cluster RCT with repeated measures between

factors, the F test - ANOVA was used as a benchmark for calculating sample size using G*Power version 3.1.9.0. A Cohen's moderate effect size of 0.25 was used for generating power analysis (Cohen, 1988). It is generally recommended that the power of the study should be 0.80 or above, and the probability of alpha error should be 0.05. There were two (2) groups of participants (control and intervention) and four (4) numbers of measurement: at baseline (T₀), at the 3rd month immediately after students had participated in the SBHHP (T₁), at the 6th month compliance evaluation (T₂) and at the 9th month for sustainability testing (T₃). Therefore, the sample size calculated for individual randomisation was 82. However, adjusted for attrition at an 80% response rate with an anticipated dropout rate of 20%, the sample size was $82/0.80 = 103$. A 20% non-response rate was determined in a study done on students' health and hygiene practices in Kenyan primary schools (Patel et al., 2012). In order to cater for the clustering effects, the calculated total number of participants was 164. This figure was arrived at by multiplying the total sample size (103) of the assumed individual randomisation by the design effect, which was 1.59. Below are the formula and explanation for how the design effect was calculated:

Formula:

$$DE = 1 + (n - 1) \rho,$$

where DE is the design effect, n is the number of individuals per cluster, and ρ is the intra-cluster correlation coefficient (ICC).

It is a common practice to use unadjusted estimates for the ICC ($\rho = 0.010$) for the estimation of sample size (Adams, Gulliford, Ukoumunne, Eldridge,

Chinn, & Campbell, 2004). The number of individuals per cluster (n) was 60, comprised of 30 from elementary one and another 30 from elementary six. Malawi education standards/policy recommend that one class has no more than 60 children (RIPPLE Africa, 2015). In this study, half (30/60) of the recommended number per class were involved. This approach has the following advantages for this study: (1) It helps to cushion the sample size if other participants decline to give consent to participate, which would see the number dropping below 60 if we were to use the total class capacity number of 60; (2) It gives more chance to allocate participants to the study randomly, where each one will have an equal chance to participate in the study in the ratio of 1:2; and (3) It provides better flexibility for the matching of participants.

Therefore $DE = 1 + (60 - 1) \times 0.010$

$$DE = 1.59$$

Catering for clustering, the total sample size was 103×1.59 , which equals 164.

The number of clusters was therefore found by dividing the total sample size (164) by the number of participants per cluster/cluster size (60). $\{164/60 = 2.7295\} = 3$ clusters. However, the number of clusters was increased to three per arm to ensure a valid analysis. There is well-documented evidence that a study with a larger number of clusters is better able to distinguish intervention effects than does a study with fewer clusters (Christie, O'Halloran, & Stevenson, 2009). Therefore, three clusters were randomly allocated to the intervention and another three to the control

group, translating into six clusters with a total of 375 schoolchildren in the entire study.

3.6 Randomisation procedure

Six private primary schools out of twelve were randomly sampled and allocated into the intervention or control group. All of the schools were located within Mzuzu and had treated, safe and clean running water provided by the same source (The Northern Region Water Board) to avoid heterogeneity. The schoolchildren, both girls and boys, who were enrolled to participate in each school were in grades one or six. Children in grade one were chosen because they are the most vulnerable group of children in primary school. These are the children who have just joined the school, where the risk of getting infected is high, from home, where the risk is normally low. Primary school students in grade six were chosen for intra-cluster comparison, since they are the senior class. Their ages ranged from four to 13 years. Eligible schools based on the set inclusion criteria were identified through consultation with the District Education Manager (DEM), the Chairperson of the Independent Schools Association of Malawi (ISAMA - north) and heads of schools. All private schools with piped running water facilities were invited to participate, forming the study's sampling frame. Upon getting consent from the DEMO and the school headmasters/headmistresses/directors, all the eligible schools (clusters) were included in the randomisation process to select six schools. Six out of twelve eligible private schools in the city were randomly selected using an online randomisation <http://www.graphpad.com/quickcalcs/index.cfm>

process to generate a randomisation plan for intervention assignment to clusters (Sureth, 2011). An independent person not involved in the study was used to come up with sequentially numbered, opaque sealed envelopes (SNOSE) to allocate the randomly selected clusters into intervention and control clusters. The intervention and control groups had three schools each. The study flow chart below (Figure 5) uses the school as a unit of randomisation.

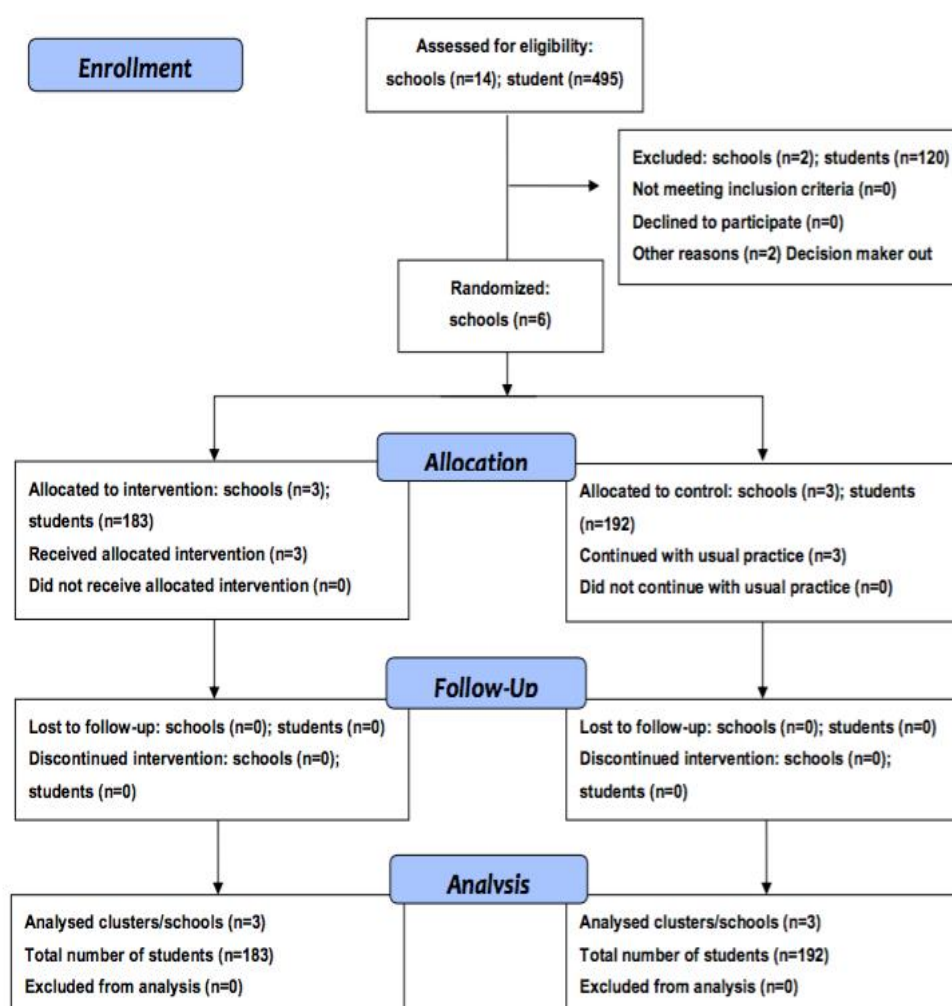


Figure 5. Study flow chart using school as a unit of randomization

3.7 The school-based hand hygiene programme for the intervention group

In this study, the components of the SBHHP consisted of integrating hand hygiene protocol in the school health curriculum, setting up proper handwashing facilities, training school teachers, delivering health talks to schoolchildren on how, why and when to wash hands, developing reminders and posters of the simplified 5-step handwashing technique, peer briefing sessions, demonstrations and return demonstrations. Parents were reached through a take-home package, which comprised a simplified 5-step handwashing poster, leaflets/pamphlets and a commitment letter. Parents were also given details of the programme through an information sheet, which was given to each parent of a participating child before they consented for their child to participate. The components of the intervention employed in this SBHHP, as described above, fall within the three areas of intervention of WHO's HPS framework (1) school curriculum, teaching and learning, 2) school ethos, environment and organization, 3) school community partnership and services).

The SBHHP was delivered once a week by the research assistants for a period of 6 months, while the teachers continued to teach the schoolchildren every day of the week using the developed guidelines/protocol. The teachers also reminded the schoolchildren several times a day, such as before break and lunch, and at morning assembly during the entire academic year. Briefing of teachers and school authorities was done at the beginning of the

programme and was ongoing for teachers in the two participating classes/grades (one and six).

A simplified 5-step handwashing technique was used as a standard procedure to follow when washing hands. This technique was adopted from a study conducted in Hong Kong (Lee et al., 2015) on the comparative efficacy of a simplified handwashing programme for improvement in hand hygiene and reduction of school absenteeism among children with intellectual disability. It consisted of the following: (1) *the simplified 5-step handwashing technique, including demonstrations and return demonstration*; (2) *a handwashing song*; (3) *a video for behaviour modelling*; (4) *a poster giving visual cues for the 5 step of the handwashing procedure*; (5) *a reward card system for behaviour reinforcement*; and (6) *a validated handwashing checklist concordance observation* (Lee et al., 2015, pp.907-912). The simplified 5-step handwashing technique was validated in a pilot study done by Lee and Lee (2014), in which the aim was to evaluate the effects of a simplified handwashing improvement programme in school children with mild intellectual disability. In this study, the video for behaviour modelling was not used, because most classrooms at the schools were not connected to electricity during the period of the study project. As such, it was not possible to use a video player/television.

The simplified 5-step handwashing technique was developed as a result of reducing the number of steps in the procedure by two from WHO's 7-step handwashing technique. "*The simplified 5-step technique combines steps 1 and 3, rubbing palms and fingers together (palm-to-palm and palm-to-palm*

with fingers interlaced steps), and omits the wrist-rubbing procedure. The simplified 5-step technique is as follows: (1) between fingers, (2) backs of hands, (3) backs of fingers, (4) finger tips, and (5) thumbs” (Lee et al., 2015, pp.907-912). Omitting the wrist rubbing helps to reduce the spreading of microorganisms, which could be facilitated by wetting long-sleeved clothes that children put on during the cold season. Since children’s cognitive and motor skills are not fully developed, it is very easy to wet long-sleeved clothes as they practise washing their hands and wrists using the 7-step handwashing technique. Wet sleeves create an environment that enables microorganisms to live and multiply, thereafter being transferred through direct contact to the hand, then the mouth or eyes, completing the epidemiological triad of the infectious disease transmission cycle (hand-to-mouth or hand-to-eye). Transmission of microorganisms via the wrists is not common in the school set up. Instead, pathogen transmission is mainly achieved via hand-to-mouth or hand-to-eye, and rarely via the wrists. By contrast, in the clinical setting, health workers are at higher risk of contaminating both the hands and the wrists. This occurs while they take care of patients or are involved in a clinical procedure. The palm-to-palm and palm-to-palm with fingers interlaced steps are combined as step 1 to make the procedure easier to master (Lee & Lee, 2014; Lee et al., 2015).

The simplified 5-step handwashing technique is simpler and easier to master and memorise than the 7-step handwashing technique for children whose cognitive and motor abilities are not fully developed. The simplified 5-step handwashing technique has proven to be effective in reducing the spread of infectious diseases (Lee et al., 2015). This is evident in a comparative

efficacy study of a simplified HWP for improvement in hand hygiene and reduction of school absenteeism among children with mild intellectual disability, carried out in Hong Kong by Lee et al. (2015).

Children in the elementary stage are still young and immature socially, physiologically, psychologically and intellectually. This means that they take longer to follow instructions and master complicated procedures, and at the same time are more vulnerable to infections. This is because of their immature immune system and poor skills in preventing infections, and the hazardous environment to which they are exposed in school. In addition, they can become a source of infection to children under five and older people in the community whose immunity is also compromised. Therefore, the simplified 5-step handwashing technique was expected to be a better way of imparting the skill than using the 7-step technique, which is longer and somehow more complex for children by comparison. The other advantage of the simplified 5-step intervention is that edutainment has been incorporated in it. For example, it comprises a simplified 5-step handwashing technique with return demonstrations, songs, posters, a reward system, and a checklist (multimedia visualisation). The edutainment method is encouraged with children because it makes learning interesting, enhancing their attention/concentration and improving their effort to learn (Bandura, 1977).

3.8 Usual practice for the control group

Schoolchildren in the control group were encouraged to continue with their usual practice of hand washing. In Malawi, as in any other WHO member state, health workers and the general community are expected to wash their hands using the WHO 7-step handwashing technique. The control group continued with this routine and teachers were advised to continue encouraging students with their routine. Both teachers and students in the control group were not given any training on hand hygiene. Handwashing resources included the construction of water pipes, building handwashing sinks/station and the availability of handwashing soap throughout the study period to both groups. The resources were provided to balance the baseline characteristics between the intervention and the control groups and reduce the confounders.

In both groups, schoolchildren used the existing facilities and the newly constructed sinks. The same type of Lifebuoy handwashing soap, manufactured by Unilever, was provided to both groups throughout the entire life span of the project by our project team. The Lifebuoy soap used had an antiseptic effect that could kill 99% of microorganisms on the hands.

3.9 Multilevel interventions approach applied to SBHHP

The multilevel intervention is a specified strategy designed to change the knowledge, perceptions, skills and behaviours of individuals, groups, community and organizations with the goal to improve the health outcomes (Clauser et al., 2012). This is also supported by WHO's HPS framework

with the aim to affect the critical contextual issues and create a more efficient, effective and coordinated hand hygiene programme delivery system. The multilevel interventions approach based on ecological theory to implement hand hygiene programme that targets more than one contextual factors (schoolchildren, family, school and community), is being increasingly recognized that they will lead to more substantial and sustained changes in handwashing behaviours to improve hand hygiene compliance and reduce school absenteeism (sick leave days) than would single-level interventions with the influences from the interdependent interactions between different levels to produce desirable outcomes (Edwards et al., 2012; Taplin et al., 2012). In this study, the intervention targeted five different contextual levels: Schoolchildren, teachers, school directors, research assistant, and parents. This was implemented and achieved through multilevel interventions approach (policy driven, behaviour-based training, environmental influences and resources availability) identified from the researcher's systematic review target more than one contextual factor (individual, group, community and organizational) to guide the implementation of this intervention study.

These contextual levels are synonymous to the ecological/environmental layers of the child in the Bronfenbrenner's ecological systems theory (microsystem, mesosystem, exosystem, macrosystem and chronosystem). Below is a table showing how the multilevel intervention approach based on the Bronfenbreener's ecological theory which link with the WHO's HPS has been applied in this study.

Table 3 Components of SBHHP linked to study conceptual framework

SBHHP component	Bronfenbrenner's ecological theory	Multilevel intervention strategies	WHO's HPS framework
-Integrating handwashing practice in the school health protocol.	-Exosystem -Macrosystem -Chronosystem	-Policy / protocol	-School curriculum, teaching and learning
-Setting up proper handwashing facilities	-Microsystem -Exosystem	-Environment -Resources	-School ethos, environment and organisation
-Training school teachers.	-Microsystem	-Training	-School curriculum, teaching and learning
-Delivering a 30-minute health talk to schoolchildren on how, why and when to wash hands once a week for six months.	-Microsystem	-Training	-School curriculum, teaching and learning
-Developing reminders (posters) of simplified 5-step handwashing technique	-Exosystem -Microsystem	-Policy	-School ethos, environment and organisation
-Peer briefing sessions.	-Microsystem -Mesosystem	-Training	-School ethos, environment and organisation
-Demonstrations and return demonstrations.	-Microsystem	-Training	-School curriculum, teaching and learning
-Take-home package comprising of a simplified 5-step handwashing poster, leaflets/pamphlets and a	-Mesosystem -Microsystem	-Training	-School community partnership and services

3.10 Treatment fidelity

Treatment fidelity means putting procedures in place to make sure the intervention has been implemented as intended. Treatment fidelity describes whether the interventionist delivered the treatment as planned. Intensive training of the interventionist (research assistant), including assessment of their skills, was conducted prior to commencement of the SBHHP. Their knowledge and skills were assessed to make sure they scored 100% prior to commencing the project. To make sure their teaching technique were standardised, both research assistant could be in the same class when the other research assistant was teaching, to observe and provide additional

information where it was necessary. In addition, the observer research assistant could take note of the delivery of the content and give each other feedback at the end.

A checklist containing the 5-step handwashing technique and why and when to wash hands was used to check that the interventionist was delivering the intervention content appropriately. In addition, video clips of the class session and practicals at the sink were periodically captured and assessed after the implementation by going through the video. Thereafter, training was ongoing depending on the gaps identified during implementation. Teachers were also trained prior to implementation of the SBHHP. All blinded assessors were trained on how to score the 5-step handwashing technique (skill) and fluorescent stain (cleanliness of hands) prior to commencing the assessment/scoring. The principal investigator underwent a special intensive training by participating in the implementation of a simplified 5-step handwashing project that took place in Hong Kong for 10 months. The researcher's participation was during the pre-test, the actual implementation of the intervention, and the post-test. Intensive supervision by the principal investigator was continued throughout the project. The researcher also enrolled, studied and passed an online Certification Training for Clinical Research Coordinator, offered by DNAYS Academy of Health Sciences in the United Kingdom during the trial implementation.

Among other strategies, bias was minimised by not relying on self-reporting of handwashing, which increases the tendency of over-reporting. Instead, intensified observational methods were adopted, such as monitoring

handwashing behaviour, usage of water and soap, and spot checking of handwashing facilities. Proper handwashing was measured objectively by allocating a score to the photo or video clip using a checklist, where five blinded assessors were involved.

Dropout rates and missing data were controlled during the intervention using a multimedia approach to motivate participating schoolchildren and emphasise the advantages of handwashing. Data collectors made sure that each form was completely filled before leaving each participant, and the form was cross-checked by the second person. Reinforcement and commitment were also achieved through seeking parental consent rather than getting consent at the cluster level only, as is usually expected in a cluster study design. Commitment letters were designed and signed by the child and the guardian to commit the child to practising handwashing using the simplified 5 steps all the time.

3.11 Developing school health policy and hand hygiene protocol in the implementation of the SBHHP

The school authority agreed to incorporate all the activities related to the SBHHP into the school schedule for the entire period of the academic year (2016/2017) during which the programme was implemented. This included the time, day and dates when the education/training on hand hygiene would take place in the school, and the four time points (T₀, T₁, T₂ & T₃) when the data was supposed to be collected. In addition, the school authority agreed

that the students should frequently be reminded when to wash their hands at such times as after playing, before eating, and after visiting the toilet, to mention just a few. The schoolchildren were to be reminded every day during the morning assembly, when going for a break, before eating, and after visiting the toilet. All this was to be done by teachers, especially those teaching grades one and six. The authorities agreed that posters containing relevant information on hand hygiene could be put around the school campus (on trees and noticeboards, and in classrooms). The 5-step handwashing technique was the standard procedure agreed upon to be followed at the intervention schools. It also encouraged students to follow the same procedure at home. The training education was administered by a well-trained research assistant once a week but reinforced by school teachers several times a day. The teachers were also trained before the implementation of the programme. It was agreed that all these steps would become part of the routine of the schools on a daily basis.

3.12 Measurements

The effects of the SBHHP were measured by assessing changes in handwashing behaviour/practice. The primary outcome measure was handwashing compliance, measured by rating the scores of the handwashing quiz (knowledge), the handwashing observational checklist (technique) and the fluorescent stain test (hand cleanliness). The secondary outcome measures were school absenteeism (sick leave days) and the acceptability of the SBHHP. Data was collected during the baseline and follow-up measures and was used to measure the outcomes. The assessment measurements were

done at the beginning of the 2016/2017 academic year, at the baseline (T₀), at the 3rd month immediately after students participated in the SBHHP (T₁), at the 6th month compliance evaluation (T₂) and at the 9th month for sustainability testing (T₃).

3.12.1 Study instruments

The following six tools were used in this study: 1) a demographic sheet, which was used to collect information on the age, gender, class/grade and location of the school; 2) a handwashing quiz, which was used to collect information on students' knowledge regarding handwashing; 3) an observational checklist, which was used to collect data on the simplified 5-step handwashing technique (skill acquisition); 4) a fluorescent stain test, which was used to capture data on the cleanliness rating of the hands; 5) a school absenteeism record form, which was used to collect data on students' illness-related absenteeism, and 6) an interview guide, which was used to collect qualitative data during the focus group discussions (see attached appendices).

All validated tools were translated from English to the local language (Chichewa) for better understanding by the children. The translator had expertise in both English and Chichewa. There was back-translation to English by another independent person to check that the meaning was maintained. Twenty children from schools not involved in the SBHHP were asked to answer questions from the translated version to see if the real meaning of the translated content was maintained. Different and

independent people who had good command of both English and the local language were involved in the translations. All tools used had already been validated in previous studies, and the content in the quiz was taken from the best practice on handwashing, published by the CDC (2015): Handwashing: Clean hands save lives. Accessed from <http://www.cdc.gov/handwashing/when-how-handwashing.html>. The 5-step handwashing technique was validated in a study by Lee and Lee (2014). The observational checklist on handwashing skill acquisition is a measurement that was validated in a study by Kaewchana, Simmerman, Somrongthong, Suntarattiwong, Lertmaharit, and Chotipitayasunondh (2012). Expert opinion was obtained to critically check the content of the interview guide to make sure it addressed the objective of the study to ensure the validity and reliability of the instrument.

3.12.2 Rating of the fluorescent stain

Fluorescent stains on the hands (a proxy measure of hand cleanliness) were measured by assessing the amount of fluorescence on both hands. This was done by looking at the visibility of the glow gel on the pictures of both hands, photographed using a digital camera in a standardised photographing environment using ultraviolet light. Schoolchildren had the palm and dorsum of both hands photographed twice at each measurement time (at baseline [T₀], at the 3rd month immediately after students participated in the SBHHP [T₁], at the 6th month compliance evaluation [T₂] and at the 9th month for sustainability testing [T₃]), thus before and after handwashing with soap and water. Initially, a validated 4-point scale (0, 1, 2, 3) showing

the amount of fluorescent stain on each hand, adopted from a study by Lee and Lee (2014), was used to allocate a proper handwashing score to each schoolchild.

A rating of 0 required a larger part of the hands (e.g. a large amount of glowing on the palms, dorsum and fingers) to be obscured with fluorescent stain (glow gel); a rating of 1 required a reduced amount of fluorescent stain to be evident and for the substance to be invisible from some sections of the hands; a rating of 2 required a significant reduction in the amount of fluorescent stain evident (e.g. only some glowing on the palms, dorsum and fingers), and a rating of 3 required almost all the fluorescent stain to be completely removed from the hands (e.g. no glowing on the palms, dorsum and fingers). A higher rating means a cleaner hand (Lee et al., 2015).

A code was assigned to each child. A photo of both hands stained with fluorescents was taken before handwashing. A total of 16 pictures were captured for each child: two (palm and dorsum) before handwashing and another two after handwashing at the baseline (T₀), at the 3rd month immediately after students participated in the SBHHP (T₁), at the 6th month compliance evaluation (T₂), and at the 9th month for sustainability testing (T₃). At each time point, there was a pre-test and a post-test of hand cleanliness. A 4-point scale was used to assess the quality of handwashing through digital photo images of the hands of schoolchildren participating in the study. To ensure the validity and inter-rater reliability of the fluorescent stain scores, five blinded assessors who were well trained used a 4-point scale to rate the pictures of all the participants in the study on a validated

ordinal scale of 0 to 3. A score of 3 represented the highest score (clean hands) and a score of 0 represented the lowest score (unclean hands). The inter-rater reliability of the five raters was measured using the intraclass correlation coefficient (ICC) function with the two-way mixed-effects model in IBM SPSS statistics 23. The results show that there was excellent agreement among the raters for both left (0.997) and right hands (0.996).

3.12.3 Skill acquisition of the simplified 5-step handwashing technique

The children's mastery and skills were assessed using the checklist. The content covered "how" to wash hands. Marks were allocated for each step of the simplified 5-step handwashing technique. After allocating a code to each child, the procedure was videotaped. Only the hands were captured in the video to ensure privacy and confidentiality. Thereafter, a blinded assessor who was well trained used the checklist objectively to allocate marks by going through the video clips for each child. This was done four times during the entire study: at baseline (T₀), at the 3rd month immediately after students participated in the SBHHP (T₁), at the 6th month compliance evaluation (T₂) and at the 9th month for sustainability testing (T₃). At each time point, there were total scores for technique scales (0-8). Higher scores meant better knowledge and technique respectively.

According to validated measurements in a study by Kaewchana et al. (2012), four practices must be included for quality handwashing technique: "*the use of soap, the technique of rubbing areas of the hand, duration, and method of drying*" (Kaewchana et al., 2012 pp.577-585). In his study,

Kaewchana and colleagues allocated a perfect handwashing technique a total score of 8.5 points. The scoring system used was as follows: *“use of soap was given a score of 1. The handwashing was divided into 7 parts: palms, backs of hands, fingers, fingers interlaced, finger tips, thumb, and wrist. If the 7 areas were rubbed, then a total score of 5.5 was given. Rubbing hands for >20 seconds was given a score of 1, and the use of a clean towel or paper to dry the hands was given a score of 1”* (Kaewchana et al., 2012 pp.577-585).

The scoring of the handwashing technique in this study was as follows: one mark was awarded for each of the following actions: use of soap and duration of hand washing, which is supposed to be more than 20 seconds, and proper air drying of the hands after washing. These three accumulated a total of three marks/points, one for each action. The 5-step handwashing technique was divided into 5 parts and accumulated a total of 5 marks. Rubbing between fingers scored 1 mark, rubbing the backs of both hands scored 1 mark and rubbing the back of one hand scored 0.5 marks, rubbing the backs of the fingers of both hands scored 1 mark, while rubbing only one hand scored 0.5 marks. Rubbing the fingertips on the palm for both hands was 1 mark, while doing it one hand only scored 0.5 marks. Rubbing the thumbs of both hands got 1 mark, while just one thumb scored only 0.5 marks. A total of 8 marks were possible for the simplified 5-step handwashing technique.

3.12.4 Changes in handwashing behaviour/practice (knowledge gain)

Handwashing behaviour was measured by assessing the knowledge gain on why and when to do handwashing so that it helped to change their behaviour. An instrument with questions and answers was used. Marks were allocated to each question, and the children were awarded one (1) mark for a correct response. All wrong responses were graded as “0” (appendix I). At each time point, there were total knowledge scale scores (0-7). Higher scores mean better knowledge.

The school teachers and research team members reinforced and monitored handwashing behaviour and practice with reminders and posters in the school setting (in the toilets, sinks, eating area, and notice boards) and via verbal communication. It was expected that the constant interaction between the environment, schoolchildren and behaviour, as well as the existence of role models, influences schoolchildren’s handwashing behaviour (Bandura, 1997). Their behavioural capabilities were augmented by intensifying the education, demonstration and return demonstration of a simplified handwashing technique once a week for half a year (two school terms). Changes in handwashing behaviour were also complemented by teachers checking the frequency of soap refill/use on a daily basis and researchers checking on a weekly basis. Further, focus group discussions were conducted for 18 schoolchildren and 19 parents, school heads and teachers from three intervention schools, and three focus groups were held to enable parents and school staff to solicit relevant information regarding behaviour change and the acceptability of the implementation of a simplified 5-step

handwashing technique in the SBHHP using a multilevel interventions approach.

3.12.5. School absenteeism

School absenteeism was calculated by counting the number of days each student was absent from school due to illness. The total number of expected school days during the entire academic year in which the SBHHP was implemented was 180 days, or 60 school days per term. Each academic year has three terms/semester. A school absenteeism record form was used to collect data on the sick leave days. To ascertain the diagnosis, children were asked the reason for the absenteeism immediately when they reported to school. Teachers also called parents of the schoolchild to inquire the reason for their child's school absenteeism.

3.13 Procedure for Data Collection

In this study, the time points for data collection were at the baseline (T₀), at the 3rd month immediately after students participated in the SBHHP (T₁), at the 6th month compliance evaluation (T₂), and at the 9th month for sustainability testing (T₃). Data was collected on socio-demographic information, knowledge of hand washing, handwashing technique (5-step technique), cleanliness of hands, and school absenteeism. The same type of data using the same instrument and collected by the same research team was done in both intervention and control groups.

Data on the acceptability of the SBHHP was collected at the 9th month (sustainability test) using focus group discussions that were conducted in the three schools from the intervention group only.

These time points were approximately three months apart, covering the entire academic year, with each time point at the end of each of the three terms/semesters. School authorities were reminded in advance about the visit by the research team when they were coming to collect data at each school. Prior arrangement helped to ensure that enough time was planned and allocated for the data collecting team. Data collection was expected to take approximately 2 hours to complete at each school per single data collection time. In addition, prior communication also helped to reduce absenteeism on the day, since children were encouraged by their teachers to come on the data collection day. Upon arrival at school, the authorities allocated a designated place where the research team could get ready for data collection. Students were released from the class in groups of 10 until all students participating in the programme were finished. Special arrangements could be made to come on a special day to follow up on students who were not available on the designated data collection day. This arrangement helped to ensure that all the necessary data was collected from all participating students. In order to collect data in a systematic and highly monitored manner, clear and comprehensive operational/procedure manuals were used. These manuals guided the data collectors, who were trained prior to data collection in order to achieve validity and reliability in the outcome measures. The adjudicators/outcome assessors were blinded by making sure

that different people were trained and used to assess the outcome measures, not the interventionist (blinded outcome assessment). They did not know whether the data was from the intervention or control clusters. Registered nurse educators, public health officers and five BSc nursing students were well trained and oriented to the intervention tools. They assessed the video clips and photographs on the cleanliness of the hands and the simplified 5-step handwashing technique at each time point.

Data was collected longitudinally over a period of one academic year from September 2016 to July 2017. This was appropriate because it anticipated a reduction in numbers due to transfers and graduation. Normally, transfers to another school and/or being promoted to a higher class are done after the end of a full academic year, which starts in September and ends in July. Data was collected from the children, the headmaster, school staff/teachers and parents/guardians. Prior to implementing the intervention, at baseline (T₀), data was collected for comparison later, at the 3rd month immediately after students participated in the SBHHP (T₁), at the 6th month compliance evaluation (T₂), and at the 9th month for sustainability testing (T₃). The intervention package on SBHHP was delivered to the intervention group one week after the baseline data was collected. Primary school teachers, research assistants and helpers were trained by the researcher on the intervention content and procedure. The school-based hand hygiene intervention group had a formal training session once a week throughout the study period. Participants were followed up every three months, at the 3rd, 6th and 9th months.

Children being the focus of the study as participants, much of the data was collected from them. Data was collected regarding their knowledge on how, why and when to wash their hands, their handwashing technique, the cleanliness of their hands, their handwashing behaviour, and the acceptability of the SBHHP. This was done using questionnaires, video recordings, photos and focus group discussion. Photos of both hands were taken before and after handwashing. Video clips of the handwashing procedure were taken during that procedure. Both the photos and video clips were graded using validated scales (appendices 3, 4 & 5).

The headmaster of each participating school was requested to fill in a form/questionnaire (appendix II) in which the following information was required: geographical information of the school, including zone, sub-location, location, division and district; enrolment of pupils in grades one and six by gender; total number of teachers for the whole school by gender; total number of teachers by gender teaching grades one and six; number of classrooms at the school; number of classrooms for grades one and six; number of schoolchildren per grade and other existing infrastructure: water sources used at the school; accessibility of water to pupils; and number of pit latrines or toilets by gender. The headmaster was given one week to fill the questionnaire, which was collected before starting the actual implementation of the programme and formed part of the baseline data.

3.14 Pre- and post-tests of the hand hygiene knowledge quiz

Pre-testing of the knowledge test/quiz instrument and interview guide was done in order to test some of the logistics of their implementation and provide valuable insights to consider in the main study so as to improve their quality and efficiency. The aim of the pre-test was to find out some of the challenges in the administering of the quiz and the interview guide. The quiz was pre-tested on 20 children purposively selected from one school that was not involved in the SBHHP, while the interview guide was pre-tested on six children, four school staff, and two parents.

3.15 Data analysis

IBM SPSS statistics 23 was used to analyse the data. Data cleaning was done by cross-checking with raw data to ensure a valid statistical analysis. The principle of intention to treat (ITT) was used. This means that each and every cluster that was randomised according to the randomised treatment assignment was included in the final analysis, ignoring noncompliance, protocol deviations, withdrawal, and anything that happened after randomisation (Gupta, 2011). The missing percentage of each variable was 2.3% or lower. No imputation was done. Little's MCAR test was insignificant (chi square = 201.44, $df = 381$, $p > .05$), indicating that the values were MCAR, or missing completely at random. The level of significance was set at $\alpha=0.05$.

The distribution of knowledge and technique scores roughly followed a normal distribution in histograms. Normal distribution was assumed, and an identity link function was used in the generalised linear model. In the distribution of hand cleanliness scores at the pre-test (baseline), only students who scored 0 (i.e. 76-100% stain on hands) by all raters were included in the data analysis. They were 94.3% of the sample. Therefore, the post-test score is the change score from the pre-test to the post-test. The average of the change scores (ACS) by all raters were calculated for each student at each time point. The ACS did not follow normal distribution at each time point. Most cases scored 0. Also, the frequencies of the ACS of 0.5, 1.5 and 2.5 were lower. The ACS were therefore categorised into 4 categories, “0” = ACS of 0-0.4, “1” = ACS of 0.6-1.4, “2” = ACS of 1.6-2.4, and “3” = ACS of 2.6-3. For “0”, at least 3 raters agreed that the ACS was 0.

Parallel line tests were conducted using PLUM procedure in a model with school, group, grade, and baseline ACS as independent variables and the ACS at each follow up as a dependent variable. The parallel line test results were significant. Therefore, the assumption of proportional odds was violated, and ordinal regression was not appropriate. The categories of “1”, “2”, and “3” were then combined into a single category of “1” = “Hand cleanliness improved”. The “0” = “Hand cleanliness not improved”. Binomial distribution was assumed, and logit link function used in the generalised linear model.

The generalised linear mixed model (GLMM) was used to model the fixed effects of time, group, and grade, and their interaction with time, the residual effects across time, and the random effects of intercepts of schools on target variables, including knowledge score, technique score and hand cleanliness. In the GLMM, the repeated measures were done on students at the four time points. The covariance type chosen was first order autoregressive. The fixed effects were time, group, group by time interaction, grade, and grade by time interaction. The random effect was the intercepts of the schools. The covariance type chosen was diagonal. Each school was allowed to have its own variance, but no covariance. The calculation of *df* was residual-based because the data were balanced between groups and the sample size was satisfactory. A robust covariance matrix estimator was adopted. After running a model, any cases with absolute value of Pearson residual larger than 3.3 were excluded, and then the model was run again for final results. The significance level (α) was set at .05. The Chi-square test and the independent t-test were performed in IBM SPSS statistics 23 to check whether there were significant differences between the intervention and control groups at the baseline, in terms of their demographic characteristics. Patterns of Pearson residuals of knowledge score and technique score were checked with boxplots, scatterplots, LOESS curve and normal Q-Q plots to examine whether there were violations of statistical assumptions of independence of observations, homoscedasticity, linearity and normality respectively. Patterns of boxplots of Pearson residuals among the 6 schools were similar, suggesting independence of observations. Pearson residuals were roughly randomly scattered around 0 against predicted values in scatterplots, suggesting acceptable

homoscedasticity. LOESS curves on scatterplots were roughly straight lines, suggesting linearity. Normal Q-Q plots of Pearson residuals were roughly straight lines, suggesting normality.

Absence records for a full academic year (2016/2017) were extracted from the school attendance register and used as input data. Generalised estimating equations (GEE) was used to analyse number of sick leave days between groups across school terms.

3.16 Focus group discussions nested in a cluster randomised controlled trial

A qualitative approach with focus group discussion was used to explore the acceptability and sustainability of the SBHHP. The researcher used a qualitative approach to identify factors that influence the acceptability and value of the SBHHP. Six semi-structured focus group discussions were conducted with 37 participants, including parents, school staff and primary school students. An interview guide was developed (see appendix IV) based on the literature review to identify factors that influence compliance with proper hand hygiene technique.

3.16.1 Focus group discussions

In this study, focus group discussion with 6-7 participants were conducted at the 9th month (T₃). The focus group discussions were based on the

discussion guide (see appendix IV). The focus group discussions were important because they helped to assess individuals' attitudes and values, which could not be obtained through highly structured questions. The rationale for using this approach was to explore the acceptability and sustainability of the SBHHP. Using purposive sampling, the school authority of each intervention school selected three parents whose children were involved in the SBHHP, and three school staff. Among the staff members, one was a grade 1 teacher, one a grade 6 teacher and one represented the administration staff. Grades 1 and 6 are the two classes that were involved in the programme at each school. Each focus group had at least six participants, and each intervention school had two focus groups, making a total of six focus groups for the entire study. At each school, one focus group comprised parents and school staff, while the other comprised children in grades 1 and 6.

A simple random technique was used to select schoolchildren to participate in the focus group discussion. Six schoolchildren participated from each of the three intervention schools, three from grade 1 and the other three from grade 6. The names of students in each of these classes who participated in the SBHHP were written on small pieces of paper, folded and mixed in an opaque carton. The teacher was asked to pick three pieces of paper from the carton one at a time to represent students to participate in the interview from each class. A total of 18 schoolchildren finally participated and completed the interview, six from each of the three schools.

3.16.2 Procedure for focus group discussions data collection

Focus group discussions were used to collect data on the acceptability and sustainability of the SBHHP at the 9th month (T₃). All participants in the focus group were asked to sign a consent form prior to the focus group discussions, and they answered the same questionnaire that was administered to their children in order to check their knowledge. They were also requested to provide their demographic data. The interviews were conducted on the school premises and in the morning, so that parents could go back to work. The school setting was used because it was familiar to the children, school staff and parents, and thus was expected to encourage participants to feel more at ease (MacDonald & Greggans, 2008). The interviews were recorded using a digital voice recorder, with permission from the participants to have the discussions recorded after informing and explaining to them the purpose of digitally recording the proceedings. Pseudonyms were used, and their interpretation/meanings as presented in table 3 below were used during the interviews to ensure privacy and confidentiality.

Table 4 Key to the pseudonyms

Pseudonym	Meaning
School	
H	Hilltop School
W	Wongani School
R	Royal School
Participants	
T1,2,3,4	Teacher/staff 1,2,3,4
P1,2,3,4	Parent 1,2,3,4
C1a,b,c,d,f	Child in grade 1
C6a,b,c,d,f	Child in grade 6

The discussion guide (appendix IV) was used to guide the focus group discussions. The guide was developed based on concepts in Bandura's social cognitive theory of behavioural change as applied in this study, Ajzen's theory of planned behaviour, the existing reviewed literature, and the WHO guidelines on promoting hand hygiene programmes (Bourgeault, Dingwall, & de Vries, 2013; Krake & Brinkmann, 2009). Expert opinions were obtained to critically check the content of the discussion guide to make sure it addressed the objectives of the study and ensured the validity and reliability of the instrument.

The discussion guide contained general questions, such as: tell me your experiences of participating in the school's hand hygiene programme; share with me any handwashing behavioural changes you have observed in the children since implementing the school's hand hygiene programme; and what do you like most about the school's hand hygiene programme? The discussion guide was developed by the researcher and validated by experts. The discussion guide made sure that issues related to the underpinning study aims were discussed. In addition, the interview guide also ensured that the other emergent issues were discussed. Data collection through focus groups was conducted at the 9th month post implementation. This was the ideal time, to explore the acceptability of the programme and the participant's true opinions and reflections on the programme after participating in the SBHHP for almost the entire academic year. Furthermore, the interview guide could be further enriched based on the key interesting findings from the quantitative data collected prior to conducting the focus group discussion. A registered nurse with expertise in qualitative methods and

conducting interviews was recruited to conduct the focus group discussion. He had a master's degree in child health nursing and was not involved in any part of the programme except the focus group discussions. The registered nurse had no affiliation to the participants. The researcher was involved in the focus group discussions as a moderator, took field notes and recorded the proceedings. A person other than the researcher conducted the focus group discussion, to avoid bias. The moderator asked about specific dimensions that were not naturally brought up in response to the predefined general framework surrounding the SBHHP within the HPS framework using the whole-school approach. Occasionally, the moderator asked extra questions or changed the order of the questions for the purpose of creating a group working relationship and gaining the trust of participants, as well as to maintain the natural flow of discussion.

3.16.3 Analysis of qualitative data

The focus group discussions were conducted in Chichewa and recorded using a digital voice recorder. Field notes were also made by the researcher during and soon after the focus group discussion. The interview data were transcribed verbatim by a nurse educator who was not involved in any other part of the study, and the researcher. The nurse educator has a vast experience in qualitative study, and a master's qualification. The transcripts were then checked against the original recorded audio to ensure that they had been transcribed accurately. Thematic analysis was used to analyse the qualitative data obtained through focus group discussion on the acceptability

of the SBHHP (Braun & Clarke, 2006). Thematic analysis was defined by Braun and Clark (2006) as a method for identifying, analysing and reporting patterns (themes) within data. Specifically, a theoretical or deductive or top-bottom analysis pathway was adopted (Boyatzis, 1990; Hayes, 1997, quoted in Braun & Clarke, 2006). Data was manually coded, and subthemes and themes were then identified. The data from the interview scripts were categorised, coded and read line by line (Lee & Wang, 2016). Key statements and phrases that were associated with proper handwashing, knowledge gain, attitude, practice, behavioural change, and the acceptability and sustainability of a SBHHP were underlined and extracted from each transcript. Meanings were emerged and reflected as themes, and ensured that the formulated meaning accurately reflected their true intention (Mayan, 2009, quoted in Lee & Wang, 2016). The transcripts were reviewed until a thematic framework was reached. Two coders including the researcher and one doctoral student established themes independently, compared codes and the third person (another doctoral student) resolved the differences brought up by the two coders to ensure rigour. Analysis was concluded when coding overlapped sufficiently, and coders reached a consensus that the themes satisfactorily represented the main issues regarding the SBHHP using the whole-school approach of the HPS framework. In summary, throughout the analysis of the focus group discussions qualitative data, the researcher ensured that the six phases of thematic analysis according to Braun and Clarke (2006) were carefully applied to guide the analysis of data from the focus group discussions. These phases, adapted from Braun and Clauke (2006), are:

(1) Reading and rereading the entire set of transcripts, in order to become

familiar with and get immersed into the data content; (2) generating initial codes by systematically arranging the data into meaningful groups; (3) searching for themes by combining related or connected codes into potential themes; (4) reviewing themes to make sure that they are related and represent both the identified codes and the whole data; (5) defining and naming themes to create transparent, meaningful and interpretable names for the themes identified; (6) producing a report that evokes extracts of interest and their analysis.

The qualitative analysis aimed at identifying specific information related to the acceptability and sustainability of the SBHHP by the school staff, parents and primary school students. For example, specific questions related to acceptability and sustainability are: would you recommend this hand hygiene programme to other parents or friends and relatives, or to schoolchildren?; what do you like most about the school's hand hygiene programme; do you have any suggestions for improvement of the school's hand hygiene programme; can you share any suggestions to improve the planning and implementation of the school's hand hygiene programme; tell me your experiences of working with the other disciplines, such as health professionals and parents, to coordinate and implement the school's hand hygiene programme.

3.16.4 Establishing rigour and trustworthiness

Rigour and trustworthiness were established through adhering to the principles of credibility, dependability, confirmability and transferability (Guba & Lincoln, 1994; Guba, 1981).

Credibility, according to Lincoln and Guba (1985), involves tasks that increase chances that quality and trusted results will be produced. In this study, this was achieved through peer debriefing. This process was done in order to explore the characteristics of the inquiry that might otherwise have remained clear and understood in the researcher's mind only (Lincoln & Guba, 1985). All responses were recorded, categorised, and compared with items in the refined coding system. Two nurse educators with expertise in child health were invited to review the data scripts. The research team met with the nursing experts and sought consensus on the identified categories and themes. The two independent researchers checked the congruence of data accuracy, relevance and meaning.

To address the dependability, the research design approach used to explore the acceptability of the SBHHP might enable readers to develop a thorough understanding of the methods and their effectiveness. In addition, the whole methodology was well detailed and reported in order to allow other researchers to replicate the study.

Confirmability, which is a process criterion, was achieved through detailed documentation of the findings to leave an audit trail that was later checked by another person to demonstrate clearly the evidence and thought process

that led to the conclusion (Lincoln and Guba, 1985). The researcher took the analysed interview scripts back to the school personnel/staff to validate the meanings with them for member checking. The researcher also took the analysis of the interview scripts to the professional groups, which included school nurses and academic staff conducting school health research for professional checking (Lincoln and Guba, 1985). The researcher ensured that the study findings were the result of the experiences that emerged from the schoolchildren who were involved in the SBHHP, the school personnel who were responsible for the students' hand hygiene at school, and parents whose children were fully involved in the SBHHP. In-depth interviews were conducted among these three categories of participants and generated a description. The researcher also made sure that there was an unbiased representation of the participants selected to participate in the study. For example, children from grades 1 and 6 were selected to participate in the individual interviews using a simple random technique at each of the intervention schools. In addition, the characteristics of the schools and students involved in the study were similar to those in studies conducted elsewhere, such as in Blantyre, Malawi, and other developing countries (Kalenga, 2012). Participants were assured that they could speak freely and share their opinions, which were accurately transcribed to promote authenticity. Finally, the transcripts were re-read many times to ensure credibility and authenticity.

For the transferability criterion, the researchers established the context of the study and gave a detailed description of the phenomenon by interviewing six school personnel, 13 parents and 18 children with various

experiences, to allow comparisons to be made. In addition, transferability was enhanced by providing adequate data extraction to support themes and subthemes (Lincoln and Guba, 1985).

3.17 Ethical considerations

Permissions to conduct the study were obtained from The Hong Kong Polytechnic University Research Committee and the Malawi National Health Sciences Research Committee (NHSRC) for ethical approval, and protocol numbers HSEARS20160619001 and 1653 were given respectively. This was done to fulfil the Council for International Organization of Medical Sciences (CIOMS) requirements / guidelines on carrying out research on human beings. The guidelines state that any research carried out on a human being should be approved by an ethical research committee to make sure that it meets all the ethical issues to protect the population. The protocol was also submitted and registered with the Clinical Trial Register (ClinicalTrials.gov), with the following identifier: NCT02968251. The schoolchildren and their parents were informed of the nature of the study and its purpose and objectives, as indicated on the information sheet. Informed consent was obtained before participants were enrolled, thereby following the principle of respect for human dignity, which says that participation in studies should be voluntary, after informing subjects of the possible risk and benefits (Polit & Beck, 2008).

Clearance was obtained from the Malawi government, the Independent Schools Association of Malawi (ISAMA) Northern Region, and the District

Education Manager (DEM). Consent was obtained at the cluster level (heads/directors of private schools), as well as at the individual level (parental consent). Privacy was ensured by avoiding the use of names on the questionnaires and all other necessary instruments in the study, and using only numbers. Pseudonyms were used during the focus group discussions. Use of numbers instead of names also ensures anonymity and confidentiality. Anonymity is defined by Polit and Beck (2008) as protection of the participants in a study such that even the researcher cannot link them individually to the information provided. Confidentiality is the protection of the participants in a study such that their individual identities will not be linked to the information they provided and will never be publicly divulged (Polit & Beck, 2008). Participants were also told that they had the right to participate or not, and that they could withdraw at any time during the study. The DEM and ISAMA chairperson were also consulted for clearance. The data was stored under lock and key for safety.

3.18 Summary

The methodology section was presented, with several subsections describing how the project was executed. The emphasis was on the cluster RCT design employed in this study in order to evaluate the effect of the SBHHP. The acceptability of the SBHHP by the school staff, parents and children was explored using qualitative data from the focus group discussions to enhance the quality of data. The setting, recruitment of study sample, sampling, handwashing programme/intervention, outcome measures, study tools, treatment fidelity, and procedure for data collection, analysis and ethical

considerations, were presented. The next chapter (chapter 4) presents the study findings.

CHAPTER FOUR

RESULTS

4.0 Introduction

This chapter presents the findings of a cluster randomised controlled trial study that was conducted in Mzuzu, Malawi, in sub-Saharan Africa. The quantitative results are presented based on the primary outcome (the primary students' compliance with proper handwashing i.e. knowledge refers to the scores of handwashing quiz; skills/technique refer to the scores of handwashing observational checklist; and hand cleanliness refers to the scores of the fluorescent stain test on both hands) and the secondary outcome (their number of sick leave days of school absenteeism). Firstly, the chapter presents findings regarding the schoolchildren's knowledge through a quiz score on handwashing. Secondly, their skills/technique through the scores of handwashing observational checklist is presented. Thirdly, the findings on their hand cleanliness through the scores of the fluorescent stain test on both hands are presented. The chapter concludes with their school absenteeism results.

The results on the acceptability of the SBHHP are presented based on the generated themes. There are four themes altogether: working together to develop policy and integrate the hand hygiene programme into the school curriculum, being committed to the school's hand hygiene programme, practising proper handwashing technique as a routine, and the benefits of

the SBHHP. The follow-up section, therefore, starts with the characteristics of the study sample.

4.1 Study findings

This section presents the demographic characteristics of the schoolchildren who participated in this study. It also presents findings focusing on knowledge (handwashing quiz), skills/technique (handwashing observational checklist), hand cleanliness (score of the fluorescent stain test on both hands), and school absenteeism (sick leave days).

4.1.1 The characteristics of the study sample

A total of six schools were recruited in the study, with a total of 375 schoolchildren. Out of the total participants recruited, 183 (48.8%) were from the three schools in the intervention group, and 192 (51.2%) were from the three schools in the control group. Boys made up 49.3% (n=375) of the sample, with 88 in the intervention group and 95 in the control group. Girls made up 50.7% (n=375), with an equal number of 95 in each group. The mean age of the children in the intervention group was 8.14 (SD=2.8), while the mean age in the control group was 8.08 (SD=2.4). The total number of schoolchildren in primary one was 188, with 93 in the intervention group and 95 in the control group. The children in primary six totalled 187, with 90 in the intervention group and 97 in the control group. See Table 4 below for more details.

Table 5 Demographic characteristics

		Intervention <i>N</i> =183 <i>n</i> (%)	Control <i>N</i> =192 <i>n</i> (%)	Chi square	<i>df</i>	<i>p</i>
Gender	Male	88(48.1)	97(50.5)	.14	1	.71
	Female	95(51.9)	95(49.5)			
Grade	1	93(50.8)	95(49.5)	.02	1	.88
	6	90(49.2)	97(50.5)			
		Mean(<i>SD</i>)	Mean(<i>SD</i>)	<i>t</i> (<i>df</i>)	<i>p</i>	95%CI
Age	in year	8.14(2.77)	8.08(2.40)	.22(359.95)	.83	[-.49, .67]

There were no significant differences in age, gender or grade between the intervention (*N*=183) and control (*N*=192) groups (Table 4). At baseline, each school had at least one tap with running water supplied from the same source by the Northern Region Water Board. As part of the project, the researcher also built water pipes and constructed at least two handwashing sinks for each of the schools involved in the study. The water was easily accessible to all the schoolchildren. The number of toilets ranged from 10-16 per school.

4.1.2 Knowledge of handwashing

The student's knowledge on hand hygiene was assessed using a quiz on why and when to do handwashing at baseline (*T*₀), at the 3rd month immediately after students participated in the SBHHP (*T*₁), at the 6th month compliance evaluation (*T*₂) and at the 9th month for sustainability testing (*T*₃). An instrument with questions and answers was used. Marks were allocated to each question. There were total knowledge scale scores (0-7). Higher scores mean better knowledge. The distribution of knowledge scores roughly

followed a normal distribution in histograms. Normal distribution was assumed, and an identity link function was used in the generalised linear model.

Table 6 The effects of the interaction of fixed effects (Time, Group, Group by Time, Grade, & Grade by Time) on knowledge score

Source	<i>F</i>	<i>df1</i>	<i>df2</i>	<i>p</i>
Corrected Model	8954.588	5	1461	<.001
Time	28.427	3	1461	<.001
Group	8.678	1	1461	.003
Group by Time	5.936	3	1461	.001
Grade	.383	1	1461	.536
Grade by Time	.985	3	1461	.399

Probability distribution: Normal

Link function: Identity^a

a. Target: Knowledge level score

Table 5 above shows that time ($F(3, 1461)= 28.427$), group ($F(1, 1461)= 8.678$), and group by time interaction ($F(3, 1461)= 5.936$) were associated with a significant effect on knowledge level score ($p<.05$). The interaction of the fixed effect of time was associated with a greater effect (higher prediction) on the knowledge score of the schoolchildren ($F(3, 1461)= 28.427$); $p<.01$). The fixed effects of grade and grade by time interaction were not associated with a significant effect in knowledge (quiz score) among the schoolchildren ($p>.05$).

Table 7 Effects of fixed coefficient of time, group and grade on knowledge

Model Term	B	SE	t	p	95% CI	
					Lower	Upper
Intercept	3.705	.3406	10.877	<.001	3.037	4.373
Baseline	-.733	.2772	-2.643	.008	-1.276	-.189
3 rd month	-.742	.2346	-3.162	.002	-1.202	-.282
6 th month	-.168	.2676	-.628	.530	-.693	.357
9 th month	0 ^b
Intervention	1.972	.4159	4.742	<.001	1.156	2.788
Control	0 ^b
[Intervention by Baseline]	-1.232	.7638	-1.613	.107	-2.730	.266
[Control by Baseline]	0 ^b
[Intervention by 3 rd month]	-.914	.4862	-1.879	.060	-1.867	.040
[Control by 3 rd month]	0 ^b
[Intervention by 6 th month]	-.696	.2027	-3.436	.001	-1.094	-.299
[Control by 6 th month]	0 ^b
[Intervention by 9 th month]	0 ^b
[Control by 9 th month]	0 ^b
Grade 1	-.072	.4626	-.156	.876	-.980	.835
Grade 6	0 ^b
[Grade 1 by Baseline]	-.271	.4843	-.560	.576	-1.221	.679
[Grade 6 by Baseline]	0 ^b
[Grade 1 by 3 rd month]	-.019	.2535	-.075	.940	-.516	.478
[Grade 6 by 3 rd month]	0 ^b
[Grade 1 by 6 th month]	-.219	.3645	-.599	.549	-.933	.496
[Grade 6 by 6 th month]	0 ^b
[Grade 1 by 9 th month]	0 ^b
[Grade 6 by 9 th month]	0 ^b

Probability distribution: Normal

Link function: Identity ^a

^a Target: Knowledge level score

^b This coefficient is set to zero because it is redundant.

Compared with control group, intervention was associated with 1.972 higher of knowledge score (B=1.972; 95%CI [1.156, 2.788]; $t = 4.742$; $p < .001$).

Compared with 9th month, group by time interaction at 6th month was significantly associated with a lower knowledge score (B=-.696; 95%CI [-1.094 -.299]; $t = -3.436$; $p = .001$) but not at baseline and 3rd month.

Compared with the 9th month, group by time interaction was not significant at the baseline ($B=-1.232$; 95%CI $[-2.730, 0.266]$; $t=-1.613$; $p = .107$). This means therefore that knowledge scores under the effect of group by time interaction were lower at baseline and 3rd month than at 9th month.

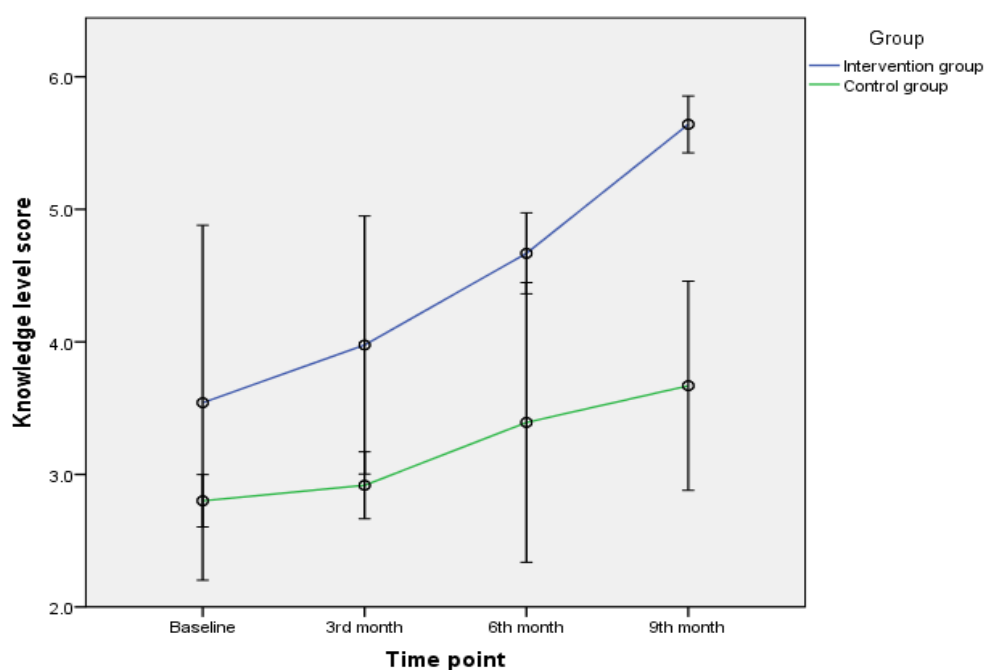


Figure 6 Estimated marginal mean and standard error of knowledge score between groups across time

Baseline knowledge scores among the schoolchildren in the intervention and control groups were not significantly different. The figure above shows that knowledge scores increased in both groups from baseline through to the 9th month. However, the scores were higher in the intervention group compared to the control group. The scores were statistically significant in the intervention group in the 6th, and 9th months ($p<0.05$). There were significant individual effects on the knowledge scores across time.

Table 8 Pairwise contrast of knowledge scores between groups across time

	Mean Intervention	Mean Control	Contrast estimate ^a	<i>SE</i>	<i>t</i>	<i>df</i>	<i>p</i> ^b	95%CI Lower ^c	95%CI Upper ^c
Baseline	3.54	2.80	0.74	0.69	1.07	1461	0.283	-0.61	2.09
3 rd month	3.98	2.92	1.06	0.51	2.06	1461	0.039	0.05	2.07
6 th month	4.67	3.39	1.28	0.56	2.28	1461	0.023	0.18	2.38
9 th month	5.64	3.67	1.97	0.42	4.74	1461	<.001	1.16	2.79

^a Mean scores of Intervention minus Control.

^b Adjusted, the sequential Bonferroni-adjusted significance level is .05.

^c Confidence interval bounds are approximate.

There were insignificant differences in knowledge score between groups at baseline. There were significant differences at the 3rd, 6th and 9th months (Table 7). The scores in the intervention group were always higher than those in the control group. The difference between groups increased across time. The highest mean difference was achieved at the 9th month (contrast estimate = 1.97; $t(1461) = 4.74$; $p < .001$). At baseline, the mean difference between the intervention and control groups was not statistically significant (contrast estimate = .74; $t(1461) = 1.07$; $p = .28$).

4.1.3 Technique of hand washing

The children's mastery and skills/technique were assessed using the checklist. Marks were allocated to each step of the simplified 5-step handwashing technique at baseline (T₀), at the 3rd month immediately after students participated in the SBHHP (T₁), at the 6th month compliance evaluation (T₂) and at the 9th month for sustainability testing (T₃). At each time point, there were total scores for technique scales (0-8). Higher scores meant better technique scores. The distribution of technique scores roughly followed a normal distribution in histograms. Normal distribution was assumed, and an identity link function was used in the generalised linear model and produced the results below.

Table 9 The effects of the interaction of fixed effects (Time, Group, Group by Time, Grade & Grade by Time) on technique score

Source	<i>F</i>	<i>df1</i>	<i>df2</i>	<i>p</i>
Corrected Model	718.951	5	1448	<.001
Time	637.701	3	1448	<.001
Group	180.565	1	1448	<.001
Group by Time	870.029	3	1448	<.001
Grade	33.760	1	1448	<.001
Grade by Time	3.079	3	1448	.027

Probability distribution: Normal

Link function: Identity^a

a. Target: Technique score

Table 8 above shows that time, group, group by time, grade and grade by time interactions were associated with a significant effect on skill acquisition ($p < .05$). The interaction of the fixed effect of time was associated with a greater effect on the technique score of the schoolchildren ($F(3, 1448) = 637.701$; $p < .001$). The interaction of the fixed effect of grade by time was associated with the least influence on the technique score among schoolchildren ($F(3, 1148) = 3.079$; $p = .027$).

Table 9 below shows that compared with the control group, the intervention group was associated with 5.14 higher of technique scores ($B = 5.14$; 95%CI [4.75, 5.54]; $t = 25.48$; $p < .001$). Compared with the 9th month, the group by time interaction at baseline ($B = -5.04$; 95%CI [-5.54, -4.54]; $t = -19.82$; $p < .001$) and 3rd month ($B = -3.27$; 95%CI [-4.18, -2.36]; $t = -7.02$; $p < .001$)

were significantly associated with a lower technique score, but higher score at 6th month ($B=.42$; 95%CI [.03, .82]; $t = 2.10$; $p = .04$).

Compared to the grade 6 students, those in grade 1 had -0.65 lower technique scores ($B= -0.65$, 95%CI [-1.10, -.20], $t = -2.83$, $p=.005$). This means that being in a higher grade (6) has an advantage in terms of attaining a better handwashing technique score.

Compared with the 9th month, grade by time interaction was not significant at the baseline ($B=.30$; 95% CI [-.05, .65]; $t = 1.67$, $p = .10$), at the 3rd month ($B= .03$; 95% CI [-.65, .71]; $t = .09$; $p = .93$), or at the 6th month ($B= -.15$; 95%CI [-.54, .24]; $t = -.76$; $p = .45$).

Table 10 Effects of fixed coefficient of time, group & grade on acquisition on handwashing technique

Model Term	B	SE	t	p	95% CI	
					Lower	Upper
Intercept	2.355	.2062	11.421	<.001	1.950	2.759
Baseline	-.392	.0775	-5.056	<.001	-.544	-.240
3 rd month	1.214	.1412	8.595	<.001	.937	1.491
6 th month	-.224	.1117	-2.007	.045	-.443	-.005
9 th month	0 ^b
Intervention	5.141	.2018	25.481	<.001	4.746	5.537
Control	0 ^b
[Intervention by Baseline]	-5.043	.2544	-19.821	<.001	-5.542	-4.544
[Control by Baseline]	0 ^b
[Intervention by 3 rd month]	-3.269	.4654	-7.024	<.001	-4.182	-2.356
[Control by 3 rd month]	0 ^b
[Intervention by 6 th month]	.423	.2018	2.095	.036	.027	.818
[Control by 6 th month]	0 ^b
[Intervention by 9 th month]	0 ^b
[Control by 9 th month]	0 ^b
Grade 1	-.649	.2292	-2.829	.005	-1.098	-.199
Grade 6	0 ^b
[Grade 1 by Baseline]	.298	.1784	1.670	.095	-.052	.648
[Grade 6 by Baseline]	0 ^b

[Grade 1 by 3 rd month]	.031	.3485	.089	.929	-.653	.714
[Grade 6 by 3 rd month]	0 ^b
[Grade 1 by 6 th month]	-.150	.1979	-.759	.448	-.538	.238
[Grade 6 by 6 th month]	0 ^b
[Grade 1 by 9 th month]	0 ^b
[Grade 6 by 9 th month]	0 ^b

Probability distribution: Normal

Link function: Identity^a

a. Target: Technique score

b. This coefficient is set to zero because it is redundant.

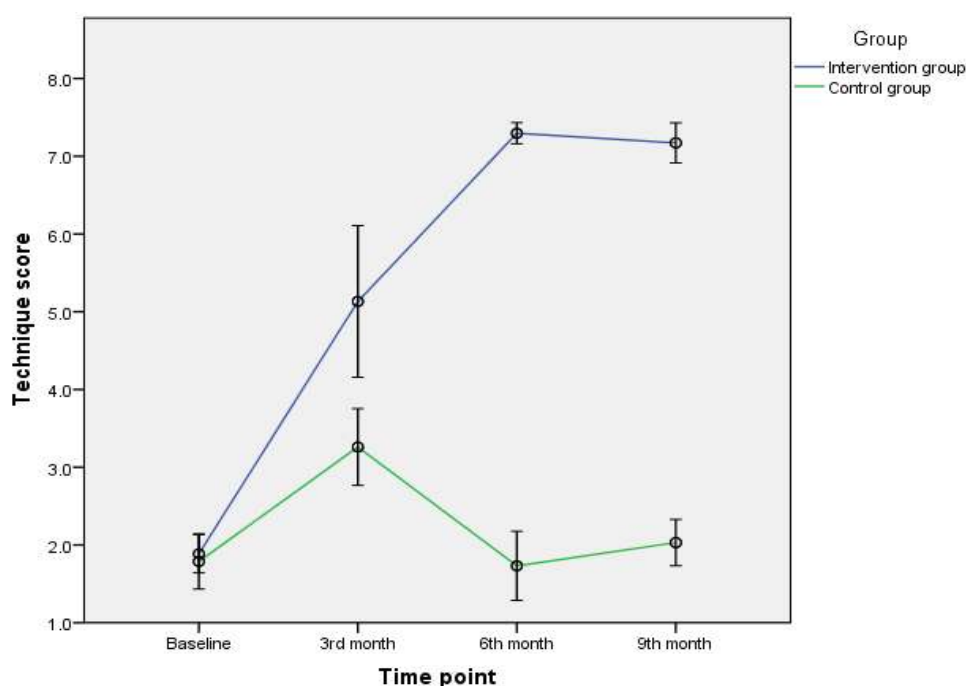


Figure 7 Estimated marginal mean and standard error of technique score between groups across time

The baseline technique scores among the schoolchildren in the intervention and control groups were not significantly different. Figure 7 above shows that technique test scores increased in both groups from baseline through to the 3rd month. While the trend continued to increase in the intervention group, scores in the control group dropped in the 6th month. The acquisition of skills/technique was higher in the intervention group compared to the control group. This was statistically significant in the 3rd, 6th, and 9th month ($p < 0.05$). There were significant individual effects on the technique scores across time.

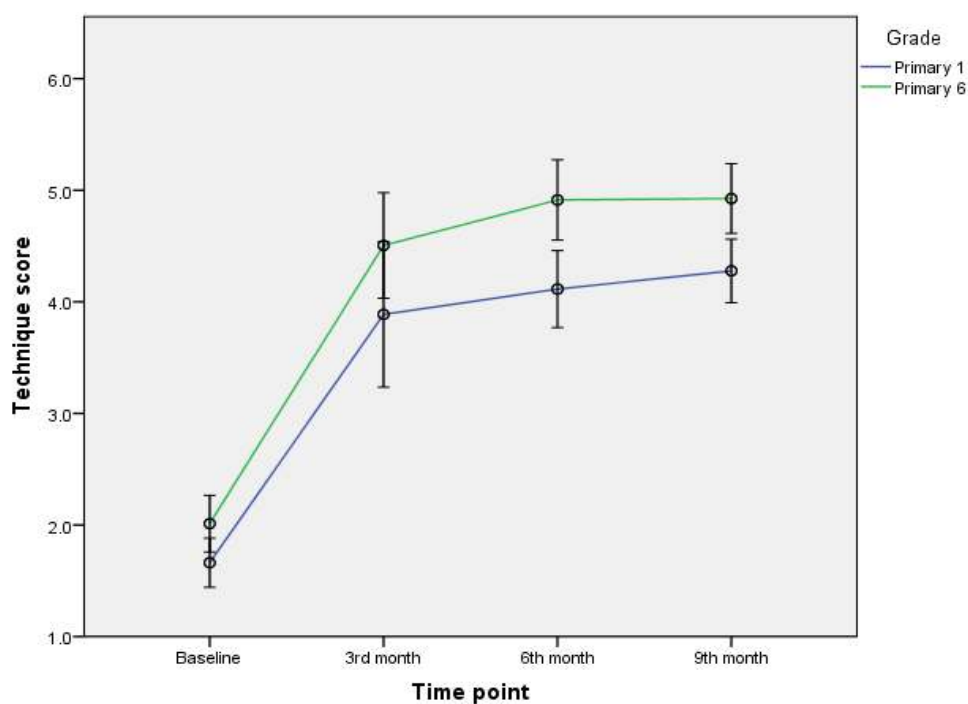


Figure 8 Estimated marginal mean and standard error of technique score between grades across time

Figure 8 above shows that there was a sharp increase in the techniques score at the 3rd month from the baseline in both the grade 1 and grade 6 students. Thereafter there was a gradual increase in both grades 1 and 6 at the 6th month and 9th month. The increase in skill acquisition measured as techniques score was always higher among grade 6 children than among grade 1 children across time.

Table 11 Pairwise contrast of technique scores between groups across time

	Mean Intervention	Mean Contro l	Contrast estimate ^a	<i>SE</i>	<i>t</i>	<i>df</i>	<i>p</i> ^b	95%CI Lower ^c	95%CI Upper ^c
Baseline	1.89	1.79	.098	.220	.447	1448	.655	-.333	.529
3 rd month	5.13	3.26	1.872	.557	3.362	1448	.001	.780	2.964
6 th month	7.30	1.73	5.564	.237	23.480	1448	<.001	5.099	6.029
9 th month	7.17	2.03	5.141	.202	25.481	1448	<.001	4.746	5.537

a Mean scores of Intervention minus Control.

b Adjusted, the sequential Bonferroni-adjusted significance level is .05.

c Confidence interval bounds are approximate.

There was no significant difference in technique score between the groups at baseline. There were significant differences at the 3rd, 6th and 9th months (Table 10). The scores in the intervention group were always higher than in the control group. The difference between groups increased across time. The highest mean difference between the two groups was achieved at the 6th month (Contrast estimate = 5.56; 95%CI= 5.10, 6.03; $t(1448) = 23.48$; $p < .01$). At baseline, the mean difference between the intervention and the control groups were not statistically significant (Contrast estimate = .098; 95%CI= -0.33, 0.53; $t(1448) = .45$; $p = 0.66$).

4.1.4 Cleanliness of hands

Fluorescent stains on the hands (a proxy measure of hand cleanliness) was measured by assessing the amount of fluorescence on both hands at baseline (T₀), at the 3rd month immediately after students participated in the SBHHP (T₁), at the 6th month compliance evaluation (T₂) and at the 9th month for sustainability testing (T₃), thus before and after handwashing with soap and water (see details in chapter 3, section 3.10.2). Initially, a 4-point scale (0, 1, 2, 3) showing the amount of fluorescent stain on each hand, was used to allocate a proper handwashing score to each schoolchild. After performing a preliminary analysis, the distribution of the average change scores (ACS) of hand cleanliness did not follow normal distribution at each time point. Therefore, the assumption of proportional odds was violated, and then the scores were categories “1” = “hand cleanliness improved” and “0” = “hand cleanliness not improved”. Binomial distribution was assumed, and logit

link function was used in generalised linear model and produced the output as presented below.

Table 12 The effects of the interaction of fixed effects (Time, Group, Group by Time, Grade and Grade by Time) on hand cleanliness

Source	<i>F</i>	df1	df2	<i>p</i> .
Corrected Model	109.288	5	1377	<.001
Time	9.207	3	1377	<.001
group	9.093	1	1377	.003
group by Time	6.020	3	1377	<.001
grade	4.940	1	1377	.026
grade by Time	1.059	3	1377	.365

Probability distribution: Binomial

Link function: Log^a

a. Target: Cleaniness

Table 11 above shows that time, group, group by time interaction and grade was associated with a significant effect on hand cleanliness ($p < .05$). The interaction of fixed effect of time was associated with a greater effect (higher prediction) on hand cleanliness score of the schoolchildren ($F(3, 1377) = 9.21$; $p < .01$). The fixed effect of grade by time interaction was not associated with a significant effect on hand cleanliness score among schoolchildren ($F(3, 1377) = 1.06$, $p = .37$)

[Grade 1 by 3 rd month]	-10.778	6.9922	-1.541	.123	-24.495	2.938	0.0000	0.0000	18.886
							21	00	
[Grade 6 by 3 rd month]	0 ^b
[Grade 1 by 6 th month]	-.897	.6130	-1.464	.143	-2.100	.305	.408	.122	1.357
[Grade 6 by 6 th month]	0 ^b
[Grade 1 by 9 th month]	0 ^b
[Grade 6 by 9 th month]	0 ^b

Probability distribution: Binomial

Link function: Loga

a. Target: Cleaniness

b. This coefficient is set to zero because it is redundant.

Compared with the control group, the intervention group was associated with a higher odds of hand cleanliness ($OR=21.51$; 95%CI [4.38, 105.72]; $t = 3.78$; $p <.001$).

Compared with the 9th month, group by time interaction at the baseline ($OR =.05$; 95%CI [.01, .40]; $t = -2.84$; $p = .005$) and 3rd month ($OR =.15$; 95%CI [.02, .98]; $t = -1.99$; $p = .047$) were significantly with lower odds of hand cleanliness.

Compared with the 9th month, group by time interaction at the 6th month was associated with higher odds of hand cleanliness ($OR =1.90$; 95%CI [.42, 8.47]; $t = .84$; $p =.40$) but not significant.

Compared with students in grade 6, students in grade 1 were significantly associated with lower odds of hand cleanliness ($OR =.11$; 95%CI [.04, .35]; $t = -3.78$; $p <.001$).

Compared with the 9th month, grade by time interaction at the baseline, at the 3rd month and at the 6th month was not significant ($p >.05$). (See Table 12 above for more details).

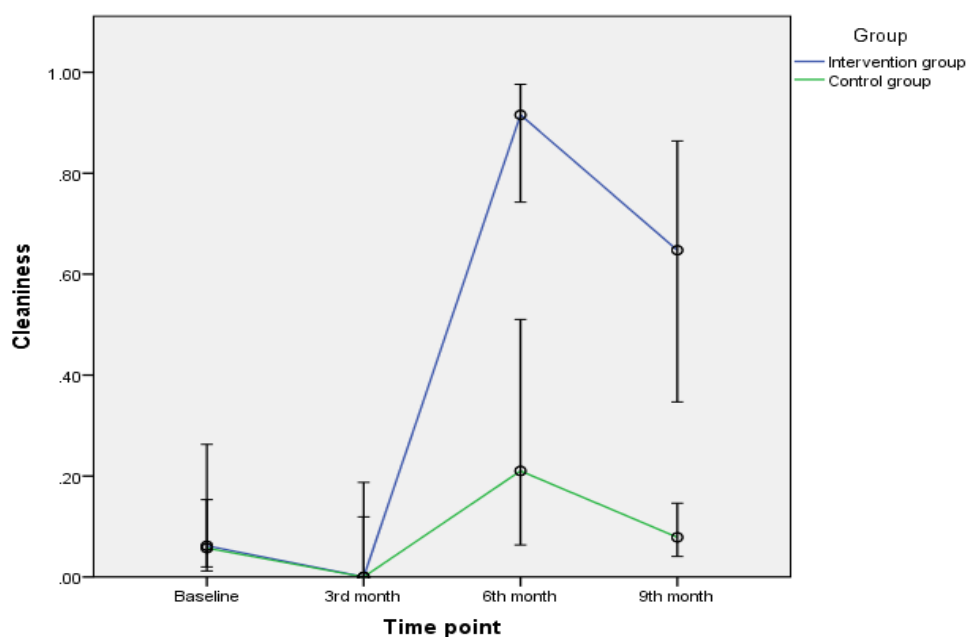


Figure 9 Estimated marginal mean and standard error of cleanliness score between groups across time

Figure 9 above shows that hand cleanliness scores among schoolchildren in the intervention and control groups were not significantly different at baseline and the 3rd month. The figure above shows that cleanliness scores dropped in the 3rd month compared to the baseline in both groups. There was a similar trend in the 9th month. The increase in scores in the 6th month was higher in the intervention group compared to the control group, and it was statistically significant ($p < 0.05$). There were significant individual effects on cleanliness scores at the 6th and 9th months.

Table 14 Pairwise contrasts of hand cleanliness scores between groups across time

	Mean Intervention	Mean Control	Contrast estimate ^a	<i>SE</i>	<i>t</i>	<i>df</i>	<i>p</i> ^b	95%CI Lower ^c	95%CI Upper ^c
Baseline	.062	.057	.005	.049	.095	1377	.925	-.092	.102
3 rd month	0.000319	0.000098	0.000220	.001	.303	1377	.762	-.001	.002
6 th month	.916	.210	.705	.124	5.667	1377	<.001	.461	.950
9 th month	.647	.079	.569	.154	3.696	1377	<.001	.267	.871

a Mean score of Intervention minus Control.

b Adjusted, the sequential Bonferroni-adjusted significance level is .05.

c Confidence interval bounds are approximate.

The mean difference in cleanliness score between groups at baseline (estimate=.005, 95%CI [-.092, .102], $p=.925$) and 3rd month (estimate= .0002, 95%CI [-.001, .002], $p= .762$) were not significant but at 6th month (estimate= .705, 95%CI[.461, .950], $p<.001$) and 9th month (estimate= .569, 95%CI[.267, .871], $p<.001$) were significant. The hand cleanliness improved after 6 months of intervention.

4.1.5 Absenteeism results

Generalized estimating equations (GEE) were used to analyse the effects of time as well as group and grade and their interactions with time on the number of sick leave days among schools, controlling for number of students in school. Normal distribution of the number of sick leave days was assumed and the identity link function was also used. The method of estimating scale parameter was maximum likelihood. Type III analysis was adopted to test model effects based on Wald chi square statistics. The covariance type of repeated measures was first order autoregressive. The robust covariance estimator was used.

Table 15 Test of Model Effects

Source	Type III		
	Wald Chi-Square	<i>df</i>	<i>p</i>
(Intercept)	1.168	1	.280
Group	.884	1	.347
School term	2.804	2	.246
Group by School term	8.138	2	.017
Grade	3.744	1	.053
Grade by School term	2.328	2	.312
No. of students	.418	1	.518

Dependent Variable: Number of sick leave days

Model: (Intercept), Group, School term, Group by School term, Grade, Grade by School term, No. of students

As shown in Table 13, there was significant group by school term/semester interaction effect on the number of sick leave days ($F(2)= 8.138$; $p=.017$).

Table 16 Parameter Estimates

Parameter	B	SE	95% Wald CI		Hypothesis Test		
			Lower	Upper	Wald Chi-Square	df	p
(Intercept)	-.268	5.6511	-11.344	10.807	.002	1	.962
Control	3.857	3.4339	-2.873	10.588	1.262	1	.261
Intervention	0 ^a
Term 1	8.417	3.8105	.948	15.885	4.879	1	.027
Term 2	3.083	1.9007	-.642	6.809	2.631	1	.105
Term 3	0 ^a
Control by Term 1	-15.500	5.6472	-26.568	-4.432	7.533	1	.006
Control by Term 2	-3.833	2.2032	-8.152	.485	3.027	1	.082
Control by Term 3	0 ^a
Intervention by Term 1	0 ^a
Intervention by Term 2	0 ^a
Intervention by Term 3	0 ^a
P1	2.500	3.2414	-3.853	8.853	.595	1	.441
P6	0 ^a
Term 1 by P1	7.833	5.6472	-3.235	18.902	1.924	1	.165
Term 1 by P6	0 ^a
Term 2 by P1	-.167	2.2032	-4.485	4.152	.006	1	.940
Term 2 by P6	0 ^a
Term 3 by P1	0 ^a

Term 3 by P6	0 ^a
No. of students	.005	.0080	-.011	.021	.418	1	.518
(Scale)	58.020						

Dependent Variable: Number of sick leave days

Model: (Intercept), Group, School term, Group by School term, Grade, Grade by School term, No. of students

a. Set to zero because this parameter is redundant.

Compared with the 3rd term of the school year, the 1st term was significantly associated with higher number of sick leave days ($B=8.417$; 95%CI [.948, 15.885]; $F(1)=4.88$; $p=.027$) as shown in Table 14.

Group by time interaction at term 1 was significantly associated with lower number of sick leave days ($B=-15.5$; 95%CI [-26.568, -4.432]; $F(1)=7.53$; $p=.006$).

At baseline the number of sick leave days was lower in control group, but the number decreased across time in the intervention group. The group by time effect was controlled in the model. (See Table 14 above for more details)

4.2 Focus group discussions as qualitative findings

This section of chapter 4 reports the findings from six focus groups of parents, school staff, and students from three intervention schools. This qualitative part of the study was nested in a cluster RCT. The main objective of the focus group discussion was to explore the acceptability and sustainability of the SBHHP by the schoolchildren, school staff and parents. The focus group discussions were conducted at the end of the programme, at the 9th month (T₃). The reason for conducting the focus group at the 9th month was to elicit real opinion and experiences after having participated in the programme for nearly the entire academic year. The following section describes the characteristics of the participants engaged in the focus group discussion. The setting in which the interviews were conducted is also

highlighted. Four themes are then presented one after the other.

4.2.2 Characteristics of the participants enrolled in the focus group discussions

Table 15 below presents data on the characteristics of participants who participated in the focus group and individual interviews. There were a total of 37 participants who participated in the focus group discussion with 14 males and 23 females. Out of the 37 participants, 18 were students, 6 were school teachers from the three intervention schools, 3 were school heads/principals or their representatives, 10 were parents whose children participated in the SBHHP. In terms of occupation, 18 participants were schoolchildren (9 from grade 1 and another 9 from grade 6), 16 participants were employed and 3 were doing business (self-employed). The age range for students was 4-13 years, while for parents and school staff was 24-64 years. The highest level of education attained by the participants were as follows; 9 participants were in primary/grade 1, another 9 participants were in primary/grade 6, four (4) participants reached secondary education level and 15 had tertiary level qualification. Schoolchildren from grades 1 and 6 formed one focus group and teachers responsible for these two grades, school staff and parents formed another focus group from each of the three intervention schools. This led to formulation of a total of six focus groups, two groups from each of the three intervention schools. Each focus group comprised of 6 to 7 participants. Each focus group lasted for 50 minutes on average. The common sources of knowledge on hand hygiene were

described by participants as being the radio, television, parents and school. All participants were able to read, write and communicate in both the local language and in English. However, students from grade 1 had some difficulties in fluently communicating in English. Interviews were conducted within the school premises in a room provided by the school authority in the morning on a normal school day.

Table 17 Characteristics of the participants in the focus group

	Frequency	Per cent
Gender		
Male	14	37.8
Female	23	62.2
Age		
<15 years	18	48.6
15 – 24 years	1	2.7
25 – 34 years	3	8.1
35 – 44 years	9	24.3
45 – 54 years	4	10.8
>54	2	5.4
Education		
Primary grade 1	9	24.3
Primary grade 6	9	24.3
Secondary	4	10.8
Tertiary	15	40.5
Occupation		
Business (self-employed)	3	8.1
Employed	16	43.2
Student	18	48.6
Total	37	100

In this study, pseudonyms were used to maintain the anonymity of participants, as presented in methodology. The next section starts by presenting results from the focus group discussion interviews.

4.2.3 Themes

The evidence on how the themes were derived based on the significant statements and formulated meanings is shown in Appendix XVII. The themes describe the experiences of school staff, parents and schoolchildren's participation in the SBHHP. The following four themes were identified from the data and are presented below one after another; 1) working together to develop policy and integrate hand hygiene programme into school curricular, 2) being committed to the school's hand hygiene programme, 3) practicing proper handwashing technique as routines, and 4) the benefits of SBHHP.

4.2.3.1 Theme 1: Working together to develop policy and integrate hand hygiene programme into school curricular

All participants interviewed expressed a feeling of happiness for the introduction and existence of the SBHHP at their school. Schoolchildren in particular, were excited for participating in the simplified 5-step handwashing technique. Besides that, their parents felt relieved that their children were taught handwashing at school. The following are some of the related quotes as expressed by six participants:

“Like here at school we have welcomed the programme so well, we like the way learners are washing their hands or take care of their hands and its like there is a systematic way of washing their hands not just on the same spot/part” (T1H)

“This programme was very good and it came right on time. We have learnt a lot about the proper handwashing technique, and we have stopped the traditional way” T2H

“So to me I see that the programme has benefited them a lot, and even to us as parent because we can peacefully leave the home and not get worried about how children will take care of themselves especially concerning handwashing during eating time” PIR

“In my case I participated in this project because at first when I was washing hands germs could not be removed, especially when I had touched mud and when washing hands and at times could not use soap but now I wash hands with soap”. (C6dR)

“Aaah it’s going on fine, people have learnt how to wash their hands properly and now they are washing hands, using those 5-step”. (C6bH)

Participants proposed many suggestions on how the schoolchildren may continue to practice handwashing. Alternative source of resources was the hallmark in the discussion. Participants discussed ways of finding resources for handwashing, community mobilisation and participation. Some of the quotes expressed by five participants are presented below:

“According to me, I think all is fine, may be just to add a song so that children should be more like entertained or should dance”.

(P1H)

“I support what the madam is saying to bring it at the meeting aah PTA meeting so that parents should be aware of it but am suggesting saying not to bring the soap as such but for what they are paying school fees they have to add little amount of money whereby it will be said to be buying soap”. **(T1H)**

“For me, I think for this programme to continue very well, because at time we run out of water at school, therefore I would proposal to have a borehole in schools”. **(P3H)**

“Aah T2 sustainability will be there as and when this programme was just being introduced here aah Mr Mbakaya was even approached to extend it to kindergartten showing that everyone is ready our proprietors, are happy with the programme and the kinder is also happy that is why they made this request, can't we extend it to here so that learners would be used to this programme so the question of sustainability”. **(T2W)**

“Community/village/ homes, we also have to go and teach them how to wash hands”. **(C6aH)**

4.2.3.2 Theme 2: Being committed to the school's hand hygiene programme

During the interviews, schoolchildren expressed willingness to share both theoretical and practical knowledge which they obtained from school with parents, siblings, neighbours, friends and schoolmates. Teachers continued to teach the SBHHP to other classes besides classes one and six, which were the target classes for the SBHHP. Some of the related quotes as described by five participants are as follows:

“when playing she calls friends and start demonstrating what she was taught at school (5-step) P2H

“But even in class when teaching a topic on hygiene we could come in heeehh, which means we could also teach other in class about handwashing. Or even at school assembly again we could teach everyone in all classes meaning that they all have an idea” T2H

“If you wash like this (parent demonstration the old way) then you will hear from the child, mum mum you have not washed your hands (hihihi hehehehe- audience 6sec) you are supposed to do like this, all this area (parent demonstrating five step as taught by child)” P2W

“in these classes now the others have also learnt a lot from their friends they even ask can you teach me how you wash it and then they demonstrate you know” T2R

“Yes I will tell my neighbours and parents or brothers and sisters on how to wash hands so that they can also avoid those diseases”
(C6bH)

4.2.3.3 Theme 3: Practicing proper handwashing technique as routine

There was an impression that behaviour change had taken place among schoolchildren based on the comments from the participants. The change in handwashing practice was prevalent and sustained among students three months after the intensive implementation of the SBHHP using a multilevel interventions approach. The following are some of the quotes as expressed by seven participants:

“learners could not wash hands but now they wash, at break they can’t start eating, they go and wash hands first, in the past we could like force them to wash hands but now they remember themselves”
(TIH)

“And since that time he is always, each time he comes from the toilet goes to the sink, washes hands and he tells his brother, he has an elder brother, he tells him, have you washed your hands”. (P4R)

“What I have liked most is actually that as I mentioned earlier on is that eeeh there has been that change of behaviour where the child is very much interested to really have his hands clean you can actually see the efforts eeeeeh “. (PIW)

“so the whole school now has joined in washing hands and they in my class I should say sometimes I can say okay now it is break can you go and eat they say no washing hands they can’t touch anything without washing hands”. (T2R)

“Yes, because in the past when, before we learnt how to wash hands, others were getting diseases even if they washed their hands but now when they wash their hands using 5-step they are not getting those diseases”. (C6bH)

“In the past it could happen that we could just start eating nsima (food) without washing hands but now we wash hands first before eating”. (C6cH)

“Has changed because in the past I was not washing hands systematically (just wetting/dipping my hands) and some germs could remain on my hands but now with 5step I am able to remove all the germs from my hands”. (C6bR)

4.2.3.4 Theme 4: The benefits of a SBHHP

During the interviews, parents stated that their children demanded handwashing resources to be bought for home use. Furthermore, children wanted everyone in the home to do what they were taught at school

regarding 5-step of handwashing. Below are some of the quotes from three participants:

“They make sure that each and every one should do what they have learnt here at school (uuh uuh yes –audience chorus 3sec), which simply shows that they have mastered the programme/procedure, (you see – audience), they have internalised- another participant adding)”. (P3H)

“he said we have been told to wash hands, so you have to buy me lifebuoy soap for washing my hands”. (P4R)

“Actually, it’s the kid that is insisting (hahahihihahahahaha audience 6sec) and advising us that by all means we must continue (hehehehehe –audience) and obviously we have seen the good of that why not? Hihihih –audience 2sec)”. (P2R)

Schoolchildren and school staff were for the view that the SBHHP helped to reduce illnesses such as diarrhoea and flu, consequently leading to reduction in the absenteeism of children at school. During the interviews, schoolchildren, teachers and parents expressed sentiments regarding how the SBHHP improved their health. Below are some of the quotes as described by five participants:

“In terms of sickness there is a drop, not many learners suffering from diarrhoea or coughing” (T2H)

“To us this programme has helped to reduce diseases compared to our usual traditional method of handwashing where one basin could be used by 20 people to wash their hands in it (hihihi-audience 1sec) my child now has reduced suffering especially from coughing/flu”. (PIH)

“there is a change especially on absenteeism these days when I ask why these learners are absent sometimes they say its headache and then Malaria just a few who say I was suffering from stomach ache”. (T2R)

“Nowadays she does not suffer from influenza frequently as it used to be in the past where every two weeks could get sick. Now I see a big change”. (P2W)

“It has greatly helped me in my life, in the past I used to suffer flu/coughs very frequently but now it has reduced”. (C6cH)

“No when we wash hands following 5 steps, all the germs are removed and when you are eating nsima (food) you eat without germs hence you reduce chances of suffering. While washing hands the old way it means some of the germs remain on the hands and when eating nsima you eat together with the germs”. (C6aR)

4.2.4 Summary

In this chapter, the quantitative results of the cluster RCT study are presented. The chapter addresses the primary and secondary hypotheses. The outcome measures of concern were student's handwashing compliance (knowledge, skills/technique and cleanliness) at four-time point (i.e. knowledge refers to the scores of handwashing quiz; skills/technique refer to the scores of handwashing observational checklist; and hand cleanliness refers to the scores of the fluorescent stain test on both hands) as the primary outcome, school absenteeism through sick leave days, and acceptability of the SBHHP as secondary outcomes. There was no significant difference at the baseline in the outcome measure between the intervention and control groups.

The results indicate that there was a significant improvement in the knowledge (quiz score) in the intervention group across time ($B=1.972$; 95%CI [1.156, 2.788]; $t = 4.742$; $p < .001$). This was also sustained in the 9th month. A similar trend was observed in the skill/technique acquisition, with the intervention group making significant improvements across time ($B=5.14$; 95%CI [4.75, 5.54]; $t = 25.481$; $p < .001$), and sustainability evident in the 9th month. Hand cleanliness improved significantly across time in the intervention group compared to the control group ($OR=21.51$; 95%CI [4.38, 105.72]; $t = 3.781$; $p < .001$).

Schoolchildren in the higher grade (grade six) improved significantly in all the outcome measures compared to those in the lower grade (grade one).

Overall reduction in school absenteeism days (sick leave days) differed significantly between the intervention and control schools across time ($p < 0.05$). Compared with the 3rd term, the 1st term was significantly associated with higher number of sick leave days ($B = 8.417$; 95%CI [.948, 15.885]; $F(1) = 4.88$; $p = .027$).

Generally, time, group, and group by time interactions had a significant effect on all the outcome measures (quiz score, skill acquisition and hand cleanliness). The findings revealed that the SBHHP was very effective and yielded positive outcomes, especially in the 6th month and during the follow-up sustainability measure in the 9th month ($p < 0.05$).

The results from the focus group discussions showed good acceptability of the SBHHP using the whole-school approach of the HPS framework by the schoolchildren, staff and parents, as expressed in the recorded verbatim. The acceptability was reflected in the verbatim quotes made by the focus group participants and captured throughout the four main themes. The results in this section are presented in four subsections based on the four themes as follows: 1) working together to develop policy and integrate the hand hygiene programme into school curricula, 2) being committed to the school's hand hygiene programme, 3) practising proper handwashing technique as a routine, and 4) the benefits of the SBHHP on schoolchildren's health outcomes.

CHAPTER FIVE

DISCUSSION

5.0 Introduction

Chapter five interprets and discusses the significance of the study findings presented in chapter four based on the concept of Bronfenbrenner's ecological systems theory (1987) and the domains of the WHO's HPS framework (1996) using a multilevel interventions approach. Considering what are the impacts of a structured SBHHP on schoolchildren's handwashing behaviours and how the system environments influence the behavioural changes. What was already known based on the topics outlined in the background and what are the new findings in this study considering the research objectives and hypotheses on the schoolchildren's proper handwashing technique and their compliance after participating in the SBHHP.

5.1 Answers to study objectives and hypotheses

The SBHHP was conducted with an aim to evaluate the efficacy of a SBHHP using a multilevel interventions approach targeting schoolchildren, schools and their families in the intervention group versus the routine hand hygiene practice in the control group at four-time point (T₀, T₁, T₂ & T₃) for schoolchildren who participated in this study in Malawi.

The schoolchildren's handwashing compliance was appraised by rating the scores of the handwashing quiz (knowledge), the handwashing observational checklist (technique) and the fluorescent stain test (hand cleanliness) at four time points (T₀, T₁, T₂ & T₃). The alternative hypotheses that the group by time effect on handwashing compliance (knowledge, technique, and cleanliness) would be statistically significant and that the mean scores of handwashing knowledge, technique and hand cleanliness would be higher (better) in intervention group than in control group at post tests were accepted ($p < 0.05$) because the findings revealed that there are significant results on the handwashing compliance (knowledge score, handwashing technique score, and hand cleanliness), and reduction in the school absenteeism days (sick leave days) in the intervention group compared to the control group across time. The findings of this study are similar to a study conducted in Thailand by Kaewchana and his colleagues (2012) who reported that scores for the 7-step handwashing technique were significantly improved post-intervention among participants aged older than 7 years living with a confirmed influenza-positive child in the household. In addition, the findings of this study are also similar to those in a study conducted in Zimbabwe by Friedrich, Kappler, & Mosler (2017), who found that participants in the intervention clusters had better scores for handwashing technique than those in the control clusters. The correct procedure or technique for handwashing is important in order to achieve effective, proper handwashing (CDC 2002; WHO 2009). Regarding the cleanliness of the hands, the findings of this study are consistent with those found in a study by Lee and Lee (2014; 2015) in Hong Kong, where students in the higher classes (grades 5-9) performed handwashing better

than those in the lower classes (grades 1-4) pre-, to post- test difference in the intervention group, and also those in the intervention group performed better than those in the control group.

In order to explore the acceptability of the SBHHP using multilevel interventions approach (formulating hand hygiene protocol, providing proper handwashing procedure training, creating supportive environment and ensuring resource availability) to implement it in the primary schools in Malawi, focus group discussion was conducted. The evaluation revealed that there was a good acceptability of the SBHHP among schoolchildren, school heads, teachers and parents.

5.2 The added value of multilevel interventions research

As discussed in chapter two, the multilevel intervention is a specified strategy designed to change the knowledge, perceptions, skills and behaviours of individuals, groups, community and organizations with the goal to improve the health outcomes as suggested by Clauser and his colleagues (2012). This is also supported by WHO's HPS framework with the aim to affect the critical contextual issues and create a more efficient, effective and coordinated hand hygiene programme delivery system that achieve patient outcomes, including improved survival and quality of life in a cost-effective intervention strategy.

The discussion compares the similarities and differences on its impacts of the findings of this study with previous study results on the adoption of the

multilevel interventions approach (policy driven, behaviour-based training, environmental influences and resources availability) identified from the researcher's systematic review target more than one contextual factors (individual, group, community and organizational) to guide the implementation of this intervention study. This has generated new evidence on using multilevel intervention strategies to influence the development of handwashing protocol by linking the partnership between educational and health sectors in the policy level in developing countries.

The rigorous design of this study generates scientific outcome measures of the adoption of multilevel intervention research focusing on changes in handwashing knowledge, attitudes, behaviours and practice among the schoolchildren after participating in the SBHHP. This has added value to the evidence-based practice, but it has also created challenges for developing countries with limited resources to formulate the policy and the commitments of all the sectors.

A physical and social environment with available and supportive resources is essential to promote hand hygiene in the school setting. The long-term impact of the sustainability of the SBHHP is focused on improvement in health outcomes by reducing school absenteeism (sick leave days) and improving attendance among schoolchildren. The discussion on the impacts of the SBHHP of the four contextual levels (individual, groups, community and organization) of the multilevel intervention strategies also links to the three key components of the WHO's HPS framework (1996) which include 1) school curriculum, teaching and learning; 2) school organization, ethos

and environment; and 3) school community partnerships and services. These two theories were underpinned in a multilevel interventions approach to implement the SBHHP for Malawian Schoolchildren in developing countries to improve hand hygiene compliance and reduce school absenteeism (sick leave days).

As noted in the introductory chapter, an intervention is a specified strategy or set of strategies designed to change the knowledge, perceptions, skills, and/or behaviour of individuals, groups, or organisation, with the goal of improving health outcomes. Previous studies have not rigorously addressed these in the children's health related outcome measures for the design of intervention studies on hand hygiene among schoolchildren in developing countries like in Malawi. Hence our primary interest in multilevel intervention research that influences at least individual, group, organisation, and society context in Malawi that influence health-related delivery.

The following discussions based on the study findings after adopting a multilevel approach include: 1) the four contextual levels of a multilevel interventions approach; 2) long-term impact on the schoolchildren's school absenteeism (sick leave days) and attendance; 3) focus group discussions on acceptability of SBHHP by schoolchildren, school personnel, parents and stakeholders; 4) the rigorous study design to measure the outcomes of the SBHHP in developing countries like Malawi; 5) the benefits of adopting a multilevel approach to implement the SBHHP as the intervention targeted to influence more than one contextual level such as individual, group, organization and community; 6) the first key components of the WHO's

HPS Framework on school curriculum, teaching and learning; 7) the second key components of the WHO's HPS Framework in terms of school organization, ethos and environment; and 8) the third key component of the WHO's HPS Framework on school community partnerships and services. Finally, a summary of chapter five is provided.

5.3 The four contextual factors in the child's environment interactions

The multilevel interventions approach based on ecological theory to implement hand hygiene programme that targets more than one contextual factors (schoolchildren, family, school and community), is being increasingly recognized that they will lead to more substantial and sustained changes in handwashing behaviours to improve hand hygiene compliance and reduce school absenteeism (sick leave days) than would single-level interventions with the influences from the interdependent interactions between different levels to produce desirable outcomes (Edwards et al., 2012; Taplin et al., 2012). In this study, the intervention targeted four different contextual levels: the schoolchildren themselves through school teachers' curricular teaching and peer learning, with the partnership with the parents. This conforms to the principles of multilevel approach as explained in chapters 1 and 2. The significant results of the primary outcome of hand hygiene compliance of this study ($p < 0.05$) also support the affirmative effects of using a multilevel interventions approach to implement health promotion activities on children's hand hygiene at the school community level. These multilevel components link well with the strategies based on

the concepts from Bronfenbrenner's ecological systems environment (1987) and the whole-school approach of HPS framework (WHO, 1996). Along with that, both the multilevel components and the whole school approach of HPS also link well with the multidisciplinary team approach, and it adds value to the public health agenda. It is believed that the whole-school approach facilitates the three action components of WHO's HPS framework: 1) school curriculum, teaching and learning, 2) school ethos, environment and organisation, and 3) school community partnership and services, by linking them to the community stakeholders, thereby measuring desirable outcomes, which are evident in this study (Edwards et al., 2012; Langford et al., 2014; Lee et al., 2008; Taplin et al., 2012). Previous studies have not addressed any of these three HPS domains in their outcome measures for intervention studies on hand hygiene among schoolchildren in developing countries like Malawi, sub-Saharan Africa (Langford et al., 2014). In addition, experience considering multilevel interventions approach in health care is much less robust (Taplin et al., 2012), hence the contribution of this study as discussed in the following.

5.3.1 Multilevel interventions implement at individual level

This study found that hand hygiene compliance in terms of knowledge score was better among schoolchildren in the intervention group compared to those in the control group ($B=1.972$; 95%CI [1.156, 2.788]; $t = 4.742$; $p <.001$). This improvement was prevalent across time. At baseline, the difference in knowledge mean scores between the two groups was not statistically significant. This means that at baseline, the two groups were

comparable in terms of knowledge level on hand hygiene. As such, any change and difference in knowledge score across time between the two groups could be attributed to the intervention (SBHHP). Time, group, and group by time interaction had significant effects on knowledge level scores. Knowledge (quiz) scores increased in both groups from the baseline through to the 9th month. However, the scores were higher in the intervention group than in the control group across time. The SBHHP intervention in this study was associated with a 1.97 times higher knowledge score in the intervention compared to the control group. The increase in knowledge in both groups could be attributed to the countrywide dissemination of information on WASH programme via radio and television. This is consistent with what many children from both intervention and control groups indicated, that they had already heard about handwashing. They indicated radio, television and their parents as common sources of information at baseline. However, the higher scores observed in the intervention group could be associated with the involvement of parents, who formed the community linkage and reinforced the knowledge students gained at school, peer learning, improved the physical environment to render it conducive to learning, included the hand hygiene into extracurricular activity, and made it a school routine throughout the entire academic year (2016/2017). This means that the SBHHP was implemented at four different levels by offering structured training, provision of resources, setting a conducive environment, and policy. In addition, four contextual levels (student, group, community/family, and organisation/school) were targeted in the implementation of SBHHP in the intervention group. This was not the case in the control group where resources were provided but there was no

structured training, hand hygiene policy, and environment was not very conducive to practice hand hygiene. Furthermore, the child was the only contextual level that was targeted with the resources at school.

This approach used in the intervention group of this study is described by WHO (1996) as a whole-school approach in the HPS framework. Langford and colleagues in their systematic review recommended use of the HPS framework in order to test the effectiveness of handwashing interventions in school to measure health and educational outcomes (Langford et al., 2014).

Education triggers self-efficacy, increased knowledge and an induced sense of perceived threat due to infections (Ajzen, 1988; Bandura, 1997). Training is a critical success factor and represents one of the cornerstones for improvement of hand hygiene practices (WHO, 2009). In addition, in a study conducted by Chittleborough, Nicholson, Basker, Bell and Campbell in south-west England in 2013, schoolchildren and staff had a similar understanding of when, why and how to wash their hands. The same authors further assert that the probability of a person washing their hands increases when they know why and how to perform handwashing (Chittleborough et al., 2013).

5.3.2 Multilevel interventions implement at the group level

Previous studies and projects have put much emphasis on theoretical knowledge sharing about handwashing. However, little has been documented regarding teaching the community, especially schoolchildren,

in Malawi and other developing countries in sub-Saharan Africa on the handwashing technique (skill) that children should be using when washing their hands (Mbakaya et al., 2017). This study trained schoolchildren on the simplified 5-step handwashing technique, so that they would be empowered with both theoretical and practical aspects of hand hygiene. The correct procedure or technique for handwashing is important in order to achieve effective, proper handwashing (CDC 2002; WHO 2009). Students practiced handwashing at the sinks (handwashing stations) in small groups after being taught by research team. In addition, students were encouraged to learn from each other through peer led activism. This approach is also in line with Bandura's social learning theory which states that children learn better by observing others (Bandura, 1977).

The findings of this study indicate that there was a significant improvement in the acquisition of skills (technique score) in the 5-step handwashing technique as compliance rate scores in the intervention group compared to the control group ($B=5.14$; 95%CI [4.75, 5.54]; $t = 25.48$; $p <.001$). The acquisition of skills (technique score) was higher in the intervention group compared to the control group across time. This continued observed improvement could be ascribed to the SBHHP intervention because, at baseline, the two groups were not statistically different ($p >.05$). Time, group, group by time, grade, and grade by time interactions had a significant effect on skill acquisition. The SBHHP in this study was associated with a 5.14 times higher technique score in the intervention group compared to the control group.

The context of the school set-up might have contributed as well, because the schoolchildren were able to interact and learn from each other. This is supported by the verbatim from the qualitative data, in which one participant mentioned that the schoolchildren were able to learn from each other how to wash their hands using the 5-step technique. Within-cluster comparisons revealed that skill acquisition was higher among children in grade six than those in grade one, possibly due to their older age, which is associated with the achievement of fine motor skills. Developmental milestones are considered as one of the factors that influence the behavioural change process (Prochaska, DiClemente, & Norcross, 1992).

The results of this study are in agreement with those of Kaewchana and his colleagues (2012) who reported that scores for the 7-step handwashing technique were significantly improved post-intervention among participants aged older than 7 years living with a confirmed influenza-positive child in the household.

Slightly different results were found in a study conducted by Patel et al. (2012) on the impact of a hygiene curriculum and the installation of simple handwashing and drinking water stations in rural Kenyan schools. In their study, Patel and colleagues found that the median percentage of students in the intervention schools who could demonstrate proper handwashing technique was similar to that in the comparison schools at baseline, was significantly higher in the intervention schools at the first follow-up and was similar in both groups at the second follow-up (Patel, 2012). The type of handwashing technique used in their study, that is, whether they used a 7-

step (WHO), a 5-step (Lee & Lee, 2014), or any other validated technique, was not described. While Patel and colleagues instituted a curriculum on safe water and hand hygiene and also installed water stations in intervention schools, there was a missing link of the intervention to the school community participation and services. In their study, Patel and colleagues managed to implement two out of the three areas of intervention of the whole school approach of the HPS framework. Namely; school curriculum, teaching and learning by instituting a curriculum on safe water and hygiene, and school ethos, environment and organization by installing water stations. However, there was no school community partnership and services because they did not engage with the family or community which is a critical element of the HPS for effective school health programmes (Langford et al., 2014; Lee et al., 2008; WHO, 1996). These are the major differences with the current study (SBHHP) in which the multilevel interventions approach and all the three areas of intervention of the HPS framework were applied beside social learning theory (Bandura, 1977) and theory of planned behavior (Ajzen, 1988).

The strategies/approach used in this study (training on simplified hand washing, provision of handwashing resources and involvement of school staff and authorities) are also in line with the “Guide to the Implementation of the WHO Multimodal Hand Hygiene Improvement Strategy” (WHO, 2009) and fulfils all the components of a multilevel interventions approach. The WHO’s multimodal hand hygiene implementation strategies (2009) provide a framework that recognises key components and underpinning, and is tied together by institutional structures, processes and contexts that

require multidimensional implementation strategies.

This study therefore provides new evidence to support the global determined attempts using the multilevel interventions approach to scale up the resources for implementing hand hygiene interventions, including building a supportive environment to promote hand hygiene among children in school settings to improve hand hygiene compliance and reduce school absenteeism (sick leave days), as guided by the WHO's HPS framework (1996) in developing countries like Malawi, sub-Saharan Africa, where personal hygiene is always an issue in the public health agenda.

5.3.3 Multilevel interventions implement at community level

This study found that cleanliness of the hand as a handwashing compliance rate and behavioural change improved in the intervention group compared to the control group at the 6th (T₂) and 9th months (T₃) ($OR=21.51$; 95%CI [4.38, 105.72]; $t = 3.78$; $p <.001$). The scores for hand cleanliness were similar at the baseline and then dropped at the 3rd month compared to the baseline in both groups, as presented in chapter four above. In the control group, this could be explained by inadequate use of the recommended hand hygiene strategies, such as policy, funding/resources, supportive environment and training, as well as inadequate application of the multilevel interventions approach (Mbakaya et al., 2017; Clauser et al., 2012; Taplin et al., 2012). In addition, in the control group, the whole-school approach of the HPS framework, which is recommended and associated with positive outcomes (Langfold et al., 2014; Lee et al., 2008; WHO, 1996), was not used. In the intervention group there could be two

possible explanations for the drop in the cleanliness score at the 3rd month. Firstly, it could be due to the normal process of change, where a person takes some time to master a new concept or idea or practice (Prochaska et al., 1992). Considering the three-month period, it is relatively short to acquire efficiency in the skill that will translate to or result in a clean hand. Secondly, it could be that schoolchildren in the intervention group were busy trying to master the procedure of the 5-step technique (effectiveness), which was new to them, rather than focusing on the cleanliness of their hands (efficiency). This is supported by the opposing trend observed in the technique score in the same period at the 3rd month (T₁). At the 3rd month (T₁), the technique scores increased significantly, while at the same time the cleanliness declined. Further analysis of the video clips that captured the procedure (data not reported) shows that most schoolchildren got the five steps correct at this assessment time (3rd month). However, they finished the entire procedure in less than 20 seconds, and some even less than 15 seconds, far less than the normal recommended time (>20 seconds) to achieve proper handwashing. This could be the reason for their low scores for hand cleanliness during this period. After mastering the steps correctly, it was observed that at the 6th month (T₂) the cleanliness improved due to the general efficiency employed by the schoolchildren when washing their hands. Clearly defined handwashing steps make handwashing more effective and important to effectively remove visible dirt and microorganisms (Friedrich, Julian, Kappler, Nhiwatiwa, & Mosler, 2017).

The intervention (SBHHP) was associated with higher scores of hand cleanliness in the intervention group compared with the control group.

Within-cluster comparison showed that scores for hand cleanliness were higher among grade six than grade one schoolchildren. These findings are consistent with those found in a study by Lee and Lee (2014) in Hong Kong, where students in the higher classes (grades 5-9) performed handwashing better than those in the lower classes (grades 1-4) pre-, to post- test difference in the intervention group. This could possibly be due to the cognitive development that occurs with age. The older they are, the better and more capable a person is of handling complex information and skills. In addition, developmental milestones may influence the behavioural change process (Prochaska et al., 1992).

The results of this study on hand cleanliness using the fluorescent stain test have a similar pattern to the findings of yet another study conducted by Lee et al. (2015) in Hong Kong among children with mild intellectual disability. In their study, they found that the intervention group experienced a significant increase in the rating score of their handwashing quality on the dorsum and palm, for both left and right hands. They also found that students in grades 5-9 performed better than those in grades 1-4. (Lee et al., 2015). In their study, they used the multi-sectoral approach, which proved to be successful.

Although this study was conducted in a developing country and a resource-constrained setting, the findings on the cleanliness of the hands using the fluorescent stain test are comparable and similar to those conducted in a developed country, conducted by Lee and her colleagues (2017) in Hong Kong. This may signify a positive direction for the use of the simplified 5-

step handwashing technique in the context of the whole-school approach of the HPS framework. The simplicity of the procedure means that the 5-step technique stands out and defies the challenges of cultural and resource diversification/differences, and that it could be easily learnt and adopted by people with different socio-demographic characteristics across the globe. More importantly, it could easily be incorporated into school extracurricular activities without demanding much time or other necessary resources. This may in turn improve the uptake of hand hygiene practice and compliance among schoolchildren, especially in developing countries, where the uptake is currently between 3% and 18% (Malawi Ministry of Health, 2011; UNICEF, 2015). In addition, the findings may imply that the simplified 5-step handwashing technique could easily be learnt and produce an effective outcome regardless of the physical and mental status of an individual as long as the recommended hand hygiene strategies and the HPS framework are sufficiently applied, especially with community involvement for resource mobilisation which happens to be a big barrier in developing countries (Mbakaya et al., 2017; WHO, 2009; WHO, 1996). For example, in Hong Kong, a similar study was conducted in a school setting among children with mild intellectual disability, while in Malawi it was conducted in a school setting among children with normal intellectual capabilities.

This study found that the effect of the SBHHP was upheld among the intervention group in the 9th month assessment, three months after completion of the SBHHP in the 6th month. This suggests that the SBHHP might have had prolonged effects on the schoolchildren's handwashing practice. This could be a significant indicator for behavioural change among

schoolchildren regarding handwashing compliance, especially in developing countries such as Malawi, where the real practice of handwashing with soap at critical times is still very low regardless of massive campaigns in recent decades (Malawi Ministry of Health, 2011).

In this SBHHP, the significant knowledge gain attained by schoolchildren was translated into a proper 5-step handwashing technique and significant removal of fluorescent stain on their hands, thereby keeping clean hands.

This study was guided by the whole-school approach of the WHO's HPS framework. As such, the training offered to schoolchildren on hand hygiene was incorporated in the extracurricular activities and embraced the school curriculum, teaching and learning area of intervention of the HPS framework (WHO, 1996).

The findings of this study imply a significant direction to pursue regarding improvements in compliance with proper handwashing, the adoption of handwashing behaviour among schoolchildren, and consequently the prevention of infectious disease outbreaks such as diarrhoea during the epidemic period of the rainy season in Malawi and neighbouring countries. This is even more useful in the school set-up, where children are at a higher risk of getting infectious diseases.

5.3.4 Multilevel interventions implement at organization level

Organisation level of the multilevel intervention is an important influential source in the implementation of the intervention. This can be achieved through setting conducive environment and formulating good policy that may reinforce proper hand hygiene compliance. In addition, organisation level has an impact on policy implications between the partnership of health and educational sectors to change the knowledge, perceptions, skills and behaviours of the organization with the goal to improve health outcomes. In this study, independent school association of Malawi responsible for the Northern Region to reinforce the implementation of the SBHHP. The school directors, principals, and heads were also involved in the project through resource mobilisation by making sure that water bills were timely paid to avoid water disconnection. The authority also made sure that the time allocated for the education was strictly followed.

As reported in chapter four, the findings of this study show that the structured SBHHP had significant and positive effects on the schoolchildren's handwashing technique and compliance rate, with increased scores in the handwashing quiz/knowledge ($B=1.972$; 95%CI [1.156, 2.788]; $t = 4.742$; $p <.001$), in the observational checklist/technique ($B=5.14$; 95%CI [4.75, 5.54]; $t = 25.48$; $p <.001$), and in the fluorescent stain test/hand cleanliness ($OR=21.51$; 95%CI [4.38, 105.72]; $t = 3.78$; $p <.001$). These findings show significant results in hand hygiene compliance among the intervention group compared to the control group, owing to the multilevel approach which link well with HPS framework and the hand

hygiene strategies. The compliance was measured through three main elements: 1) knowledge/quiz scores, 2) handwashing technique scores using the 5-step technique, and 3) hand cleanliness by scoring fluorescent stain.

This study (SBHHP) use the multilevel interventions approach to address hand hygiene issues among Malawian schoolchildren underpinned by Bronfenbrenner's Ecological Framework, and WHO's HPS framework and how it eventually impacts schoolchildren's ecological outcomes in terms of improved hand hygiene compliance, improved school attendance, reduced school absenteeism (sick leave days), hand hygiene protocol integration into the school curriculum, creating supportive environment for the student's hand hygiene behaviour, making resources available, and the linkage to the community or family as presented above.

5.4 Long-term impact on the schoolchildren's absenteeism and attendance

Diarrhoea has detrimental impacts on childhood growth and cognitive development, thereby affecting dual school performance through both absenteeism and cognitive performance (CDC, 2015). There is sufficient evidence that students who are absent frequently or for long periods are likely to have difficulty mastering the material presented in class, making absenteeism an important education issue (Malawi Demographic & Health Survey, 2002).

This study found that overall school absenteeism (sick leave days) significantly differed between the intervention and control groups. There was significant group by school term/semester interaction effect on the number of sick leave days ($F(2) = 8.138, p = .017$). At baseline the number of sick leave days was lower in control group, but the number decreased across time in the intervention group. The findings from this study agree with those from previous studies which have shown a positive link between handwashing and reduction of school absenteeism (Lee et al., 2015; Patel et al., 2012; Rao et al., 2006; Talaat et al., 2011).

The study findings are similar to a study conducted by Lee and her colleagues (2015) among schoolchildren in Hong Kong. They found that the intervention school experienced a significantly lower absenteeism rate (0.0167) than the control group in the same year (0.028, $p = .04$) (Lee, Leung, Tong, Chen, & Lee, 2015).

However, the findings of this study (SBHHP) are contrary to a study conducted in Jerusalem by Rosen and his colleagues (2006). They found that neither the preschool nor the home intervention programme reduced illness absenteeism or overall absenteeism. This was despite a remarkable and sustainable behavioural and environmental change over a 6-month period, as well as an observed increase in handwashing with soap among children in the intervention group (Rosen et al., 2006). The reason for the lack of change in illness absenteeism rates in their trial, despite substantial behavioral improvement, is unclear. However, it was reported that during their study period, diarrhea rates in Jerusalem were very low. A higher base

rate of gastrointestinal disease may have led to a stronger programme effect on illness absenteeism (Rosen et al., 2006).

In this study (SBHHP), the researcher linked schoolchildren to their homes/community through handouts, leaflets, information sheet brought to them by their children, and also through the focus group discussion. In addition, the researcher constructed water pipes and handwashing sinks to both the intervention and the control groups to balance the physical environment on both study sites as the baseline. The presence of handwashing sinks was a motivation for students to wash hand in both intervention and control groups. However, the significant reduction in the school absenteeism days in the intervention schools, could be attributed to multilevel interventions approach used in the intervention group.

It is therefore, high time that Malawi Government considers establishing a strong link between education and health sectors, and other relevant stakeholders as is recommended in the whole school approach of the WHO's HPS framework (WHO, 1996) in order to promote hand hygiene compliance and reduce school absenteeism (sick leave days).

5.5 Focus group discussions on the acceptability of SBHHP with the schoolchildren, school teachers/principals, parents and community stakeholders

The positive sentiments from the school personnel, parents and

schoolchildren in the focus group discussions indicated that the implementation of the structured SBHHP was feasible and acceptable by the schoolchildren, school personnel and parents. It is not just what happens in the school curriculum; it is about the entire school members' involvement at different levels, including the parents in the social environment and stakeholders at the community level as well. This type of approach is advocated for by the concepts of the multilevel interventions approach, whole school approach of the WHO's HPS framework and also the hand hygiene intervention strategies (Mbakaya et al., 2017; Taplin et al., 2012; WHO, 1996).

The participants in the focus group discussions were representative of both genders from lower grade and higher grade in the three intervention primary schools. Parents and school staff demonstrated good levels of handwashing knowledge through the quiz test they wrote prior to the interviews (data not reported). This could be considered as an advantage in terms of being able to supervise children both in school and at home for the promotion and continuity of hand hygiene practice. Good knowledge on hand hygiene among parents would help to reinforce and support children's hand hygiene initiative learned at school in the home setting, forming the community or family linkage that is important in the whole-school approach of the HPS framework and also the multilevel interventions approach. After all, some of the schoolchildren mentioned that they had heard about handwashing from their parents. The common sources of knowledge on handwashing were described by parents and school staff as being the radio, television, and school. This is consistent with what the schoolchildren mentioned as their

source of knowledge on handwashing at the beginning of this study (baseline data). The sources of knowledge on handwashing for participants in this group are similar to those found in a study conducted in England by Chittleborough and his colleagues (2013). In their study, participants indicated that they got information on handwashing mainly from radio and television. This therefore, underscores the importance of engaging different stakeholders (multi-sectoral and multilevel approaches) in promoting health among schoolchildren (Clausal et al., 2012; Taplin et al., 2012; WHO, 1996). Although this study was conducted in a developing country in Malawi, the teaching and learning materials on hand hygiene knowledge among participants was similar to those in a study conducted in a developed country (the United Kingdom). This is possibly because the target group in this study were children attending private schools in Mzuzu, implying that their parents were from at least the middle class and therefore more likely to access the radio and television. All participants were able to read, write and communicate in both the local language and in English.

Focus group discussions were conducted within the school premises in a room provided by the school authority in the morning on a normal school day. This made the participants more relaxed during the focus group discussion, because they were already used to the type of environment, either through teaching (school teachers), learning (schoolchildren) or regular meetings through PTA (parents and teachers). The setting (classroom, offices, conference rooms) for the discussions used in this study was similar to the one used in United Kingdom schools during the focus group discussion. Chittleborough and his colleagues (2013) conducted their

focus group discussion during school hours in classrooms and libraries at the school. In addition, the composition of the focus group members were students in Key Stage 1 class (ages 6-7 years) and another group comprising of Key Stage 2 class (ages 9-11). They also involved teachers who were teaching in these two grades (Key Stage 1&2) in the semi-structured interviews. This is similar to the composition of the participants in the current study (SBHHP), in which children from grades 1 and 6 formed one focus group and teachers responsible for these two grades, school staff and parents formed another focus group in each of the three intervention schools.

5.5.1 Theme 1: Working together to develop policy and integrate the SBHHP into the school extra-curricular activities

All participants expressed feelings of happiness at the introduction and existence of the SBHHP at their respective schools. The schoolchildren were excited to participate in the SBHHP. In addition, their guardians felt relieved that their children were taught how to wash their hands at school, and that they were able to take care of themselves. One of the reasons for the excitement among the schoolchildren could be that it was their first time to be introduced to a systematic technique/procedure using the 5-step technique of handwashing. All along they had just washed their hands the way they wanted or the way they had seen their parents wash their hands. For example, one of the teachers had this to say:

“We like the way learners are washing their hands or taking care of their hands, it is like there is a systematic way of washing their hands, not just on the same spot.” (T1H)

A student also shared the following comment:

“Yes, when I wash my hands using the five steps, I saw that my hands were clean and there were no germs or anything. The way we washed our hands in the past is different from the way we wash our hands now; we follow the five steps.” (C6bH)

This could therefore mean that the programme was accepted by the schoolchildren after they had participated in the SBHHP in a supportive school community. In this study, the hand hygiene activities planned in the SBHHP were integrated into the school curriculum to promote handwashing knowledge and techniques during classroom teaching and learning. There was collaboration between the health and education sectors through the health care professionals, school personnel, schoolchildren’s families and the community. This approach has never been adopted by governments in developing countries like Malawi.

In this study, another notable feature was the demand by schoolchildren from grades other than one and six to participate in the project—queuing up to wash their hands at break time, demanding soap, and complaining about increased water bills and the soap running out too quickly—as a proxy measure of the acceptability of the SBHHP among schoolchildren. The most

notable time that these were observed was during the delivery of the session and students' turnout for hand hygiene lessons.

Regarding participant attendance, there would always be a class full of children each time the session was delivered, and the schoolchildren actively participated during both theoretical and practical sessions. At the sink, evidence of the acceptability of the approach emerged in two forms. Firstly, participating children lined up at the sink in order to practise washing their hands using the simplified 5-step. Secondly, children from other classes came closer and surrounded their friends at the sink to observe how they washed their hands.

Participants proposed many suggestions for how the schoolchildren would continue to practise handwashing. Alternative sources of resources for handwashing were the focus of the discussion. Some of the proposals made by the participants in the focus groups were:

“Because some people do not know how to wash hands, we should be able to teach them.” (C6cR)

“I think all is fine. Maybe just add a song to entertain the children or to get them to dance.” (PIH)

“I support what the woman is saying about bringing it up at the PTA meeting so that parents are aware of it. I am suggesting not to bring the soap as such, but for what they are paying in school fees they

have to add a little money, which will be said to be buying soap.”

(T1H)

“I think for this programme to continue very well, because at times we run out of water at school, therefore I would propose that all schools have a borehole.” **(P3H)**

These are important points for the sustainability of the handwashing initiative, because if resources for handwashing are not available, people may not prioritise the practice (CDC, 2016; UNICEF, 2017). This could in turn enhance the linkage relationships between school, family, and community, as highlighted in the whole-school approach of the HPS framework (Lee et al, 2008; WHO, 1996). Participants proposed the need for community awareness and mobilisation. Community involvement and mobilisation are important for the sustainability of any project, because there is ownership of the project by the participants. This theme and the subsequent discussion demonstrate the process of consultation and the multi-disciplinary approach towards the formulation of a policy and incorporating the SBHHP into school curricula. The whole-school approach of the HPS framework advocates use of the three areas of intervention namely; 1) school curriculum, teaching and learning, 2) school ethos, environment and organization, 3) school community partnership and services, which is evident in this study (WHO, 1996). This approach is also paramount to resource mobilisation through community participation and mobilisation.

In this study, it is envisaged that there is a possibility of continuing the handwashing practice among schoolchildren, because the parents and school staff agreed to present the challenges of inadequate resources during the PTA meeting in order to come up with solutions. Knowing that modifying people's handwashing behaviour is a daunting task, especially in a resource-constrained setting, community mobilisation and involvement, as well as multi-sectoral collaboration, can be helpful (Edwards et al., 2012; Taplin et al., 2012).

While many participants in the focus group discussions, which was comprised of parents and school teachers, were concerned with the hardware (soap and water) support for the continuity of the programme, the schoolchildren who participated in the focus group had different ideas regarding the sustainability of the SBHHP. Their concern was about software (knowledge). They thought that dissemination of information about the simplified 5-step technique of handwashing was more important. Students had the feeling that there was a need to reach out to other students from the other grades and from other schools not involved in the current SBHHP. They further stated that project personnel and students themselves should go into the community, including hospitals, to teach people about proper handwashing, because they felt that many people did not know how to wash their hands using the 5-step technique.

Addressing the concerns of both parents (hardware) and schoolchildren (software) would help to make handwashing resources available and promote the uptake of handwashing practice in Malawi and other

developing countries, in turn making the SBHHP an established component of school activity. All this could imply good acceptability of the SBHHP to be incorporated into the school extracurricular activities and be part of the routine activities, as does the qualitative verbatim captured during the focus group discussion. In addition, none of the schools withdrew from the programme, regardless of the long duration (an entire academic year) over which it was delivered, signifying good acceptance.

Resource mobilisation is crucial for successful hand hygiene programme implementation. These findings agree with the results of a study conducted in Kenya by Aunger and his colleagues in 2009. The participants reported that soap was very expensive, and that they did not want their children to wash their hands because they wasted water (Aunger et al., 2009). Kalenga (2012), also found that the main problem in the 11 primary schools involved in his study, conducted in Blantyre, Malawi was failure by the school authorities to pay water bills, which ended up in disconnection by the water supplying company. This underscores the importance of a whole school approach that encourages a multi-sectoral approach and resource mobilization (Lee et al., 2005; WHO, 1996).

A review of the available literature, which was used in Eshuchi's study on handwashing with soap (HWWS) initiatives in Kenyan schools and globally, indicates that a successful HWWS programme depends on factors such as a policy environment that supports services and activities being put in place; infrastructure to ensure both hardware and software; an approach that ensures the participation of stakeholders; and coordination and

management of resources that are available at the school, community and national levels (Eshuchi, 2013). These factors described in Eshuchi's study are a true reflection of the three main area of intervention of the HPS framework (school curriculum, teaching and learning; school ethos, environment and organization; and school community partnership and services) which WHO advocates (WHO, 1996).

Removing the barrier of soap procurement can significantly increase handwashing among schoolchildren (Saboori, 2013). In a study by Aunger and his colleagues (2009), conducted in Kenya, participants stated that seeing soap after coming from the toilet reminded them to wash their hands with soap. In Malawi, several studies have been conducted, in which participants who were provided with hygiene kits (soap, water and hygiene education) demonstrated proper handwashing after the intervention (Masangwi et al., 2009; Loharikar et al., 2013; Russo et al., 2012; & Sheth et al., 2010). However, these studies were conducted among antenatal women and the general community, leaving out schoolchildren, who are very vulnerable because of their immature immunity and the school setting. In addition, these studies did not adopt a multilevel interventions approach in their implementation. This study targeted children in the school setting, and soap was provided throughout the academic year, placed on one sink that was constructed close to the toilet, and another one situated close to the classroom or eating area. The handwashing sinks were constructed through this project. In addition, the simplified, standardised and validated 5-step technique of handwashing was taught to the intervention group. This might have contributed to the sustained handwashing practice observed among the

intervention group.

To promote handwashing practice, the study used reminders such as the teacher's daily talks in class, at morning assembly and at break time. Also, posters describing the 5-step technique of hand washing, the reasons for washing hands, and when to wash hands were displayed on the notice board and in class. Some students took them home in addition to the provision of necessary resources. This approach is believed to have helped to promote hand hygiene compliance, which was the primary outcome of this study. The approach used demonstrates the application of the whole-school approach of the HPS framework through the involvement of the curriculum through training, manipulating the school environment to make it conducive for learning through the construction of handwashing sinks, and also the involvement of parents to form a linkage to the community (Langfield et al., 2014; Lee et al., 2008; 2005; WHO, 1996).

5.5.2 Theme 2: Being committed to the school's hand hygiene programme

During the interviews, the schoolchildren expressed a willingness to share the knowledge about hand hygiene that they had learnt at school with their parents, siblings, neighbours, friends and schoolmates. In addition, the teachers continued to teach the SBHHP to other grades besides grades one and six, which were the target grades for the SBHHP. Teachers were committed to teaching students several times a day, even if the research team was not available. This was successful because the SBHHP was

considered as part of the extracurricular routine, which is one of the area of intervention of the whole-school approach of the HPS framework. In addition, teachers reminded the children to wash their hands at the morning assembly, before eating, after visiting the toilet and after playing at break time. This contributed to successful implementation of this study. These findings are supported by the results of a study conducted by Chittleborough and his colleagues (2013), in which participants mentioned that supervision and reminding schoolchildren to wash hands helped to increase the practice. Besides being reminded by their teachers, students in this study also reminded each other about getting ill if they started eating their food before washing their hands.

It is easy for children to learn, and they are always willing to acquire new life skills, especially if edutainment is used (Bandura, 1997). Besides edutainment, the provision of resources, role models, peer learning and the simplicity of the 5-step handwashing technique in this study helped to raise enthusiasm among the schoolchildren and promoted learning and practice about hand hygiene (Bandura, 1997). The schoolchildren managed to gain the necessary knowledge and skills, which they later transferred to other students, to their siblings at home, and to their parents and friends in the neighbourhood from other schools not involved in the SBHHP. Eshuchi's study, which was conducted in Kenyan schools in 2013, states that young children are role models for their siblings in the home environment, as an older sibling can act as a change agent to influence their sibling's health behaviours. In this study, schoolchildren tried to influence the handwashing

behaviour of their friends, parents and siblings, as evidenced in the following quotes:

“When playing, she calls her friends over and starts demonstrating what she was taught at school about the 5-step of hand washing.”

(P2H)

“If you wash your hands like this (parent demonstrating the old way), then you will hear from the child, “Mum, mum! You have not washed your hands! You are supposed to do it like this—this whole area (parent demonstrating five-step as taught by child).” (P2W)

In contrast to our findings, a study conducted in Zimbabwe by Friedrich and colleagues (2017) found no overwhelming evidence that schoolchildren performed a powerful role as change agents for handwashing promotion. However, the authors further stated that there could be an additional effect of direct handwashing promotion as a result of the involvement of schoolchildren (Friedrich et al., 2017). They attributed this to an unwillingness of parents to take advice from their children. Use of schoolchildren to reach out to a community in promoting handwashing is rare; instead, many researchers directly target the community regarded as custodians of the schoolchildren.

The parents who participated in the focus group in this study (SBHHP) stated that they took instructions/advice from their children to procure soap for handwashing and allowed their children to teach them and their siblings the 5-step of handwashing. The difference between these two findings could

be due to cultural differences and also parental attitudes towards their children. Previous studies have demonstrated that children can be good role models who transfer the knowledge and skills they learn at school to friends, siblings and parents back home (Patel et al., 2012; Eshuchi, 2013).

This study therefore provides additional evidence that through schoolchildren, there is a potential to embrace the hand hygiene practice in the community and improve proper handwashing and handwashing behaviour compliance. In addition, this study shows that when children and parents work together, there is more commitment towards the handwashing practice.

5.5.3 Theme 3: Practising proper handwashing technique as routines

There was an impression that behaviour change took place among schoolchildren based on the comments from the participants. The change in handwashing practice was prevalent and sustained among the schoolchildren three months after the intensive implementation of the programme. This was manifested through the sentiments of the participants, but also by the quantifiable results, which showed sustained improvement in hand hygiene compliance three months after the implementation was stopped (in the 9th month). For example, one of the parents said:

“And since that time, each time he comes from the toilet, he always goes to the sink, washes his hands and asks his brother—he has an older brother—have you washed your hands?” (P4R)

Another participant had this to say:

“In the past we could make them wash their hands, but now they remember themselves.” (T1H)

This observed change in handwashing practice could be attributed to the intensive software (training) and hardware (sinks, soap) support given to the schoolchildren throughout the academic year, because the school ethos, environment and organization, are paramount in the successful implementation of hand hygiene programmes in school (Langford et al., 2014; Lee et al., 2008; WHO, 1996). Creating an environment conducive to learning is also described well in chapter two of this study under Bandura’s social learning theory and Ajzen’s theory of planned behaviour (Ajzen, 1988; Bandura, 1997). Handwashing becomes a challenge in settings with few resources and little water access. It is expected, therefore, that by providing resources (soft and hardware), handwashing behaviour and compliance among schoolchildren will improve. The provision of resources promises to be a workable solution to increase handwashing behaviour among schoolchildren (Pickering et al., 2013). The findings of this study are consistent with those of a study done in England by Chittleborough and colleagues (2013). They found that the attractiveness and cleanliness of the facilities encouraged handwashing among schoolchildren. They further stated that the accessibility of handwashing facilities could have a positive impact on handwashing practice (Chittleborough et al., 2013).

In this study, at least two sinks were constructed for each of the schools that did not have any. One sink was constructed close to the toilet, and another close to the eating area or classroom, and they were easily accessible to the schoolchildren. In addition, soap for handwashing was provided throughout the 2016/2017 academic year. In this study, the children stated that they would continue to wash their hands with soap and water, and that they would continue to tell friends, neighbours and family about washing their hands following the 5-step technique, signalling good adoption of handwashing practice among these children.

5.5.4 Theme 4: The benefits of SBHHP

During the interviews, parents stated that their children demanded that handwashing resources be bought for home use. For instance, one parent who participated in the focus group discussion said:

“He said, “We have been told to wash our hands, so you have to buy me Lifebuoy soap for washing my hands.” (P4R)

This could mean that in the homes of most of the schoolchildren who participated in this study, it is possible that handwashing was not emphasised, and that the use of soap for washing hands was rare. However, after the children were exposed to the SBHHP, in which the use of soap was emphasised, they realised the importance of washing hands using soap, hence they went on to demand that their parents buy soap to use for handwashing in the home.

In addition, children wanted everyone in the home to do what they were taught at school regarding the 5-step technique of handwashing. For example, one of the parents who participated in the focus group discussion said the following:

“They make sure that each and every one should do what they have learnt here at school, which shows that they have mastered the programme/procedure and have internalised it.” (P3H)

Another parent shared this:

“Actually, it’s the kid that is insisting and advising us that by all means we must continue. Obviously, we see the good in that—why not?” (P2R)

This could mean that information on handwashing that was given to a child at school managed to reach their home and change the situation regarding the procurement of handwashing resources in the home. In addition, parents were now able to appreciate the value of handwashing introduced by their children. The school setting is one of the preferred routes of communication for reaching communities (Eshuchi, 2013). Research indicates that children are also proactive in making efforts to influence people around them, especially in the school or home setting (Karama, 2011, 5, quoted in Eshuchi, 2013). This would be a positive direction to take in developing countries, where little attention is given to handwashing with soap (Malawi Ministry of Health, 2011). Since parents normally listen and respond to the demands made by their children, they are likely to procure handwashing resources and make them available for the sake of their children. This would consequently increase attention and prioritise handwashing resources and

practice in both home and school settings. In return, hand hygiene compliance could improve.

In this study, the schoolchildren were also role models, not only to parents and siblings at home, but also to children from the other grades at school, who were not directly involved in the SBHHP. The other schoolchildren learnt proper handwashing technique through observing others at the sink during break time, as quoted in this verbatim:

“You see, when they are washing their hands at the sink, their friends who have not officially learnt are curious to know what is happening. They say, “Let me try too!” and in the process they learn through their friends.” (T3H)

This observation is supported by the statement made by participants in a study by Chittleborough and his colleagues (2013), in which participants thought that seeing other people wash their hands positively influenced handwashing. In this study, learning was promoted by observation, as enshrined in Bandura’s social learning theory (Bandura, 1977). Schoolchildren were encouraged to interact freely, demonstrating to others even during assembly time, while providing a conducive environment for role modelling to take place.

The schoolchildren and school staff stated during the focus group discussion that the SBHHP helped to reduce illnesses such as diarrhoea and flu, leading to a reduction in absenteeism among children at school. For example, one of the parents who had participated in the focus group discussion said:

“To us, this programme has helped to reduce diseases compared to our usual traditional method of hand washing, where one basin could be used by 20 people to wash their hands.... My child now has reduced suffering, especially from coughing/flu”. (PIH)

In this study, the use of running water was promoted because this is the most hygienic practice. Running water from a safe source is rarely contaminated, because people wash to waste, as opposed to keeping the water in containers or a basin. For example, a study conducted by Friedrich and his colleagues (2017) in Zimbabwe found that participants who used direct tap water to wash their hands were cleaner and more effective in removing microorganisms than participants who either dipped their hands in a vessel or manually poured water on their hands. Use of running water was also promoted in a study by Masangwi, Morse, Ferguson, Zawdie, Grimason and Namangale (2009), in which they investigated the behavioural and environmental determinants of childhood diarrhoea in Chikwawa, Malawi. They found that participants who used running water from a tap (OR 1/4 0.10, 95% CI: 0.02, 0.53) for washing hands were less likely to have suffered diarrhoea than those who used cups to pour water from containers (Masangwi et al., 2009). However, it is worth noting that their hygiene promotion study was conducted among household members in the community, unlike this study, which targeted schoolchildren in a school setting.

In addition, one of the students who participated in the focus group discussion stated:

“No, when we wash our hands following the 5 steps, all the germs are removed; when you are then eating nsima (food), you eat without germs, hence you reduce your chances of suffering. Washing hands the old way means some of the germs remain on the hands, and when eating nsima you eat it together with the germs.” (C6aR)

These findings are consistent with those of Chittleborough and his colleagues (2013), namely that participants understood that washing hands was significant in preventing illness. There is overwhelming evidence from previous studies to support the sentiments made by the participant in support of the effectiveness of proper handwashing with soap to reduce infectious diseases (Bloomfield et al., 2007; Burton, 2011; Cairncross et al., 2010; Mbakaya et al., 2017; Rabie, 2006). Literature further emphasises that handwashing is the single most important action and primary measure a person can perform to reduce the spread of infectious diseases such as diarrhoea, influenza and other respiratory illnesses (Lee & Lee, 2014). The benefits of handwashing go beyond just reduction of morbidity and mortality rates to include also the reduction of school absenteeism, thereby improving school performance. That is why handwashing is regarded in public health as a cornerstone, due to its ability to break the transmission cycle of many infectious diseases (Malawi Ministry of Health, 2011). The findings in this study therefore add value and confirm that the use of a simplified 5-step technique in handwashing, applied within the social cognitive theory by Bandura and the theory of planned behaviour by Ajzen, can provide an impetus in health promotion campaigns, especially when applied in the context of the multilevel interventions approach. The more

people realise the health promotion benefits of handwashing, the more likely they are to practise proper handwashing, because it serves as a motivational factor.

5.6 Rigorous study design to measure hand hygiene outcomes in developing countries

While other studies have evaluated the whole-school approach in the HPS framework, this is the first cluster RCT conducted in Malawi, sub-Saharan Africa, and many other developing countries to evaluate the efficacy of a SBHHP for children – the most rigorous study design for assessing intervention effectiveness. Using this rigorous study design, the results show that a hand hygiene programme in schools can play a significant role in averting some of the public health challenges, such as handwashing non-compliance and illness related school absenteeism. This is evident in this study through significant sustainability test results at the 9th month ($p < 0.05$) for the compliance outcome measure (knowledge quiz score, handwashing technique score, and hand cleanliness score). It is important to generate evidence using a rigorous study design, such as a cluster RCT. This study finding reported a critical intervention strategy that is consistent with the study done on the impact of a school health programme by Langford and colleagues in 2014.

The participants in this study were typical schoolchildren in the Malawian context, similar to those in many private primary/elementary schools in sub-Saharan countries, which may allow the findings of this study to be

generalised among the private sector (self-sustaining schools). The non-response rate, calculated as missing completely at random (MCAR), was not significant (chi square = 201.44, $df = 381$, $p > .05$) and was far less compared to the 20% non-response rate that was determined in a study done on students' health and hygiene practices in Kenyan primary schools (Patel et al., 2012). Many children were willing to participate in this study, as evidenced by both the numbers and the comments from the qualitative discussion. This could be the reason for the high response rate, as well as an indicator of the acceptability of the SBHHP by children, staff and parents in schools in Malawi. The high participation rate could be attributed to the edutainment method used according to Bandura's social learning theory and Ajzen's theory of planned behaviour, which were applied in this study. The songs that were sung by the interventionist and the schoolchildren themselves, and the interactive delivery of both theory and practical aspects in class and at the sink respectively made the schoolchildren excited and happy with the programme. The approach motivated the students through songs and empowered them with self-efficacy through training (Ajzen, 1988; Bandura, 1997). As a result, they did not want to miss any sessions. This is evident in the verbatim quotes from the schoolchildren during the focus group discussion, in which they stated that they liked the programme because of the song.

In addition, the participant foresaw the benefits of the programme through the weekly education session, such as prevention of diarrhoea and influenza. This agrees with Bandura's social cognitive theory, used in this study, which states that humans are active information processors and think about

the relationship between their behaviour and its consequences in order to get motivated and act (Bandura, 1977). The schoolchildren in this study vehemently stated in the qualitative verbatim that they were participating in this programme because they wanted to wash their hands with soap and avoid getting diarrhoea and influenza germs, or dirt on their hands. Students in this study further stated that compared to the past, now they experience fewer frequent coughs and less influenza after participating in the SBHHP. All these reasons might have contributed to the children's continued participation in the study throughout the entire academic year (2016/2017) when the SBHHP was in effect.

Minimal missing data was achieved because the research assistants made efforts to follow up on those who did not report to school on the day of data collection. Another day was re-arranged with the school authorities to meet students who were absent on the day of data collection. In addition, the research team ensured that each form was completely and correctly filled. The photos and video clips captured during data collection were counted and cross-checked against the number of participants before leaving each data collection site, to make sure no students were missed. The two groups (intervention and control) were similar at baseline, which warrants cause and effect conclusions to be made on the observed difference on the outcome measures after implementation of the SBHHP.

The internal validity of this study can be considered as high, taking into account the trial's cluster RCT design, baseline balance between the intervention and the control groups on baseline characteristics of the clusters

and individual participants. The similarity of the two groups at baseline, warrants the cause and effect conclusions to be made on the observed difference on the outcome measures after implementation of the SBHHP. The study used identical procedures in both groups except the intervention. There was controlled contamination and blinded the assessors and allocation concealment.

External validity was also high. Inclusion criteria for the private school was inclusive, so that most private primary schools located within Mzuzu City were eligible and included in the computer-generated randomization plan. All student's parent who were contacted agreed to participate in the SBHHP except one parent. The programme relished a high level of programme acceptability to the schoolchildren, school personnel and parents. Thus, the study results are generalizable to private schools in Mzuzu City, Malawi.

Lee and colleagues stated in their study that a rigorous approach to generate evidence on HPS by measuring the outcomes with both quantitative and qualitative data to check the acceptability of the school health programme has been lacking in many previous studies in the last two decades (Lee et al., 2008). In this study, a cluster randomised controlled trial design was employed, with a nested focus group discussion. A total of six schools participated in the entire study. None withdrew, representing 100% participation. The lack of dropouts was a strength of the study, because dropouts would have meant compromising the power of the study due to the reduced number of clusters, since a study with a larger number of clusters is better able to distinguish intervention effects than a study with fewer

clusters (Christie et al., 2009). Each school had at least one tap with reliable running water from the same source, supplied by the Northern Region Water Board for all the schools. Use of the same source of water for all the schools helped to reduce the explanatory confounders of the results of the intervention used in our study. This further justifies the comparability of the results between the intervention and control groups, meaning that the resulting outcome was certainly due to the intervention. The water was easily accessible to all children in all six schools involved in this study. This was done to balance the baseline characteristics of the sites and render them homogenous for possible comparison and detecting the effects of the intervention (Giraudeau & Ravaud, 2009). In addition, extra sinks were constructed where there were none or was only one sink, in order to increase the number of sinks and thereby ease congestion and waiting times when children were washing their hands at break time. The constructed sinks were at a height of approximately one metre, to ensure that schoolchildren in grade one could easily reach the taps and wash their hands without difficulties or wetting their clothes, which would in turn become a barrier to handwashing among schoolchildren. The shortest distance between schools involved in this study was approximately one kilometre, while the most distant schools were approximately eight kilometres apart. This is very significant to this study, because the distance helped to reduce interaction among schoolchildren from the intervention and control clusters, in turn reducing the chances of contaminating the intervention. The total number of teachers per school ranged from 11 to 20. It is important to know the number of teachers, because they play a leading role in the adoption and sustainability of programmes at school. If there are few teachers, they tend

to be under strain and are not motivated to teach. This was revealed in a study done in United Kingdom (UK) primary schools, where constraints and competing health issues were identified as barriers to implementing intensive hygiene interventions. The study also stated that the motivation of teachers to teach hygiene and enforce hygienic behaviour among schoolchildren was primarily educational rather than immediate control of infection (Schmidt et al., 2009).

In this study, teachers were involved in the planning, implementation and monitoring role using the elements in the HPS. Hence forming part of the microsystem (immediate environment) of the student according to Bronfenbrenner's ecological system's theory (1987). Teachers also reminded schoolchildren to wash their hands at recommended times, such as before eating, after visiting the toilet and after playing at break time. Morning assemblies were used as avenues by teachers to reach many students at once with the benefits and risks of health messages related to hand hygiene. This approach might have contributed to the effective outcome of this study and satisfied a very important element of the whole-school approach in HPS: ethos and curriculum (Lee et al., 2008; WHO, 1996).

The baseline characteristics of the schools involved in this study are comparable to those in a study conducted by Kalenga (2012) in Blantyre, Malawi. The purpose of his research project was to assess the successes and failures of WASH in Malawi primary schools. He found that all 11 schools involved in his study had a reliable source of water supplied by a tap, a

borehole, or both. He also found that water was accessible to the schoolchildren and well positioned at distances of 5-20 metres from a classroom. Only two schools had handwashing facilities, and none had handwashing soap. The characteristics of the schools involved in this study can therefore be compared to those in the study by Kalenga, which was conducted in Blantyre, Malawi. The findings of his study further proved that there was little progress in primary school WASH, and additional commitment would be required. He recommended that primary school WASH needs a collaborative effort among various stakeholders, like pupils, teachers, government, NGOs, water utility companies and local councils. Failure to address WASH challenges in Malawi primary schools can affect pupils' school performance (Kalenga, 2012). It is worth noting that the recommendations made by Kalenga in his study are typical of the domain of HPS, which WHO advocates (WHO, 1996), and the multilevel interventions approach used in this study (SBHHP).

5.7 The benefits of adopting a multilevel interventions approach

An intervention is multilevel if it addresses the individual client, as well as at least two levels of contextual influence, such as organisations and providers, thereby targeting at least three different sources of influence (Edwards et al., 2012; Taplin et al., 2012). Multilevel interventions influence the interdependent interaction of different stakeholders in order to produce desirable health outcomes (Clauser et al., 2012).

In this SBHHP study, the delivery of the intervention targeted four different contextual levels of influence (individual, group, community and organisation) the health outcomes: the students themselves through peer learning, the research team, the school staff, and the parents. Owing to these multilevel interventions approach, this study managed to produce significant results on the primary outcome measure $p < 0.05$. The significant results of the primary outcome of hand hygiene compliance of this study also support the affirmative effects of using a multilevel interventions strategy to implement health promotion activities on children's hand hygiene at the school community level. (Edwards et al., 2012; Taplin et al., 2012).

The study findings of the multilevel approach are similar to five key action strategies in the WHO's Ottawa Health Promotion. These five key areas in health promotion are: 1) build healthy public policy, 2) create supportive environments for health, 3) strengthen community action for health, 4) develop personal skills, and 5) re-orient health services) and three basic HP strategies (to enable, mediate, and advocate) (WHO, 1986). Overall, the logo visualises the idea that Health Promotion is a comprehensive, multi-strategy approach. Health promotion applies diverse strategies and methods in an integrated manner - one of the preconditions "for Health Promotion to be effective" (Jakarta Declaration, 1997). Health Promotion addresses the key action areas identified in the Ottawa Charter in an integrated and coherent way (WHO, 1986).

This study put much emphasis on application of the multilevel interventions approach based on Bronfenbrenner's social system theory and the three

areas of intervention within the schools and outside the communities of the WHO's HPS framework. The three areas of intervention of WHO's HPS Framework (1996) are: are 1) school curriculum, teaching and learning, 2) school ethos, environment and organisation, and 3) school community partnership and services, as previous studies have not addressed any of these in their outcome measures for intervention studies on hand hygiene among schoolchildren in developing countries like Malawi, sub-Saharan Africa.

5.8 Key component of the WHO's HPS framework on school curriculum, teaching and learning

A formal health curriculum helps students develop the knowledge, attitudes and skills needed to make healthy choices (WHO, 1996). In this study, schoolchildren were taught about proper hand hygiene, with an emphasis on using soap, clean water and following the 5-step technique of handwashing. The education content covered the why, how and when to wash hands. This helped to increase students' self-confidence and self-efficacy according to Ajzen's theory of planned behaviour (Ajzen, 1988), and Bandura's social learning theory (Bandura, 1977).

It was possible to achieve statistically significant results on the hand hygiene compliance in this study because of the use of the whole-school approach of HPS framework, one of whose area of intervention advocates for curriculum, teaching and learning (WHO, 1996). For example, the intervention included developing a hand hygiene protocol and incorporating

iy into a school extra curriculum, training of schoolchildren, in which there were demonstrations and return demonstrations, peer learning, and the use of reminders and songs that formed part of the routine extracurricular activities, one of the important area of intervention of HPS (IUHPE, 2008; Lee et al., 2005).

Curriculum, teaching and learning is a critical component of the HPS framework. This domain of the HPS framework plus the school ethos, environment and organisation as well as school community partnership and services (engaging family and community) enhances effective implementation of the school-based programmes as evidenced in this current study on SBHHP.

During the session delivery, the researcher managed to deliver all weekly sessions as planned. There was good support from the school authorities and teachers during each session. The school authorities made sure that the training sessions for students were not interrupted with other activities. Teachers were very helpful in promoting and monitoring the impacts of the SBHHP, and they delivered the sessions to other classes at their own time, as well as reminding the children on a daily basis in class and during morning assembly. All this could signify that the school staff were interested and welcomed the SBHHP. Working with school authorities is critical in establishing school-based health promotion programmes in the curricula (Lee et al., 2005; WHO, 1996).

5.9 Key component of the WHO's HPS framework on school ethos, environment and organization

The school ethos, environment and organisation of the school that promote the health and wellbeing of students and staff in the informal curriculum consist of values and attitude promoted within the school and the physical environment and setting of the school, such as providing hand hygiene resources to promote proper handwashing technique (WHO, 1996). In this study, this domain was achieved through promotion of health messages beyond the classroom in the wider school environment. For example, there were posters, information displays, and school assemblies, and teachers were trained on the SBHHP. This study also used peer-led activism among students. Changes to the physical environment of the school were also implemented, for example the provision of handwashing soap to schools for the entire academic year, construction of water pipes, construction of handwashing sinks, and water bills paid in some situations to facilitate handwashing.

Use of resource modality with support from the physical environment in the school has proven to be a successful approach to the implementation of SBHHP, as evidenced by the positive results in this study. This also attests to the importance of one of the HPS components of school ethos, environment, and organization (Langford et al., 2014; Lee et al., 2008; WHO, 1996). The school ethos, environment and organisation of the school emphasises the fact that the health and general well-being of schoolchildren and school personnel are promoted through the values and attitudes

promoted within the school and the physical environment and setting of the school (Langford et al., 2014).

The results of this study are similar to findings in studies conducted by Oswald and his colleagues in 2008 and O'Loughlin (2006), which identified inadequate resources such as water, soap, hand rubs and hand hygiene facilities as some of the barriers to children's handwashing practice. Provision of such resources would promote hand hygiene practice (O'Loughlin, 2006; Oswald et al., 2008).

Reports by the CDC (2016) and UNICEF (2017) further emphasize that where water or water stations are not readily available, people may not deem handwashing a priority. In this study, barriers to handwashing were reduced by providing the necessary resources such as soap, water for handwashing and construction of handwashing stations. Bandura's social learning theory, Ajzen's theory of planned behaviour and the HPS also stipulates the significance of equipping the environment with the necessary resources and support to make it conducive to learning through observation and sustenance of behavioural change resulting from motivation and self-efficacy (Ajzen, 1988; Bandura, 1977; Langford et al., 2014; WHO, 1996).

This multilevel intervention approach based on Bronfenrenner's social system theory has integrated the principles of WHO's whole-school approach of HPS (WHO, 1996) to provide training on proper handwashing technique for schoolchildren and accessible environments for performing proper hand hygiene in their daily living in the school settings. The study

also measured the intervention's effectiveness by measuring the sustainable impact of children's school absenteeism and their acceptability of the hand hygiene programme in the school setting as these measures are missing in many studies (Langford et al., 2014).

Apart from the research team, teachers reminded the children several times a day to wash their hands. The children were empowered to learn from each other. In addition, there was a continued supply of handwashing resources throughout the academic year (2016/2017). The availability of handwashing resources helps to promote handwashing behaviour, because people will prioritise the practice (CDC, 2016; UNICEF, 2017). In this study, the school ethos, environment and organisation laid down for the implementation of the SBHHP, led to successful and significant results in terms of students' hand hygiene compliance. The findings are similar to the results in a study by Halder, Tronchet, Akhter, Bhuiya, Johnston, and Luby (2010), who found that economic status and the availability of handwashing resources were significantly associated with hand cleanliness. Another study, conducted in Kenyan schools, found that the proportion of schoolchildren who were observed practising handwashing with soap was significantly higher in schools that received a soap intervention compared to in schools that did not receive a soap intervention (Saboori et al., 2013).

In this study, the school ethos and school physical environment were manipulated as required in the whole-school approach of the HPS framework, so as to create a conducive environment for learning to take place (WHO, 1996). The changes instituted in the school environment in

this study included promotion of hand hygiene messages beyond the classroom in a wider school environment, for example, via posters, information displays, and school assemblies, teachers were trained on the SBHHP. The researcher also used peer-lead activism among students. There was also role modelling from peers, teachers and the research team. In this study, changes to the physical environment of the school were also implemented, for example the researcher provided handwashing soap to schools for the entire academic year, constructed water pipes, constructed handwashing sinks, and paid water bills in some situations to facilitate hand washing. This was done in order to promote health and wellbeing of schoolchildren through hidden or informal curriculum which encompassed values and attitudes promoted within the school and physical environment and setting of the school.

5.10 Key component of the WHO's HPS framework on school community partnerships and services

School community partnerships and services refers to engagement with families, non-governmental organisations (NGOs) and community stakeholders to promote children's health in school communities (WHO, 1996). In this study, parents were reached through schoolchildren by giving them the take-home package, which contained the same information that was given to students at school. The information contained was on how, why and when to wash hands. An information sheet was also given to parents with detailed information to read and understand before consenting to their child's participation in the SBHHP. Focus group discussion with

schoolchildren, parents and school teachers solicited their opinions, suggestions, challenges and opportunities, which helped to advise policy making and the incorporation of the SBHHP into the school curriculum and evaluate the acceptability of implementing the SBHHP in primary schools in Malawi. There was a planning meeting with the directors of the private schools, and the researcher also discussed the SBHHP with the private school committee responsible for the whole northern region of the Independent Schools Association of Malawi (ISAMA).

The findings of this study agree to the recommendations made by Grimason and colleagues (2012) conducted in two primary schools in Malawi to determine; (1) presence of *Escherichia coli* on the hands of 126 primary school pupils, (2) knowledge, awareness and hygiene practices amongst pupils and teachers and (3) the school environment through observation. They found that pupil appreciation of hygiene issues was reasonable; however, the high percentage presence of *E. coli* on hands (71%) and the evidence of large-scale open defaecation in school grounds revealed that apparent knowledge was not put into practice. However, the authors recommendations for future studies which are in line with the whole school approach of the HPS frame work, especially the domain that advocates for linkage to the community for effective results. Grimason and colleagues concluded that in order to improve sanitation and hygiene, and, therefore, reduce the spread of diarrhoeal diseases in schools in Malawi, a multidisciplinary approach is required, including: (1) appropriate design, construction and location of sanitary and hygiene facilities; (2) incorporation of hygiene education into teacher training and school curricula

activities; (3) reinforcement of health and hygiene messages with pupils in all school activities; (4) implementation of pupil led hygiene initiatives, e.g. sanitary surveys and action plans; and (5) involvement of community health workers (both government and voluntary) with school activities to promote hygiene messages. In the current study (SBHHP) all the three domains of the HPS framework were applied and produced effective results on all the outcome measures. The activities implemented in this study under the three domains, are similar and reflects the recommendation made in the study conducted by Grimason and his colleagues (2012) as already described in this paragraph. For example, in the current study, the researcher (1) constructed water pipes and appropriate handwashing sink to the relevant height suitable for young children; (2) incorporated hygiene education into extra- curricular activities; (3) reinforced education by training students; (4) encouraged peer activism; (5) the community linkage, was achieved through engagement with the parents, through PTA and ISAMA.

Providing theory/education only may not be enough but training should be tailored to the target community. WHO recommends partnerships and services engagement with families and/or communities, non-governmental organizations (NGOs) and community stakeholders in promoting child health in the school communities (WHO, 1996). The HPS domains of engagement of families, communities (school community partnership and services) have proven to produce effective intervention outcomes if the protocol is properly applied (Langford et al., 2014; Lee et al., 2008; 2006; 2005; WHO, 1996).

5.11 Success of SBHHP leading to WHO's HPS establishment in

Malawi

Results of the SBHHP using the multilevel interventions approach show significant effect on the study outcomes at different contextual levels such as organisation (resource mobilisation, hand hygiene protocol, training), community (community/family linkage, supportive environment), group (peer and social influence) individual level (improved hand hygiene compliance, reduced sick leave days). These significant results provide evidence for the need to fully establish the WHO's HPS framework in all schools in Malawi. Once the HPS framework is established and adopted by the schools and its stakeholder including the government would help to enhance the expansion of the SBHHP to other government subsidised schools, in which resources are a big barrier. This would contribute to an improvement in hand hygiene compliance (knowledge, technique & hand cleanliness) among schoolchildren and reduce sickness related school absenteeism on a larger scale in Malawi. The future direction of research taken and recommended by this study agrees with the findings of a study conducted by Lee and colleagues (2008) in Hong Kong. Their study substantiated that schools participated in HPS activities through the HSA scheme in Hong Kong had more favourable hygiene practice of students, school environment and atmosphere in health and hygienic practice (Lee et al., 2008).

Considering the barriers (resources) to hand hygiene practice in developing countries, through this study constructed water pipes, handwashing stations

and provided handwashing soap. For scaling up and sustainability of this approach, there is need for whole school approach of the WHO's HPS, with multilevel interventions approach which advocates amongst others a supportive environment. Therefore, this study provides evidence to support setting approach to improve health and the importance of supportive environment. The significant outcome of the SBHHP would pave the way to advocate for more school-based initiative leading to a fully established WHO's HPS framework approach. The SBHHP is an intervention beyond conventional classroom learning covering skills development. It is kind of experiential learning and has the capacity to create a subjective and objective norm (Ajzen, 1988). This type of teaching and learning (applied in SBHHP) is needed by schoolchildren to acquire social learning and have the motivation and intention to change (Ajzen, 1988; Bandura, 1997) as evidenced in the results of this study. The findings from a study conducted by Lee and colleagues (2006) suggest that if the HPS framework is fully adopted, then it is very likely that there will be significant benefit in health and educational outcomes (Lee et al., 2006).

The challenges associated with hand hygiene practices call for multilevel research that advocates for policy development, adequate training, supportive environment and resource mobilisation to promote hand hygiene compliance embraced in the whole school approach of the WHO's HPS (Lee et al., 2008; Lee et al. 2006; IUHPE, 2008; WHO, 1996).

5.12 Summary of chapter five

This chapter presented a discussion of the study findings using the multilevel interventions approach based on Bronfenrenner's social system theory targeted the four contextual levels in the school community. Relevant literature to support the discussion was cited accordingly. The SBHHP needs to be given attention by relevant stakeholders and adopted in schools in Malawi and other developing countries to increase the uptake of handwashing compliance. There is a high possibility for adoption of the programme, since it found high acceptance among schoolchildren, school personnel and parents, as evidenced by the verbatim quotes and quantifiable results. The impacts of the SBHHP were discussed relating to the study objectives and hypotheses by comparing them to the previous results on handwashing intervention studies to claim new knowledge generated in this study.

The next chapter (chapter six) presents the limitations of this study, implications for nursing practice, recommendations for future studies, and the conclusion.

CHAPTER SIX

LIMITATIONS, RECOMMENDATIONS, POLICY IMPLICATIONS AND CONCLUSIONS

6.0 Introduction

This is the last chapter of thesis. It presents the limitations of the study, policy implications, recommendations for future studies, and conclusions.

6.1 Limitations

While this study was executed and reported using rigorous scientific methods, there were some limitations that were beyond the control of the researcher. The first is that a single-blinded assessor was used to score the video clip depicting the 5-step handwashing technique (skill acquisition) of schoolchildren. As such, no inter-rater correlation for reliability analysis could be calculated, unlike in the fluorescent stain score (hand cleanliness), where five blinded assessors were used and inter-rater correlation for reliability test was performed. Secondly, observational bias (Hawthorne effect) may have resulted in increased proper handwashing, including skill display, because participants knew that they were being observed through photography and video capturing. Thirdly, there may have been a possibility of recall bias across time, especially on the quiz. The fourth limitation is that the study was conducted in private schools only, which could be different from government-subsidised public schools in terms of educational

background, available resources, environment set-up of the school and the school culture. As such, the results of this study may not be able to be generalised to public schools.

6.2 Implications for future practice, research, training and policy

The SBHHP has shown to be effective in improving proper handwashing compliance (knowledge refers to the scores of handwashing quiz; skill/technique refers to the scores of handwashing observational checklist; and hand cleanliness refers to the scores of the fluorescent stain test on both hands) among schoolchildren in Malawi. The findings of this study provide new evidence for the public health agenda using multilevel interventions approach to facilitate the development of hand hygiene protocol and incorporate it into the school curriculum to reinforce and monitor proper handwashing technique for schoolchildren in developing countries. The simplified five-step of handwashing may provide an alternative solution to conventional handwashing practice to enhance proper handwashing technique. The multilevel interventions approach provides an impetus for health promotion campaigns to improve practical knowledge and specific life living skills among vulnerable groups. In addition, these findings may also inform school health workers and community stakeholders as they plan relevant interventions targeting specific groups in terms of what works best in what circumstances to prevent and reduce infectious disease outbreaks in school communities, especially in developing countries. In addition, future practice may consider areas of intervention of the WHO's HPS using the

whole school, especially in developing countries, where the schoolchildren's compliance with hand hygiene remains poor.

6.3 Recommendations

The future studies should scale up to all the public schools in other developing countries using the multilevel interventions approach to strive for the attainment of HPS. The simplified 5-step handwashing technique should also be introduced for children with disabilities in special schools in developing countries. The availability of manpower resources is a critical factor in planning and implementing hand hygiene programmes especially in developing countries where resources are limited. As such, the researcher recommends that the school coordinator and governments' stakeholders, city assemblies, parents and water boards (multi-disciplinary approach) to ensure that resources such as water, soap and sinks are available to promote handwashing. There is a need to reinforce behaviour that has been learnt by schoolchildren, by making sure that hand hygiene protocol covers the strategies used in this study to promote hand hygiene. There is a need for the government of Malawi to consider adopting the simplified 5-step handwashing technique as a standard for handwashing procedure in the country, rather than the current 7-step technique, which students are expected to use but have seldom practised. This study findings of multilevel functions on the role of policies, training and resources can be a new framework for child health promotion in building capacity and foundations of early childhood health.

Future studies should consider using more blinded assessors for rating the handwashing technique scores. There is also a need to conduct similar studies targeting children in paediatric wards, in order to reduce hospital-acquired infections. More stringent methods of monitoring absenteeism data are also recommended in order to measure the school absenteeism rate due to infectious diseases that occur due to poor hand hygiene practice. Use of the whole school approach in the WHO's HPS framework integrated into Bronfenbrenner's Ecological Systems Theory is highly recommended for future studies especially in developing countries in order to scale up population to promote effective hand hygiene practice. Finally, use of multilevel interventions approach in other life living behavioural change intervention is recommended.

6.4 Conclusion

The SBHHP is one of the most effective strategies for promoting hand hygiene compliance and reducing infectious diseases among schoolchildren, thereby reducing sickness related school absenteeism. The results of this study suggest that the implementation of SBHHP using multilevel interventions approach has shown evidence of increased hand hygiene compliance (knowledge: score on handwashing quiz; skills: observational checklist: score on handwashing technique; fluorescent stain test: hand cleanliness score) and advance public health. The significant outcome of the SBHHP would pave the way to advocate for more school-based initiative leading to fully established WHO's HPS framework in Malawi. The whole-school approach in the health-promoting school framework, as well as using

the social learning theory and the theory of planned behaviour were also applied in this study. A whole-school approach of the WHO's HPS framework is often discussed as a strategy of health promotion in the literature.

The results of this study also suggest that health education in a supportive school environment to implement a hand hygiene programme with health experts' input is one of the most consistent and influential characteristics influencing schoolchildren's competency and compliance in performing proper handwashing technique in schools, especially in developing countries like Malawi. The SBHHP with expert advice and adequate facilities for hand hygiene has provided additional evidence in the public health agenda for incorporating a SBHHP into the school health policy to reinforce and monitor proper hand hygiene, and especially to promote proper hand hygiene practice among primary school students in developing countries. The results provide an impetus for health promotion campaigns to enhance lifestyle behaviours among vulnerable groups and increase handwashing practice in developing countries. School-based hand hygiene programmes should be integrated within a formal student welfare support structure and link students with relevant community agencies for support and assistance when they need it.

6.5 Summary of the thesis

This study evaluated the efficacy of a SBHHP using a multilevel interventions approach targeting schoolchildren, schools and their families in the intervention group versus the routine hand hygiene practice in the control group at four-time point (T₀, T₁, T₂ & T₃) for schoolchildren who participated in this study in Malawi, sub-Saharan Africa. In chapter one, the background of the study was presented, along with the purpose of undertaking this research project. The objectives that this research was trying to address were: 1) To appraise the impact of a SBHHP on schoolchildren's handwashing compliance in Malawi by rating the scores of the handwashing quiz (knowledge), the handwashing observational checklist (skill/technique) and the fluorescent stain test (hand cleanliness) at four time points at baseline (T₀), at 3rd month immediately after students had participated in the SBHHP (T₁), at 6th month compliance evaluation (T₂) and at 9th month for sustainability testing (T₃); 2) To assess the impact of the SBHHP on reducing children's sickness-related school absenteeism by evaluating the number of sick leave days; and 3) To explore the acceptability of the implementation of the SBHHP in primary schools in Malawi.

The first chapter went on to explain the significance of the SBHHP. Operational definitions were presented, depicting the meaning they represent in this study. The chapter concluded by presenting the organisation of the whole thesis.

Chapter two addressed the gap that this study was trying to close by reviewing the literature from previous studies. The review explicitly or implicitly unveiled the significance of using the right technique for proper handwashing (cleanliness). The information in this chapter was presented under the following sub-sections; 1) multilevel interventions approach, 2) implementation of hand hygiene programmes across the globe, 3) factors influencing hand hygiene, 4) barriers and enablers to implementing hand hygiene programmes, 5) a whole school, WHO's health-promoting school framework, 6) World Health Organisation's 7-step handwashing technique, 7) a simplified 5-step handwashing technique, and 8) use Social Learning Theory to facilitate schoolchildren's learning of the proper handwashing technique. Finally, this section also presents information on rationale for using two theories in this study, theory of planned behaviour, Badura's Social Learning Theory, WHO's health-promoting school framework, research gaps, the study conceptual framework, and summary of chapter two

Chapter three presented the methodology used in this study in order to address the proposed hypothesis. This chapter covered areas such as study design (cluster randomised controlled trial) and a qualitative study nested in a cluster RCT. Justifications were also presented for employing these types of designs. Other areas in this chapter included inclusion and exclusion criteria, sample size and sampling technique, study setting, description of the instruments used, measures of effects, procedures for data collection and analysis, and ethical considerations.

Chapters four and five presented the finding/results and discussion of the study respectively. In general, this study showed that the SBHHP using a multilevel interventions approach was effective in improving theoretical and practical knowledge on proper handwashing and compliance among schoolchildren in Malawi. This in turn translated into increased uptake of handwashing practice/adoption among schoolchildren, thereby reducing infectious diseases (diarrhoea and flu) and consequently school absenteeism. In addition, this SBHHP was well received (accepted) by the schoolchildren, school staff and parents/guardians. It is important for Malawi and other developing countries to have a standardised and simple handwashing technique that young schoolchildren can easily follow. This may help to provide the dual benefits of improving handwashing behaviour/practice in the upcoming young generation and reducing infectious diseases that are transmitted from hand to mouth or nose or eyes.

Chapter six, the last in the study, presents the study limitations, implications, recommendations and conclusions. This study has developed goal-oriented recommendations regarding the sustainability of a simplified 5-step handwashing technique in schools. If widely embraced by all concerned stakeholders, this programme will greatly contribute to achieving WHO's Sustainable Development Goal number 3 (WHO, 2015), which aims among other things to combat water-borne and other communicable diseases by 2030.

One of the new initiatives of this interventional study is the application of multilevel interventions approach targeting more than one contextual levels

based on Bronfenbrenner's ecological systems theory which also aligns with the three areas of intervention of the WHO's HPS framework. This has added value to the intervention strategies in promoting hand hygiene care among schoolchildren in the developing countries for public health agenda. Bandura's social learning theory and Ajzen's theory of planned behaviour are also adopted to facilitate teaching, learning and behavioural change in handwashing uptake among schoolchildren in school settings in Malawi, Southern Africa, and other developing countries. This study is an important contribution to new evidence research on the effectiveness of long-term behaviour change strategies for the adoption of handwashing practice among schoolchildren in developing country settings to reduce the outbreaks of infectious diseases.

Appendices

Appendix Ia Schoolchild's Demographic & quiz Questionnaire

Appendix Ia Schoolchild's Demographic & quiz Questionnaire



Study title: Designing and evaluating a school-based hand hygiene program in Malawi: A Cluster Randomized Controlled Trial

The purpose of this questionnaire is to obtain general information on hand washing practices.

The questionnaire will take 10 minutes to complete. Please respond to all questions with honesty, completeness and accuracy. You are free to withdraw from participating in this study at any time without penalty. All answers you give will be confidential. Please use the pen to complete the questionnaire.

Tick the box that corresponds to your answer and write clearly where required.

Questionnaire

A1. Have you heard about hand washing?

Yes

No

A2. If yes, what was the source of the information?

School

Parents

Friend

Radio

Television

Other (please specify)

A3. Why do you wash hands?

A4. Under which circumstances did you wash hands with soap?

Before cooking

After defecation

Before eating

After cleaning the baby's bottom

Before feeding a baby

After playing outside

A5. Since this time yesterday, how often did you wash hands with soap?

1 to 2

1 to 4

5 or more

Appendix Ib Mafunso okhudza mbili ya mwana wa sukulu

Appendix Ib Mafunso okhudza mbili ya mwana wa sukulu



Study title: Designing and evaluating a school-based hand hygiene program in Malawi: A Cluster Randomized Controlled Trial

Cholinga cha mndanda wa mafunsowa ndi kutenga fundo zokhuzana ndi kusamba mmanja

Mafunso atenga mphindi khumi kuti athe. Chonde yankhani mafunsowa moona, momalizitsa ndi molondola. Ndinu wololedwa kusiya kutenga nawo gawo nthawi inailiyonse popanda kuzengedwa mlandu. Mayankho onse omwe mutapeleke akhala achinsinsi. Chonde gwilitsani ntchito cholembela poyankha mafunsowa.

Chongani mukabokosi kamene kakugwilizana ndi yankho lanu ndipo lembani zowoneka pamene pakufunika kulemba

Mafunso

A1. Munamvapo zakusamba mmanja?

Inde

Ayi

A2. Ngati inde, munamva bwanji?

Sukulu

Makolo

Mzanga

Wayilesi

Kanema

Kwina (chonde nenani)

A3. Chifukwa chani mumasamba mmanja?

Kuchepetsa tizilombo

Kuti manja akhale oyela bwino

A4. Ndi nthawi iti pamene mumasamba mmanja ndi sopo?

Tisanayambe kuphika

Tikachoka kodzithathiza kuchimbudzi

Tisanayambe kudya

Tikamaliza kupuputa mwana kumusi

Tisanayambe kudyetsa mwana

Tikamaliza kusewela kunja

A5. Kuyambila dzulo nthawi ngati zino, mwasamba kangati mmanja ndi sopo?

Kamodzi mpaka kawiri

katatu mpaka kanayi

kasanu kapena kupitilila

Appendix II Headmaster's Questionnaire

Appendix II Headmaster's Questionnaire



Study title: Designing and evaluating a school-based hand hygiene program in Malawi: A Cluster Randomized Controlled Trial

The purpose of this questionnaire is to obtain general information about the school.

The questionnaire will take 10 minutes to complete. Please respond to all questions with honesty, completeness and accuracy. You are free to withdraw from participating in this study at any time without penalty. All answers you give will be confidential. Please use the pen to complete the questionnaire.

Tick the box that corresponds to your answer and write clearly where required.

Information about school:

This information is to be obtained from the headmaster of the school

B1. Geographic information of the school:

Name

Location in the city

Division

District

B2. Enrollment of pupils by gender:

Total number of pupils at school: Boys Girls

Total number of pupils in elementary one: Boys Girls

B3. Number of teacher by gender:

The whole school: Males Females

Teachers in elementary one: Males Females

Teachers in elementary two: Males Females

B4. Number of classrooms at school:

For the whole school For elementary one only For elementary two only

B5. Water sources used at the school

Piped water Borehole

Well None

B6. Place within the school where the water source is found/placed

Central point Close to classrooms

B7. Distance from the school to the water source in meters

Within 10m

> 10 to 20m

>20 to 50m

>50m

B8. Accessibility of water to pupils

Fully accessible

Less accessible/restrictions

Not accessible

B9. Number of functional latrines/toilets by gender

Boys

Girls

**Appendix IIIa Questionnaire & demographic data for participants
involved in focus group**

**Appendix IIIa Questionnaire & demographic data for participants involved in focus
group**



Study title: Designing and evaluating a school-based hand hygiene program in Malawi: A Cluster Randomized Controlled Trial

The purpose of this questionnaire is to obtain general information on hand washing practices.

The questionnaire will take 10 minutes to complete. Please respond to all questions with honesty, completeness and accuracy. You are free to withdraw from participating in this study at any time without penalty. All answers you give will be confidential. Please use the pen to complete the questionnaire.

Tick the box that corresponds to your answer and write clearly where required.

Questionnaire

Age

Sex (Male/Female)

Your highest level of education

Type of employment

Location

School where your child is learning

Class in which your child is learning

Have you heard about hand washing?

Yes

No

If yes, what was the source of the information?

School

Parents

Friend

Radio

Television

Other (please specify)

Why do you wash hands?

To keep hands clean

To remove germs

Others (specify)

Under which circumstances did you wash hands with soap?

Before cooking

- After defecation
- Before eating
- After cleaning the baby's bottom
- Before feeding a baby
- After playing outside
- Others (specify)

Since this time yesterday, how often did you wash hands with soap?

- 1 to 2
- 2 to 4
- 5 or more

**Appendix IIIb Questionnaire & demographic data for participants
involved in focus group**

**Appendix IIIb Questionnaire & demographic data for participants involved in focus
group**



Study title: Designing and evaluating a school-based hand hygiene program in Malawi: A Cluster Randomized Controlled Trial

Cholinga cha mndanda wa mafunsowa ndi kutenga fundo zokhuzana ndi kusamba mmanja

Mafunso atenga mphindi khumi kuti athe. Chonde yankhani mafunsowa moona, momalizitsa ndi molondola. Ndinu wololedwa kusiya kutenga nawo gawo nthawi inailiyonse popanda kuzengedwa mlandu. Mayankho onse omwe mutapeleke akhala achinsinsi. Chonde gwilitsani ntchito cholembela poyankha mafunsowa.

Chongani mukabokosi kamene kakugwilizana ndi yankho lanu ndipo lembani zowoneka pamene pakufunika kulemba

Mafunso

Muli ndi zaka zingati

Ndinu amuna kapena akazi

Maphunziro munalekeza kalasi liti

Mumagwira ntchito yanji

Mumakhalira kuti

Dzina la sukulu komwe mwana wanu amaphunzira

Mwana wanu amaphunzira kalasi liti

Munamvapo zakusamba mmanja?

Inde

Ayi

Ngati inde, munamva bwanji?

Sukulu

Makolo

Mzanga

Wayilesi

Kanema

Kwina (chonde nenani)

Chifukwa chani mumasamba mmanja?

Kuchepetsa tizilombo

Kuti manja akhale oyela bwino

Ndi nthawi iti pamene mumasamba mmanja ndi sopo?

Tisanayambe kuphika

Tikachoka kodzithathiza kuchimbudzi

Tisanayambe kudyanya

Tikamaliza kupuputa mwana kumusi

Tisanayambe kudyetsa mwana

Tikamaliza kusewela kunja

Kuyambila dzulo nthawi ngati zino, mwasamba kangati mmanja ndi sopo?

Kamodzi mpaka kawiri

katatu mpaka kanayi

kasanu kapena kupitilila

Appendix IVa. Discussion guides

For schoolchildren:

1. Tell me your experiences in participating the school's hand hygiene programme.
2. Have you changed your handwashing procedures and habits in your daily life after participated the school's hand hygiene programme?
3. What do you like the most of the school's hand hygiene programme?
4. What do you like the least of the school's hand hygiene programme?
5. In what ways the school's hand hygiene programme helping you to keep your hands clean and stay healthy?
6. Any suggestions that the school's hand hygiene programme for improvement.
7. Would you recommend this school's hand hygiene programme to your siblings and friends?

For school personnel (school principals and teachers)

1. Tell me your experiences in planning and coordination to implement the school's hand hygiene programme.

2. Share with us how much the school management team involved (support, resources allocation, policy, integrate into the school curricular) in planning and coordinating the preparation work of the school hand hygiene programme.
3. What do you like the most of the school's hand hygiene programme?
4. What do you like the least of the school's hand hygiene programme?
5. Share with us the strategies to initiate the school's hand hygiene programme.
6. Tell me your experiences in working with the other disciplines such as health professionals and parents to coordinate and implement the school's hand hygiene programme
7. Share with me is there any handwashingbehavioral changes that you have observed on the schoolchildren after implemented the school's hand hygiene programme
8. Tell me the enhancers to implement the school's hand hygiene programme
9. Tell me the barriers to implement the school's hand hygiene programme
10. Can you share any suggestions to improve the planning and implementation of the school's hand hygiene programme?
11. Would you recommend this school's hand hygiene programme to other schools?

For parents / caregivers (mother, father, siblings, grandparents)

1. Tell me your experiences in observing your child/ brother/ sister/ grandchild handwashing procedure and habit at home after participated the school's hand hygiene programme
2. Do you like your child/sibling/grandchild's handwashing procedure reinforcing from the school and extended to home setting.
3. Have you found your child/sibling/grandchild's symptoms of infectious diseases reduced after participated the school's hand hygiene programme?
4. What do you like the most of the school's hand hygiene programme?
5. What do you like the least of the school's hand hygiene programme?
6. Would you recommend this hand hygiene programme to other parents or friends and relatives?

Appendix IVb kalozela wa kukambilana kwa ana a sukulu, aphunzitsi

ndi makolo



Ana a sukulu

1. Tandiuzani zomwe mukudziwa pa za pulogalamu ya kasambidwe ka m'manja pa sukulu
2. Kodi mukusiyantsa bwanji panthawi ino pamene mwaphunzira za kasambidwe ka m'manja ndi nthawi imene munali musanaphunzire?
3. Kodi ndichiyani chimene chimakusangalatsani kwambili pa nkhani ya ukhondo wa kasambidwe ka m'manja?
4. Kodi ndichiyani chimene sichikusangalatseni kwambili pa nkhani ya ukhondo wa kasambidwe ka m'manja?
5. Kodi pulogalamuyi ikukuthandizani bwanji kukhala aukhondo ndi athanzi
6. Mukuganiza kwanu ndipati pamene pakufunika kukonza kuti pulogalamuyi iziyenda bwino?
7. Kodi ana ndi anzanu mungawauze zotani za poulogalamuyi?

Aphunzitsi ndi atsogoleri a sukulu

1. Tandiuzani mmene mumapangila pulani komanso kukwanilitsa pulogalamu yakasambidwe ka mmanja?

2. Tatiuzeni m'mene akuluakuli a sukulu amakuthandizilani pa za pulani ndi kukwanilitsa ntchito ya ukhondo wa kasambidwe ka m'manja pa sukulu?
3. Kodi ndichiyani chimene chimakusangalatsani kwambili pa nkhani ya ukhondo wa kasambidwe ka m'manja?
4. Kodi ndichiyani chimene sichikusangalatseni kwambili pa nkhani ya ukhondo wa kasambidwe ka m'manja?
5. Tatiuzani mwadongosolo m'mene munayambila pologalamu ya ukhondo wamkasambidwe ka m'manja?
6. Tandiuzani m'mene mumagwilira ntchito ndi ma bungwe ena monga a akuluakulu a zaumoyo komanso makolo pa za plani ndi kakwanilitsidwe ka pologalamu ya ukhondo wakasambidwe wa m'manja?
7. Kodi kulikunsintha kulikonse kumene kwa ana a sukulu mutakwanitsa pologalamu ya ukhondo wa kasambidwe ka m'manja?
8. Ndi ati amene amakuthandizani kuti mukwanilitse pologalamu ya ukhondo ndi kasambidwe ka m'manja pa sukulu?
9. Ndizovuta zANJI mumakumana nazo pa kukhazikitsa pologalamu ya ukhondo wa kasambidwe ka m'manja pa sukulu?
10. Kodi tingaonjezere ziti pa pulani ndi kukwalitsa pulogalamu ya ukhondo wa kasambidwe ka m'manja?
11. Would you recommend this school's hand hygiene programme to other schools?

Kodi sukulu zina mungaziuze zotani za poulogalamuyi?

Makolo

1. Kodi mukusiyantsa bwanji ku ana, achimwene, achemwali, komanso zidzukululu zanu nthawi ino pamene aphunzira za kasambidwe ka m'manja ndi nthawi imene munali anali asanaphunzire?
2. Kodi kukhala okondwera kuti mwana kapena mdzukululu wanu azikamizidwa kusamba m'manja chomwenchonso kufikira ku makuka (manyumba) anu?
3. Kodi mwapezapo kuti mwana kapena mdzukululu wanu sakudwaladwala matenda a kudza kamba ka kusasamba m'manja atalandila nawo ukadaulo wa ukhondo wakusamba m'manja ndi sopo?

Kodi mukusiyantsa bwanji pa nkhani ya matenda akudza kamba kusasamba manja panthawi imene ana kapena adzukululu anu atalandila ndi pamene asanalandire maphunziro a kasambidwe ka m'manja?

4. Kodi ndichiyani chimene chimakusangalatsani kwambili pa nkhani ya ukhondo wa kasambidwe ka m'manja?
5. Kodi ndichiyani chimene sichikusangalatseni kwambili pa nkhani ya ukhondo wa kasambidwe ka m'manja?
6. Kodi mkolo ndi anzanu mungawauze zotani za poulogalamuyi?

Appendix Va Handwashing education package/information



Education package/information

Handwashing education will take 15 to 20 minutes. The handwashing education will comprise of five main approaches: discussion/lessons, individual handwashing training practical, video show, music/lyrics, provision of various written materials (posters, pamphlets etc)

Why do we wash hands

Keeping hands clean through improved hand hygiene is one of the most important steps we can take to avoid getting sick and spreading germs to others. Many diseases and conditions are spread by not washing hands with soap and clean, running water. Examples of such conditions are; diarrhea, flu, other ARI

Washing hands with soap and water is the best way to reduce the number of germs in most situations.

Implication of not washing hand on health, for example suffering from ARI and diarrhea which may lead to school absenteeism and loss of money for hospital fees, transport to hospital and absenteeism of parents from their job and business to take care of a sick child. These infections can also lead to death.

When should you wash your hands?

When do we wash hands?

- **Before**, during, and after preparing food
- **Before** eating food
- **Before** and after caring for someone who is sick

- **Before** and after treating a cut or wound
- **After** using the toilet
- **After** changing diapers or cleaning up a child who has used the toilet
- **After** blowing your nose, coughing, or sneezing
- **After** touching an animal, animal feed, or animal waste
- **After** touching garbage
- **After handling pet food or pet treat**

How should you wash your hands

- Wet your hands with clean, running water (warm or cold), turn off the tap, and apply soap.
- Lather your hands by rubbing them together with the soap. Be sure to lather the backs of your hands, between your fingers, and under your nails.
- Scrub your hands for at least 20 seconds. Need a timer? Hum the "Happy Birthday" song from beginning to end twice.
- Rinse your hands well under clean, running water.
- Dry your hands using a clean towel or air dry them.

NB: the procedure will take 20 to 40 minutes/seconds

Refer to procedure information on how to wash hands

Source: CDC, (2015). Hand washing: Clean hands save lives. Accessed from

<http://www.cdc.gov/handwashing/when-how-handwashing.html>

Appendix Vb Uthenga wa chiphunzitso cha kasambidwe ka mmanja



Ndondomeko ya chiphunzitso

Chiphunzitso chakusamba mmanja chitenga pakati pa mphindi khumi ndi mphambi zisanu ndi mphindi makumi awili. Chiphunzitsochi chitenga madela asanu: kukambilana, munthu payekha kuziphunzitsa kusamba mmanja, kuonela kanema, munyimbo, kupatsidwa zolembedwa monga zokhomedwa kepena timapepala ting'onoting'ono.

Chifukwa chani timasamba mmanja

Kusunga manja aukhondo ndi posamba mmanja mwamakono ndi njila imodzi yomwe tingatsatile kuti tisadwale ndiponso kufalitsa tizilombo kwa ena. Matenda ambili amafala chifukwa chosamba mmanja ndi sopo ndi kugwilitsa ntchito madzi abwino a kumpope (kapena madzi woyenda). Zitsanzo za matendawa ndi monga kutsegula mmimba, chimfine ndi matenda ena amuchifuwa.

Kutsamba mmanja ndi sopo ndi madzi ndi njila yabwino kwambili yochepetsela tizilombo mmadela ambili.

Zotsatila za ku sasamba mmanja pa ukhondo ndi monga kudwala matenda amuchifuwa ndi kutsegula mmimba; zomwe zikhoza kupangitsa kujomba kusukulu ndi kuononga makobidi pokalipila kuchipatala, mayendedwe a kuchipatala ndiponso makolo kujomba ku ntchito kapena ku mabizinesi kuti asamale mwana wodwalayo. Matendawa akhozanso kubweletsa imfa.

Mmanja timasamba nthawi yanji?

- Tisana, pamene tiku, ndi pamene tamaliza kukoza chakudya

- Tisanayambe kudya chakudya
- Tisanayambe ndi pamene tamaliza kusamala amene akudwala
- Tisanayambe ndi pamene tamaliza kusamala pochekedwa kapena chilonda
- Tikamaliza kugwilitsa ntchito chimbuzi
- Tikamaliza kusintha thewela kapena kupuputa mwana woti wachita chimbuzi
- Tikamaliza kumina, kutsokomola kapena kuyethyemula
- Tikagwila chiweto, zakudya za chiweto kapena chimbuzi cha chiweto
- Tikagwila zinyalala

Mmanja ungasambe bwanji?

- Nyowetsani mmanja ndi madzi abwino a pampope (otentha kapena ozizila), tsekani mpope ndipo pakani sopo.
- Sambani pokwecha manja pamodzi ndi sopo. Onetsetsani kuti kuseli kwamanja kwasambidwa, pakati pazala ndi muzikhadabo.
- Kwechani manja anu kwa masekondi khumi. Mufuna powonela nthawi?.
Ng'ung'udzani nyimbo yoti "Happy birth day" kuyambila pachiyambi mpaka pamapeto kawili.
- Tsukuluzani mmanja ndi madzi abwino aku mpope.
- Umitsani mmanja anu ndi kansalu kochapa bwino kapena umitsani ndi mphepo.

Appendix VI Scale for scoring simplified 5-steps handwashing technique



Step	Left hand	Right hand	Total	Awarded mark
Rub palm to palm between fingers	–	–	1	
Rub back of hand	0.5	0.5	1	
Rub back of fingers	0.5	0.5	1	
Rub fingers on palm	0.5	0.5	1	
Rub the thumb	0.5	0.5	1	
Use of soap	–	–	1	
Duration of rubbing (>20sec)	–	–	1	
Proper air drying	–	–	1	
Total marks	–	–	8	
Total %	–	–	100%	

Source: Adapted from Kaewchana et al, (2012)

Appendix VII Checklist for delivery of the intervention



Name of school

Name of interventionist

Time of assessment









Name of the assessor

Title of the assessor

	Tick if does & cross if not done							
Delivered content on when to wash hands such as; before and after eating, after visiting toilet, after playing, after coughing, after touching pets, before preparing food.								
Delivered content on why to wash hands such as; to keep hands cleans, to remove germs from the hands.								
Delivered content on how to wash hand following 5-steps as follows;								
Rinse the hand with water and soap								
Rub palm to palm between fingers								
Rub back of hand								
Rub back of fingers								
Rub fingers on palm								
Rub the thumb								
Use of soap								
Duration of rubbing (>20sec)								
Proper air drying								

Source: The content of the checklist was adapted from Lee & Lee (2014)

Appendix VIII Rating of fluorescent stain test, 4-point scale to rate the palm and dorsum. Source: Lee R & Lee P, (2014)

Left hand	Right hand	Score
		0
		1
		2
		3

Appendix IXa Handwashing procedure (5-steps). Source: PolyU, SN



Appendix IXb Ndongomeko ya kasambidwe ka mmanja (madela asanu)



1. Kwechani mkati mwa zala
2. Kwechani kuseli kwa manja anu
3. Kwechani kuseli kwa zala
4. Kwechani mkati mwa manja anu ndi nsonga za zala zanu
5. Kwechani chala chanu chachikulu

Appendix Xa: Consent Form**PARENTAL CONSENT FOR CHILD'S PARTICIPATION IN RESEARCH****Designing and evaluating a school-based hand hygiene programme in Malawi: A Cluster Randomized Controlled Trial**

I _____ hereby consent my son/daughter to participate in the captioned research supervised by _____ and conducted by _____.

I understand that information obtained from this research may be used in future research and published. However, my right to privacy will be retained, i.e., my personal details will not be revealed.

The procedure as set out in the attached information sheet has been fully explained. I understand the benefits and risks involved. My participation in the project is voluntary.

I acknowledge that I have the right to question any part of the procedure and can withdraw at any time without penalty of any kind.

Name of participant

Signature of participant

Name of parent or guardian (if applicable)

Signature of parent or guardian (if applicable)

Name of researcher

Signature of researcher

Date

Appendix Xb: Pepala la chilolezo

**CHILOLEZO KUCHOKELA KWA MAKOLO KUTI MWANA
APANGE NAWO KAFUKUFUKU**

**Designing and evaluating a school-based hand hygiene programme in
Malawi: A Cluster Randomized Controlled Trial**

Ine_____ ndikupeleka chilolezo kuti mwana wanga wamkazi
kapena mwamuna apange nawo kafukufukuyu mooneledwa
ndi_____ kupangidwa ndi_____

Ndikumvetsa kuti fundo zotuluka kuchoka mukafukufuku uyu zingathe
kuzagwilitsidwa ntchito mukafukufuku wina mtsogolo ndikuzalengezedwa.
Komabe ufulu wanga kundisungila zinsinsi zanga monga mbiri yanga
sizizaululidwa.

Ndondomeko yomwe yalembedwa pachipepala yalongosoledwa kwathuthu.
Ndamvetsa ubwino ndi zovuta zomwe zingakhalepo. Kutengapo mbali
ndikufuna kwa munthu. Ndikudziwa kuti ndili ndiufulu kufunsa china
chilichonse ndikusiya kutengapo mbali nthawi iliyonse popanda
kuzengedwa mlandu

Dzina la wochita kafukufuku_____

Chidindo cha wochita Kafukufuku_____

Dzina la kholo kapena wachibale_____

Chidindo cha kholo kapena wachibale_____

Tsiku_____

Dzina la wochititsa kafukufuku_____

Chidindo cha wochititsa Kafukufuku_____

Tsiku_____

Appendix XIa: Information Sheet for child's parent

INFORMATION SHEET

Designing and evaluating a school-based hand hygiene programme in Malawi: A Cluster Randomized Controlled Trial

You are invited to participate in a study supervised by _____ and conducted by _____, who are students in the School of Nursing at The Hong Kong Polytechnic University.

The aim of the study is to design and evaluate school-based hand hygiene programme. This study will run for a period of nine months. Data will be collected using a questionnaire, checklist through observation, photos and video clips of hands only. It is envisaged that the results of this study may have an influence on health policy resources, health care services, education and research. The results may also be impetus for health promotion campaigns to promote proper handwashing technique and improve handwashing practice/behaviour.

Your child has every right to withdraw from the study before or during the measurement without penalty of any kind. All information related to your child will remain confidential, and will be identifiable by codes known only to the researcher.

If you have any complaints about the conduct of this research study, please do not hesitate to contact Miss Cherrie Mok, Secretary of the Human Subjects Ethics Sub-Committee of The Hong Kong Polytechnic University in person or in writing (c/o Research Office of the University), stating clearly the person and department responsible for this study.

If you would like more information about this study, please contact _____ at telephone number _____ or my supervisor Dr. Regina

Lee at telephone number +852 2766

Thank you for your interest in participating in this study.

Principal Investigator _____

Appendix XIb Chi pepala cha uthenga wa makolo



CHIPEPALA CHA UTHENGA

Designing and evaluating a school-based hand hygiene programme in Malawi: A Cluster Randomized Controlled Trial

Mukuitanidwa kutengapo mbali pa kafukufuku amane ali oyang'anilidwa ndi **Dr. Regina Lee** ndi kupangidwa ndi **B.C. Mbakaya**, amene ali ana a sukulu ku sukulu ya ukache njede ya The Hong Kong Polytechnic University, ku Hong Kong.

Cholinga cha kafukufukuyu ndi kupanga ndi kuona ndondomeka yakusamba mmanja pa sukulu. Kafukufukuyu adzatenga miyezi isanu ndi inayi. Uthenga udzatengedwa kudzela mmafunsu, kumangoona zochitika, zithunzi, ndi kanema wa manja okha. Pali maso mphenya oti zotsatila za kafukufukuyu zizathandizila a zaumoyo; kagwilidwe ntchito ka azaumoyo, ziphunzitsa zawo ndi kafukufuku wina. Zotsatila zakafukufukuyu zizapelekasu mangolomela potukula miyoyo ya anthu pa kulimbikitsa kasambidwe kabwino kammanja ndi kusintha chikhalidwe chakasambidwe kammanja.

Mwana wanu ali ndi ufulu kusiya kafukufukuyu tisanayambe kapena tili mkati popanda kulandila chilango china chilichonse. Uthenga wonse wokhudza mwana wanu udzasungidwa mwachisinsi ndipo tidzagwilitsa ntchito manambala omwe azidzadziwika ndi wochititsa kafukufuku yekha.

Ngati muli ndi zodandaula zokhudzana ndi zochitika mukafukufukuyu; musachedwe auzeni a Mai Cherrie Mok, omwe ndi aSekeletale ku Human Subjects Ethics Sub-Committee ku sukulu ya ukache njede ya unamwino ku

Hong Kong kapena lembelani ku ofesi ya kafukufuku ku sukulu yomweyi ya ukachenjede, kunena momveka bwino munthu ndi nthambi yomwe yikuyang'anila kafukufukuyu.

Ngati mukufuna kumva zambili za kafukufukuyu, chonde onanani ndi

B.C. Mbakaya panambalayi **088815** kapena wondiyang'anila **Dr.**

Regina Lee nambala yake ndi

+852 2766

Zikomo kwambili chifukwa cha chidwi chanu potengangapo mbali pakafukufukuyu.

Woyang'anila wamkulu _____

Appendix XII Focus group discussion invitation letter



To: The Parent/guardian
 From: B.C. Mbakaya, The Hong Kong Polytechnic University, Hong Kong
 Date: 8/05/17
 Re: **Invitation to a focus group discussion.**

I am a PhD candidate at The Hong Kong Polytechnic University in Hong Kong, pursuing a

I am conducting a study entitled **“Designing and evaluating a school-based simplified hand hygiene programme in Malawi: A Cluster Randomized Controlled Trial”**, which started in September, 2016.

Your child happens to be one of the participant in this study, in which you gave consent last year.

The purpose of this letter therefore is to invite you to participate in the focus group discussion regarding this project. The group will comprise of at least six people (parents and teachers responsible for your child).

Refreshments will be provided during the 1hour meeting. MK5,000 will be provided towards transport costs.

Venue :

Time :

Date :

I will be grateful if my request meets your favourable consideration.

For feedback and more details, call the undersigned on **088815** .

Yours faithfully,

Principal Investigators

Appendix XIII: Request for clearance to The District Education**Manager**

To: The District Education Manager, Mzuzu, Malawi

From: Balwani-mbakaya Chingaticlifwe, Hong Kong Polytechnic University, Hong Kong

Date: 20/03/15

Re: **Request to conduct a study in private primary schools in Mzuzu City, Malawi.**

I am a PhD candidate at The Hong Kong Polytechnic University in Hong Kong, pursuing a Doctor of Philosophy Degree (PhD).

I am conducting a study entitled “**Designing and evaluating a school-**

Therefore, I would like to request for permission to conduct a study in government primary schools in Mzuzu City.

based hand hygiene programme in Malawi: A Cluster Randomized Controlled Trial”

Before I commence the study, the ethical approval letters from The Hong Kong Polytechnic University and Malawi National Health Sciences Research Committee (NHSRC) will be obtained.

The study will be conducted under the supervision of Dr. Regina Lee.

I will be grateful if my request meets your favourable consideration.

Yours

faithfully,

Principal Investigator**Appendix XIV: Request for clearance to the head of the school**

To: The Head of the school

From: Balwani-mbakaya Chingaticifwe, Hong Kong Polytechnic University, Hong Kong

Date: 20/03/15

Re: **Request to conduct a study at your primary schools.**

I am a PhD candidate at The Hong Kong Polytechnic University in Hong Kong, pursuing a Doctor of Philosophy Degree (PhD).

I am conducting a study entitled “**Designing and evaluating a school-**

Therefore, I would like to request for permission to conduct a study at your school.
based hand hygiene programme in Malawi: A Cluster Randomized Controlled Trial”

Before I commence the study, the ethical approval letters from The Hong Kong Polytechnic University and Malawi National Health Sciences Research Committee (NHSRC) will be obtained.

The study will be conducted under the supervision of Dr. Regina Lee.

I will be grateful if my request meets your favourable

Yours

faithfully,

Principal Investigator

Appendix XV Consent Form**THE HEAD OF THE SCHOOL****Designing and evaluating a school-based hand hygiene programme in
Malawi: A Cluster Randomized Controlled Trial**

I _____ hereby consent to participate in the captioned research supervised by **Dr. Regina Lee** and conducted by **Balwani Mbakaya Chingaticlifwe**

I understand that information obtained from this research may be used in future research and published. However, my right to privacy will be retained, i.e., my personal details will not be revealed.

The procedure as set out in the attached information sheet has been fully explained. I understand the benefits and risks involved. My participation in the project is voluntary.

I acknowledge that I have the right to question any part of the procedure and can withdraw at any time without penalty of any kind.

Name of participant _____

Signature of participant _____

Name of researcher _____

Signature of researcher _____

Date _____

Appendix XVI Focus group discussion



Consent Process

Thank you for agreeing to participate. We are very interested to hear your valuable opinion on how a school-based hand hygiene programme can promote your child's hand hygiene behaviors/practice, and in return reduce diarrhea, respiratory conditions, and school absenteeism.

- *The purpose of this focus group discussion is to learn how teachers and parents/guardians view the designed school based simplified hand hygiene programme, which has been implemented at this school since September 2016. We hope to learn things that we may recommend to Ministry of Education and Ministry of Health, which can be used to improve and promote hand hygiene behaviour/practice among schoolchildren.*
- *The information you give us is completely confidential, and we will not associate your name with anything you say in the focus group.*
- *We would like to tape the focus groups so that we can make sure to capture the thoughts, opinions, and ideas we hear from the group. No names will be attached to the focus groups and the tapes will be destroyed as soon as they are transcribed.*
- *You may refuse to answer any question or withdraw from the study at any time.*

- *We understand how important it is that this information is kept private and confidential. We will ask participants to respect each other's confidentiality.*
- *If you have any questions now or afterwards, you can always contact the Principal Investigator on 088815*
- *Please sign below to show you agree to participate in this focus group.*

Name: **Signature:**

Date

Introduction:

1. Welcome

Introduce yourself and the note taker, and send the Sign-In Sheet with a few quick demographic questions (age, gender, cadre, location) around to the group while you are introducing the focus group.

Review the following:

- Who we are and what we're trying to do
- What will be done with this information
- Why we asked you to participate
- If you are a supervisor, we would like to excuse you at this time

2. Explanation of the process

Ask the group if anyone has participated in a focus group before. Explain that focus groups are being used more and more often in health and human services research.

About focus groups

- We learn from you (positive and negative)
- Not trying to achieve consensus, we're gathering information
- In this project, we are doing both questionnaires and focus group discussions. The reason for using both of these tools is that we can get more in-depth information from a smaller group of people in focus groups. This allows us to understand the context behind the answers given in the written survey and helps us explore topics in more detail than we can do in a written survey.

Logistics

- Focus group will last about one hour
- Feel free to move around
- Where is the bathroom? Exit?
- Help yourself to refreshments

3. Ground Rules

Ask the group to suggest some ground rules. After they brainstorm some, make sure the following are on the list.

- Everyone should participate.

- Information provided in the focus group must be kept confidential
- Stay with the group and please don't have side conversations
- Turn off cell phones if possible
- Have fun

4. Turn on Tape Recorder

5. Ask the group if there are any questions before we get started, and address those questions.

6. Introductions

- Go around table:

Discussion begins, make sure to give people time to think before answering the questions and don't move too quickly. Use the probes to make sure that all issues are addressed, but move on when you feel you are starting to hear repetitive information.

Questions:

-
-
-

Probes for Discussion:

-

-
-

That concludes our focus group. Thank you so much for coming and sharing your thoughts and opinions with us. We have a short evaluation form that we would like you to fill out if you time. If you have additional information that you did not get to say in the focus group, please feel free to write it on this evaluation form.

Materials and supplies for focus groups

- Sign-in sheet
- Consent forms (one copy for participants, one copy for the team)
- Evaluation sheets, one for each participant
- Name tents or numbers
- Pads & Pencils for each participant
- Focus Group Discussion Guide for Facilitator
- 1 recording device need to add one more (functional)
- Batteries for recording device
- Extra tapes for recording device
- Permanent marker for marking tapes with FGD name, facility, and date
- Notebook for note-taking
- Refreshments

Appendix XVII Theme Clustering and Forming Emergent Theme



No	Formulating Meanings	Theme Cluster	Emergent Theme
1.	<p><i>“Aaaa like here at school we have welcomed the programme so well, we like the way learners they are washing their hands or take care of their hands..... it’s like there is a systematic way of washing their hands not just on the same spot/part” (T1H)</i></p> <p><i>“So to me I see that the programme has benefited them a lot, and even to us as parent because we can peacefully leave the home and not get worried about how children will take care of themselves especially concerning handwashing during eating time” (PIR)</i></p> <p><i>“In my case I participated in this project because at first when I was washing hands germs could not be removed, especially when I had touched mud and when washing hands and at times could not use soap but now I wash hands with soap”. (C6dR)</i></p>	School staff, teachers and schoolchildren liked the SBHHP and felt that it was very useful	Working together to develop hand hygiene policy and integrate SBHHP into the school extra-curricular activities
	<p><i>“I support what the madam is saying to bring it at the meeting aah PTA meeting so that parents should be aware of it but am suggesting saying not to bring the soap as such but for what they are paying school fees they have to add little amount of money whereby it will be said to be buying soap” (T1H)</i></p> <p><i>“For me, I think for this programme to continue very well, because at time we run out of water at school, therefore I would proposal to have a borehole in schools” (P3H)</i></p> <p><i>“Aah T2 sustainability will be there as and when this programme was just being introduced here aah Mr Mbakaya was even approached to extend it to kinder showing that everyone is ready our proprietors, are happy with the programme and the kinder is also happy that is why they made this request, can’t we extend it to</i></p>	Participants suggesting ways of securing resources for handwashing and initiative for community mobilisation and participation.	

	<p>here so that learners would be used to this programme so the question of sustainability “ (T2W) “Community/village/homes, we also go and teach them how to wash hands”. (C6aH)</p>		
2.	<p>“when playing she calls friends and start demonstrating what she was taught at school (5 steps) (P2H) “If you wash like this (parent demonstration the old way) then you will hear from the child, mum mum you have not washed your hands (hihihi hehehehe- audience 6sec) you are supposed to do like this, all his area (parent demonstrating five steps as taught by child)” (P2W) “in these classes now the others have also learnt a lot from their friends they even ask can you teach me how you wash it and then they demonstrate you know” (T2R) “Yes I will tell my neighbours and parents or brothers and sisters on how to wash hands so that they can also avoid those diseases” (C6bH)</p>	<p>Schoolchildren showed willingness to share the knowledge and skills acquired through the SBHHP to parents, siblings and friends</p> <p>Teachers making extra effort to teach students from other grades and also reminded student about when, why and how to wash hands during morning assembly</p>	<p>Being committed to the school’s hand hygiene programme.</p>
3.	<p>“learners could not wash hands but now they wash, at break they can’t start eating, they go and wash hands first at break they can’t start eating, they go and wash hands first, in the past we could like force them to wash hands but now they remember themselves” (T1H) “<i>And since that time he is always, each time he comes from the toilet goes to the sink, washes hands and he tells his brother, he has an elder brother, he tells him, have you washed your hands</i>”. (P4R). “<i>What I have liked most is actually that as I mentioned earlier on is that eeh there has been that change of behaviour where the child is very much interested to really have his hands clean you can actually see the efforts eeeeh</i>” (PIW) “<i>In the past it could happen that we could just start eating nsima (food) without washing hands but now we wash hands first before eating</i>”.</p>	<p>Children washing hands routinely and making frequent efforts during important timing like before eating and after toilet.</p>	<p>Practicing proper handwashing technique as routines.</p>

	(C6cH)		
4.	<p><i>“They make sure that each and every one should do what they have learnt here at school (uuh uuh yes –audience chorus 3sec), which simply shows that they have mastered the programme/procedure, (you see – audience), they have internalised-another participant adding)” (P3H)</i></p> <p><i>“at household level there are already changes since I even told you that they are even demanding for soap” (PIR)</i></p> <p><i>“Actually it’s the kid that is insisting (hahahihihahahaha audience 6sec) and advising us that by all means we must continue (hehehehehe –audience) and obviously we have seen the good of that why not? Hihihih –audience 2sec)” (P2R)</i></p>	<p>Children demanding resources for handwashing at home and also want everyone in the home to follow the 5-steps of handwashing programme</p>	<p>The benefits of SBHHP.</p>
	<p><i>“In terms of sickness there is a drop, not many learners suffering from diarrhoea or coughing” (T2H)</i></p> <p><i>“To us this programme has helped to reduce diseases compared to our usual traditional method of handwashing where one basin could be used by 20 people to wash their hands in it (hihihi-audience 1sec) my child now has reduced suffering especially from coughing/flu” (PIH)</i></p> <p><i>“No when we wash hands following 5 steps, all the germs are removed and when you are eating nsima (food) you eat without germs hence you reduce chances of suffering. While washing hands the old way it means some of the germs remain on the hands and when eating nsima you eat together with the germs”. (C6aR)</i></p>	<p>Participants from focus group felt that the SBHHP helped schoolchildren to experience reduced episodes of illnesses such as diarrhoea and flu.</p>	

Appendix XVIII Clinical Trial Register

ClinicalTrials.gov

A service of the U.S. National Institutes of Health

Now Available: Final Rule for FDAAA 801 and NIH Policy on Clinical Trial Reporting

Designing and Evaluating a School-based Hand Washing Program in Malawi

This study is currently recruiting participants. (see [Contacts and Locations](#))

Verified October 2016 by The Hong Kong Polytechnic University

Sponsor:

The Hong Kong Polytechnic University

Information provided by (Responsible Party):

The Hong Kong Polytechnic University

ClinicalTrials.gov Identifier:

NCT02968251

First received: October 11, 2016

Last updated: November 17, 2016

Last verified: October 2016

[History of Changes](#)

[Full Text View](#)

[Tabular View](#)

[No Study Results Posted](#)

[Disclaimer](#)

[How to Read a Study Record](#)

Purpose

The aim of the study is to design and evaluate a school-based hand washing program for children in Malawi, Sub-Saharan Africa, using a cluster randomized controlled trial (CRCT), so as to improve proper hand washing, increase knowledge level and also reduce school absenteeism.

Condition	Intervention
School-based, Hand-washing, Program, Malawi	Behavioral: Hand Washing Program (HWP)

Study Type: Interventional

Study Design: Allocation: Randomized

Intervention Model: Parallel Assignment

Masking: Single Blind (Outcomes Assessor)

Primary Purpose: Prevention

Official Title: Designing and Evaluating a School-based Hand Washing Program in Malawi

Further study details as provided by The Hong Kong Polytechnic University:

Primary Outcome Measures:

- Proper hand washing [Time Frame: 9 month] [Designated as safety issue: No]

This will be achieved by giving a score to the amount of fluorescents stain on the hand.

Secondary Outcome Measures:

- Knowledge gain [Time Frame: 9 month] [Designated as safety issue: No]

A quiz will be administered to assess knowledge of school children.

Estimated Enrollment: 360

Study Start Date: October 2016

Estimated Study Completion Date: July 2017

Estimated Primary Completion Date: July 2017 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
<p>Experimental: Hand Washing Program (HWP)</p> <p>Clusters in this arm will be given a Hand Washing Program (HWP) which will consist of: integrating hand washing practice in the school health policy, setting up proper hand washing facilities in the intervention schools, training to school teachers, delivering of health talk to schoolchildren and their parents, developing reminders and posters of a simplified 5-step hand washing technique, peer briefing session, take home package (5-steps hand washing, commitment letter, poster, leaflet). The program will be</p>	<p>Behavioral: Hand Washing Program (HWP)</p> <p>HWP consists of integrating hand washing practice in the school health policy, setting up proper hand washing facilities in the intervention schools, training to school teachers, delivering of health talk to schoolchildren and their parents, developing reminders and posters of a simplified 5-step hand washing technique, peer briefing session, take home package (5-steps hand washing, commitment letter, poster, leaflet). The program</p>

delivered once every week.

will be delivered once every week.

No Intervention: No Hand Washing Program (NHWP)
Clusters in this arm will be allowed to continue with their usual practice regarding hand washing/hygiene

Detailed Description:

A cluster randomized controlled trial (CRCT) design with pre-, mid- and post-interventions and follow-up measures will be randomized into intervention or control groups. A simplified 5-steps hand washing program will be implemented in the intervention group while the control group will continue with their usual practice where schoolchildren do not follow any standard recommended handwashing technique.

► Eligibility

Ages Eligible for Study: 5 Years to 12 Years (Child)
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Schools that have piped tap water source situated in Mzuzu City,
- Private primary schools,
- Children in elementary one and six,
- Written parental consent allowing their child to participate in the study.

Exclusion Criteria:

- Schools without piped tap water source,
- Government primary schools,
- Children whose parents will not give consent.

► Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see [Learn About Clinical Studies](#).

Please refer to this study by its ClinicalTrials.gov identifier: NCT02968251

Contacts

Contact: Balwani M Chingatchifwe, MPH +265 888 159 balwani-mbakaya.chingatchifwe@
Contact: Regina Lee, PhD (852) 2766 regina.Lee@

Locations

Malawi

St John's College of Nursing and Midwifery
Mzuzu, Northern, Malawi, 00000

Recruiting

Contact: Balwani M Chingatchifwe, MPH (265) 888 159 balwani-mbakaya.chingatchifwe@
Contact: Regina Lee, PhD (852) 2766 regina.Lee@

Sponsors and Collaborators

The Hong Kong Polytechnic University

► More Information

Responsible Party: The Hong Kong Polytechnic University
ClinicalTrials.gov Identifier: [NCT02968251](#) [History of Changes](#)
Other Study ID Numbers: HSEARS20160619001
Study First Received: October 11, 2016
Last Updated: November 17, 2016
Health Authority: Malawi: National Health Sciences Research Committee
Hong Kong: The Hong Kong Polytechnic University

ClinicalTrials.gov processed this record on November 22, 2016

Appendix XIX Ethical clearance from The Polytechnic University



To Lee Regina Lai Tong (School of Nursing)
 From Mak Kit Yi, Delegate, Faculty Research Committee
 Email margaret.mak@ Date 18-Jul-2016

Application for Ethical Review for Teaching/Research Involving Human Subjects

I write to inform you that approval has been given to your application for human subjects ethics review of the following project for a period from 05-Sep-2016 to 14-Jul-2017:

Project Title: Designing and evaluating a school-based hand washing program in Malawi: A Cluster Randomized Controlled Trial
Department: School of Nursing
Principal Investigator: Lee Regina Lai Tong
Reference Number: HSEARS20160619001

Please note that you will be held responsible for the ethical approval granted for the project and the ethical conduct of the personnel involved in the project. In the case of the Co-PI, if any, has also obtained ethical approval for the project, the Co-PI will also assume the responsibility in respect of the ethical approval (in relation to the areas of expertise of respective Co-PI in accordance with the stipulations given by the approving authority).

You are responsible for informing the Faculty Research Committee in advance of any changes in the proposal or procedures which may affect the validity of this ethical approval.

You will receive separate email notification should you be required to obtain fresh approval.

Mak Kit Yi
 Delegate
 Faculty Research Committee

Appendix XX Ethical clearance from Ministry of Health Malawi

Telephone: + 265 789 400
 Facsimile: + 265 789 431
 e-mail doccentre@malawi.net
 All Communications should be addressed to:
 The Secretary for Health and Population



In reply please quote No. MED/4/36c
 MINISTRY OF HEALTH
 P.O. BOX 30377
 LILONGWE 3
 MALAWI

5 September 2016

Balwani Mbakaya Chingaticlifwe
 Hong Kong Polytechnic University
 Hong Kong

Dear Sir/Madam,

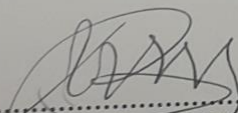
**RE: PROTOCOL # 1653: DESIGNING AND EVALUATING A SCHOOL BASED
 HANDWASHING PROGRAM IN MALAWI: A CLUSTER RANDOMIZED
 CONTROLLED TRIAL**

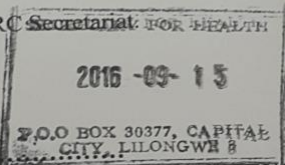
Thank you for the above titled proposal that you submitted to the National Health Sciences Research Committee (NHSRC) for review.

Please be advised that the NHSRC has **reviewed** your application and recommended that you should address the following concerns before approval is given.

- Make specific objectives "SMART"

Kind regards from the NHSRC


 FOR CHAIRMAN, NATIONAL HEALTH SCIENCES RESEARCH
 COMMITTEE



PROMOTING THE ETHICAL CONDUCT OF RESEARCH
 Executive Committee: *Dr. C. Mwansambo (Chairman), Prof. Mjuso Bengo (Vice Chairperson)*
 Registered with the USA Office for Human Research Protections (OHRP) as an International IRB
 (IRB Number IRB00003905 FWA00005976)

Appendix XXI Clearance from The District Education Manager

Ref. No. B/1A

30th March, 2016

FROM: THE DISTRICT EDUCATION MANAGER, BOX 629, MZUZU.
TO : THE HEAD TEACHER, MZUZU CITY PRIMARY SCHOOLS.

LETTER OF INTRODUCTION

The bearer of this letter is Balwani-mbakaya Chingatichifwe, a student at Hong Kong Polytechnic University. He would like to conduct a study in government schools here in Mzuzu city.

Please assist him accordingly.


A.B Chavula
DISTRICT EDUCATION MANAGER

Appendix XXII Clearance from Independent School Association of Malawi

Independent school Association of Malawi (ISAMA)
P.O. BOX 342
Mzuzu, Malawi.

4th July 2016

To whom it may concern

Dear sir/ Madam

I, Pastor Stephen kalua permit Mr. Balwani-mbakaya Chingaticlifwe a PhD candidate at Hong Kong Polytechnic University in Hong Kong to conduct his study in private primary schools in Mzuzu city.

The study he is conducting is entitled "designing and evaluating a school based hand hygiene program in Malawi: a cluster randomized controlled trial"

May you please assist him.

Your consideration will be highly appreciated.

Yours faithfully,



Pastor Stephen kalua (chairman of ISAMA, Northern region)

cell - 08885
09999

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