

**ALCOHOL-BASED HAND RUB IN THE PREVENTION OF  
DIARRHOEA AND RESPIRATORY-TRACT INFECTION AMONG  
CHILDREN IN COMMUNITY SETTINGS: A SYSTEMATIC REVIEW**

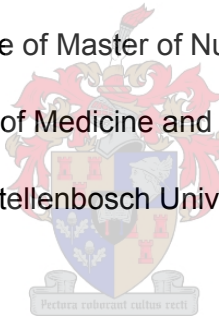
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## DECLARATION

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## ABSTRACT

Annually more than 3.5 million children worldwide, less than five years of age die of diarrhoea and acute lower respiratory-tract infections. Over the last two decades, the care of pre-school children outside of their homes has become more common in most parts of the world and has contributed to an increased risk of respiratory-tract and gastrointestinal infections in children. Children attending day-care centres are at an increased risk for diarrhoea and respiratory-tract infections and hands are the primary vehicle for transmission of infectious diseases. Thus, hand hygiene is essential for preventing and controlling of infection in the health care and community settings. Waterless hand sanitizer as an alternative to hand washing was investigated. Rinse-free hand sanitizer programmes in the community may be effective, safe and feasible.

The aim of the study was to systematically appraise evidence on the effect of alcohol-based hand rub in the prevention of diarrhoea and acute respiratory-tract infection among children aged five years and below in community settings.

The primary outcome of the study was to assess the incidence of respiratory-tract infection and diarrhea. Diarrhoea is defined by the World Health Organization as the excretion of three or more loose or liquid stools per day (or more frequent excretion than is normal for the individual). The secondary outcome was to assess mortality, admission to hospital and duration of hospital stay.

A comprehensive search for relevant studies was conducted on the following databases from 1990 to 2014: EMBASE, MEDLINE, CINAHL, Google Scholar and Cochrane Central Register of Controlled Trials (CENTRAL). We searched the reference lists of all relevant articles and textbooks for more studies. Unpublished data previously presented at international and scientific meetings have been included in the review. Proceedings of international conferences on diarrhoea and respiratory-tract infection among children were searched for relevant articles. Subject experts were contacted.

Two reviewers, Joelynn Steyn (JS) and Oswell Khondowe (OK) selected studies following a two-step study selection process. This review considered all published

randomized controlled trials and quasi-experimental designs published from January 1990 to July 2014. The first step was the selection of studies based on titles and abstracts. Both reviewers selected eligible studies which met the set criteria. During the second step, both reviewers retrieved the full-text articles of the studies and assessed the methodological quality of the studies. Four studies were included in this review. The included studies met most of the quality assessment criteria as stipulated in the Cochrane risk assessment tool. Two studies were cluster-randomized controlled trials, one was a block randomized controlled trial and one was a randomized controlled trial. Disagreements were resolved by discussion and where a lack of consensus existed, consultation with a third reviewer occurred.

The use of alcohol hand rub as compared to control interventions significantly reduced the incidence of diarrhoea in children (RR 0.79, 95% CI 0.63 to 0.99). Statistical heterogeneity was observed among the included studies ( $I^2=69$ ,  $p=0.04$ ). However this review found no significant difference in respiratory-tract infections between intervention groups versus control as observed from the confidence interval (RR 0.98, 95% CI 0.90 to 1.07,  $p=0.63$ ). The results should be interpreted with caution due to the limited number of studies conducted in communities with alcohol-based hand rub used by caregivers. Due to limited studies in this review, it makes it difficult to make strong conclusions on findings and to provide sufficient evidence to guide future research. We therefore recommend that more studies with high quality methodologies, using randomized controlled trial designs be conducted especially in poor resourced communities.

## OPSOMMING

Meer as 3.5 miljoen kinders jonger as vyf jaar oud sterf jaarliks wêreldwyd as gevolg van diarree en akute laer respiratoriese lugweginfeksies. Oor die laaste dekades het die versorging van voorskoolse kinders buite hul tuiste meer algemeen geword in die meeste dele van die wêreld wat bygedra het tot 'n risiko in die toename van respiratoriese en spysverteringskanaalinfeksies by kinders. Kinders by dagsorgsentrums het 'n groter risiko vir diarree en respiratoriese lugweë infeksies want die oordra van siekte-infeksies word veral deur die hande wat as die primêre bron daarvan beskou word, gesien. Dus is hand-higiëne noodsaaklik om infeksies in gesondheidsorg en gemeenskapsentrusms te voorkom en te beheer. 'n Waterlose hande-ontsmettingsmiddel as 'n alternatief om hande te was, is ondersoek. Spoel-vrye hande-ontsmettingsmiddel programme in die gemeenskap mag effektief, veilig en uitvoerbaar wees.

Die doel van die studie was om sistematies die geslaagdheid van bewyse op die effek van alkoholgebaseerde hande-smeermiddel in die voorkoming van diarree en akute lugweginfeksies by kinders 5 jaar en jonger in gemeenskapsentrusms te ondersoek.

Die primêre uitkoms van die studie was om die voorkoms van respiratoriese lugweginfeksie en diarree te asseseer. Diarree soos gedefinieer deur die WGO is die uitskeiding van drie of meer los- of waterige stoelgange per dag (of meer gereelde uitskeiding wat normaal vir die individu is). Die sekondêre uitkoms was om mortaliteit, toelating tot die hospitaal en duur van hospitaalverblyf te asseseer.

'n Omvattende soektog vir relevante studies was op die volgende databasisse van 2004-2014 uitgevoer: EMBASE, MEDLINE, CINAHL, Google Scholar en Cochrane Sentrale Register van Beheerde Toetse. Ons het die verwysingslyste van alle relevante artikels en handboeke vir meer navorsingstudies nagegaan. Ongepubliseerde data wat voorheen aangebied is by internasionale en wetenskaplike vergaderings, is ingesluit in die oorsig. Bevindings by internasionale konferensies oor diarree en lugweginfeksies by kinders was nagegaan in die soektog na relevante artikels. Onderwerpdeskundiges was gekontak.

Die twee navorsers, Joelynn Steyn (JS) en Oswald Khondowe (OK) het studies geselekteer deur 'n twee-stap studieselektierungsproses te volg. Die oorsig het alle gepubliseerde, ewekansige gekontroleerde proewe en kwasi-eksperimenteerde studies oorweeg tussen Januarie 1990 en Julie 2014. Die eerste stap was die selektierung van studies gebaseer op hul titels en opsommings. Beide navorsers het geskikte studies slegs geselekteer as die studie aan die bepaalde kriteria voldoen het. Tydens die tweede stap het beide navorsers die volledige artikels geneem van die studies geselekteer en die gehalte van die metodologie geassesseer. Vier studies is in die oorsig ingesluit. Die ingeslote studies het aan die meeste vereistes soos deur die Cochrane risiko assesseringsinstrument gestipuleer voldoen. Twee studies was groep-ewekansige gekontroleerde proewe, een was 'n blok ewekansige gekontroleerde proef en een was 'n ewekansige gekontroleerde proef. Verskille is opgelos deur bespreking en waar daar onderbreking in konsensus was, het 'n konsultasie met 'n derde beoordelaar plaasgevind.

Die gebruik van 'n alkohol handreiniger, soos vergelyk met kontrole-intervensies, het die voorkoms van diarree in kinders beduidend verminder (RR 0.79, 95% CI 0.63 to 0.99). Statistiese heterogeniteit is egter tussen die ingeslote studies waargeneem ( $I^2=69$ ,  $p=0.04$ ). Hierdie studie het geen beduidende verskille in lugweg infeksies tussen die intervensiegroepe teenoor die kontrolegroep gevind nie soos waargeneem uit die vertrouwe interval (RR 0.98, 95% CI 0.90 to 1.07,  $p=0.63$ ). Die resultate moet met omsigtigheid geïnterpreteer word as gevolg van die beperkte aantal studies wat in gemeenskappe uitgevoer was met alkohol-gebaseerde handreiniger wat deur versorgers gebruik word. As gevolg van die beperkende aantal studies in hierdie studie, is dit moeilik om sterk gevolgtrekkings te maak op bevindinge en om voldoende bewyse te gee om toekomstige navorsing te rig. Ons beveel dus aan dat meer studies met hoë kwaliteit metodologie en wat ewekansige gekontroleerde proef-ontwerpe gebruik, uitgevoer word, veral in swak-toegeruste gemeenskappe.

(RR 0.98, 95% CI 0.90 to 1.07,  $p=0.63$ ). Die resultate moet met omsigtigheid geïnterpreteer word as gevolg van die beperkte aantal studies wat gedoen is in gemeenskappe met alkohol-

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## LIST OF ACRONYMS

HH	Hand hygiene
HSW	Hand washing with soap and water
JG	Joelynn Steyn
OK	Oswell Khondowe
RA	Research assistant
RCT	Randomised controlled trial
URTI	Upper respiratory tract infection
RevMan	Review Manager Software
CDC	Centers for Disease Control and Prevention
MDG	Millennium Development Goal
ES	Prof Ethelwynn Stellenberg

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## CHAPTER 1: SCIENTIFIC FOUNDATION OF STUDY

### 1.1 BACKGROUND AND RATIONALE

Annually, more than 3.5 million children worldwide aged less than 5 years die of diarrhoea and acute lower respiratory-tract infections (Luby, Agboatwalla, Feiken, Painter, Altef & Hoekstra, 2005:225). Gudnason, Hrafnkelsson, Laxdal and Kristinsson (2013:397) state that over the last decades, out of home child care of pre-school children has become more common in most parts of the world and has contributed to an increased risk of respiratory-tract and gastrointestinal infections in children. Kinnula, Tapiainen, Renko, Uhari and Finland (2009:318) also confirmed that children attending a child day-care centre are at increased risk for diarrhoea and respiratory tract infection. Hübner, Hübner, Ojan and Kramer (2011:1) argue that hands are the primary vehicle of transmission of infectious diseases. Therefore, hand hygiene is essential for preventing and controlling infection in the health care and community settings. Waterless hand sanitizer as alternative to hand washing was investigated (Hübner et al., 2011:1), thus rinse-free hand sanitizer programmes in the community may be an effective safe and feasible method.

A study on hand hygiene compliance and environmental determinants in child day-care centres reported a 16% compliance among caregivers after diapering (Zomer, Erasmus, Vlaar, van Beeck, et al., 2013:497). Furthermore, in other settings, compliance was also found to be generally low. A systematic review reported the median compliance to hand hygiene guidelines of health care workers in hospitals to be 40% (Zomer et al., 2013:497). Rotavirus, one of the micro-organisms that cause diarrhoea, are most often found in stools and are transmitted through ingestion (Farrer, 2010:12). Respiratory-tract infections are easily transmitted when contaminated secretions from an infected individual are deposited on the fingers, which could in turn come into contact with the hands or mucous membranes of the nose or mouth of a susceptible person (Farrer, 2010:12). Children are two to three times at greater risk of acquiring infections than adults. They place their hands and objects in their mouths and are in very close interpersonal contact with others. Furthermore, the absence of habitual hand washing and other hygienic practices and

the need for constant direct physical contact with adults, increases their risk (Nesti & Goldbaum, 2006: 299).

Respiratory tract infections and gastrointestinal in children may result in severe morbidity and are a significant cost burden for families and society. As such, it is imperative that implementable and practical intervention programmes are developed to reduce the risk of these illnesses (Gudnason et al., 2013:397). Zomer et al., (2013: 497) state that day-care centre attendance is a risk factor for acquiring gastrointestinal and respiratory-tract infection. In addition, the authors state that these infections may cause stress for both children and their parents, incur cost for health care and parental work absence, and result in secondary transmission (Zomer et al., 2013 2).

The Millennium Development Goals (MDG) one to four are aligned with improving child health through the reduction of diarrhoea in children under five years of age (United Nations Millennium Development Goals, 2010:np). South Africa has adopted the universal MDG. Goal number four of the MDG which concerns the reduction of mortality in children under five is considered very important and the objective is to achieve a mortality rate of no more than 2% in such children by 2015 (Millennium Development Goals, 2010:np).

## **1.2 DESCRIPTION OF THE INTERVENTION**

The two main hand hygiene methods are hand rub and the use of soap and water followed by thorough drying of the hands (WHO, 2009:28). Alcohol-based hand rub is the preparation of 60% to 95% ethanol or Isopropanol alcohol designed for hand application to reduce the number of viable micro-organisms (CDC, 2002:8). Hand washing requires the application of plain soap and water to wash hands (CDC, 2002:3), which is problematic in settings without access to constant running water. In such settings, the availability of alcohol-based hand rub may be useful to promote effective hand hygiene practices (WHO, 2005:23).



### **1.3 HOW THE INTERVENTION MIGHT WORK**

Alcohol has excellent in-vitro germicidal activity against gram-positive and gram-negative vegetative bacteria and several viruses (CDC, 2002:8). The introduction of alcohol-based hand rub has led to increased hand hygiene compliance among healthcare workers and decreased healthcare-associated infections (WHO, 2005:26). Hand hygiene is a simple and effective measure to prevent infection (Zomer et al., 2013:2). Hand hygiene is the most effective way to stop the spread of micro-organisms and to prevent healthcare associated infections (Margiorakos, Leens, Douvrot, May-Michelangeli, Reichardt & Gastmeier, et al., 2010:1). This view is also supported by the WHO (2005:5) and other researchers (Jumaa, 2005:3). Regular hand hygiene decreases infection. It may improve child health by reducing the transmission of pathogens that cause diarrhoea and respiratory-tract infection among children in low to middle income countries (WHO, 2005: 23).

### **1.4 SIGNIFICANCE OF THIS REVIEW**

No reported studies were found on the effect of alcohol-based hand rub used by community-based caregivers in child health in South Africa. This situation raised questions about methods for hand hygiene in communities with no running water in their dwellings. The researcher identified the importance of conducting research on alcohol-based hand rub used by caregivers in the communities. The rationale for conducting this review was thus to determine the significance of the effect of alcohol hand rub in reducing the incidence of diarrhoea and respiratory-tract infection in children. Results may influence future child health policy in reducing the incidence of diarrhoea and acute respiratory-tract infections in community settings.

### **1.5 RESEARCH QUESTION**

What is the effect of alcohol-based hand rub in the prevention of diarrhoea and respiratory-tract infections among children in community settings?

## **1.6 RESEARCH AIM**

The aim of the study was to systematically appraise evidence on the effectiveness of alcohol-based hand rub in the prevention of diarrhoea and respiratory-tract infections among children in community settings.

## **1.7 OBJECTIVES**

- To identify studies comparing hand rub versus other interventions for the prevention of diarrhoea and acute respiratory-tract infection.
- To synthesize results of studies that compare hand rub over other interventions for the prevention of diarrhoea and acute respiratory-tract infection.
- To evaluate the methodological quality of studies included in the review.

## **1.8 SELECTION OF STUDIES**

This review considered all published randomized controlled trials and quasi-experimental designs published from January 1990 to July 2014. The systematic review included studies on children aged five years and below in community settings. Outcome measures of interest included the incidence of diarrhoea and respiratory tract infection. Databases searched included EMBASE, MEDLINE, CINAHL, Google Scholar and the Cochrane Central Register of Controlled Trials. Reference lists of all relevant articles and textbooks were searched for additional studies. Search terms used were; randomized, randomization, alcohol hand rub, diarrhoea, respiratory tract infection, caregivers, children, pre-school and day care.

## **1.9 ASSESSMENT OF RISK OF BIAS**

The assessment of risk of bias in the included studies will be discussed in detail in Chapter 3.

The Cochrane collaboration risk of bias tool was used to assess the methodological quality of the included studies (Higgins & Green, 2008:84).

1. Random sequence generation (selection bias) to check for possible selection of bias.
2. Allocation concealment to check for possible selection bias.
3. Blinding of participants and personnel to checking possible performance bias.
4. Blinding of outcome assessment to check for possible detection bias.
5. Incomplete outcome data to check for possible attrition bias due to the amount, nature and handling of incomplete outcome data.
6. Other bias to check for bias due to problems not covered by (1) to (6) and overall risk of bias.

### **1.10 ETHICAL CONSIDERATIONS**

Permission was obtained from the Research Committee of the Division of Nursing, Stellenbosch University prior to commencement of the proposed study. In a systematic review no actual participants are recruited, and only available studies on the topic are consulted.

### **1.11 DISSEMINATION OF RESULTS**

The report was compiled in the form of a thesis and submitted to Stellenbosch University. Results will be presented at local and international conferences and published in a peer-reviewed accredited journal.

### **1.12 STUDY LAYOUT**

#### **Chapter 1: Introduction: Scientific foundation of the study**

In chapter 1 the background of the research and the rationale for the review is described.

#### **Chapter 2: Literature review**

Chapter 2 provides the reader with an in-depth review of evidence on alcohol-based hand rub in the prevention of diarrhoea and respiratory-tract infection among children in community settings.

### **Chapter 3: Research methodology**

Chapter 3 describes the research methodology applied in the review.

### **Chapter 4: Results**

The findings, data synthesis, interpretation and presentation of the results in the form of tables and figures are described in this chapter.

### **Chapter 5: Discussion**

Chapter 5 provides the findings, conclusions and recommendations derived from this study.

## **1.13 OPERATIONAL DEFINITIONS**

### **Systematic review**

A systematic review is a structured, comprehensive synthesis of quantitative studies in a particular health care area to determine the best research evidence available for expert clinicians to use to promote an evidence base practice (Burns & Grove, 2009, 27-28). A systematic review tries to identify, appraise, criticize, select and synthesize all high-quality research evidence relevant to research question.

### **Meta-analysis**

Meta-analysis is a technique for quantitatively integrating the findings from multiple studies on a given topic (Polit & Beck, 2006:504).

A meta-analysis was conducted that allowed for a more objective appraisal of the evidence, provided a precise estimate of a treatment effect, and explained heterogeneity between the results of individual studies.

### **Heterogeneity**

The Cochrane Handbook for Systematic Reviews of Intervention (2006:136) refers to heterogeneity as any kind of variability amongst studies in a systematic review.

#### **1.14 SUMMARY**

Chapter 1 provided a brief introduction of the review. Important aspects in this chapter include the background of the research, and ethical considerations. The next chapter is a literature review on evidence related to this study.

## **CHAPTER 2: LITERATURE REVIEW**

### **2.1 INTRODUCTION**

Brink, Van der Walt and Van Rensburg (2006:67) describes literature as sources that are effective in providing the in-depth knowledge the researcher requires to study the selected problem. A literature review involves finding, reading, understanding and formatting conclusions about the published research and theory as well as presenting it in an organised manner (Burns & Grove, 2005:38). This chapter focuses on literature relating to hand hygiene in the community and the usage of alcohol-based hand rub.

For the purpose of this review, namely alcohol-based hand rub in the prevention of diarrhoea and respiratory-tract infection among children in community settings, the following findings from the literature are discussed: overview of hand hygiene, history of hand hygiene, different definitions of hygiene, hand hygiene practices and epidemiology, communicable diseases in children, hand hygiene in South Africa, highlights of successful hand hygiene implementation strategies, the role of hand hygiene in healthcare-associated infection prevention, factors influencing hand hygiene compliance and the importance of hand hygiene in a community setting.

### **2.2 SYSTEMATIC REVIEW: AN OVERVIEW AND IMPORTANCE**

No published systematic review study on alcohol-based hand rub in the prevention of diarrhoea and respiratory tract infection among children in community settings has been undertaken. A systematic review is a structured, comprehensive synthesis of quantitative studies in a particular health care area to determine the best research evidence available for expert clinicians to use to promote an evidence-based practice (Burns & Grove, 2009:27,28). A systematic review identifies, appraises, criticizes, selects and synthesizes all high quality research evidence relevant to the research question. A meta-analysis is a type of systematic review that uses statistical methods to combine and summarize the results of several primary studies (Higgins & Green, 2006:128).

Healthcare providers, consumers, researchers and policy makers are inundated with unmanageable amounts of information (Higgins & Green, 2006:15). A need for systematic reviews exists to efficiently integrate valid information and provide a basis for rational decision making (Higgins & Green, 2006:15). Consistent research results may be applied across populations and settings. The use of explicit, systematic methods in reviews limits bias and reduces chance effects, thus providing more reliable results from which to draw conclusions and make decisions. Clarke and Stewart (2011:4) reported that systematic reviews are promoted and accepted as a gold standard for summarizing existing research evidence in a way that improves precision, minimizes bias and in some sense establishes “the truth of the matter”. Systematic reviews therefore have great potential to influence clinical decision-making and health policy. However, systematic reviews also require significant investment of time and resources if they are to be done well. Systematic reviews make considerable efforts to address the potential for bias in individual studies. Indeed there is emerging evidence of outcome reporting bias in systematic reviews. Users need to be able to make judgements about risk of bias in reviews (Higgins & Green, 2006:15).

### 2.2.1 Steps in conducting a systematic review:

There are five main steps followed in conducting systematic reviews. Higgins and Green (2008:16) describe these steps as formulating a research problem, identifying relevant literature, assessing the quality of studies, extracting data from the identified studies, summarizing and analyzing it, and finally interpreting the results.



**Figure 1.1: Steps of conducting a systematic review (Higgins & Green, 2008:59)**

#### **Step 1: Formulating the problem**

The problem to be addressed by the systematic review should be specified in the form of clear, unambiguous and structured questions before beginning the review (Khan, Kunz & Kleijnen, 2003:118; Higgins & Green, 2008:59). Serious reviewers



devote a substantial amount of time and effort in formulating accurate questions before commencing the review. A structured approach often used to frame questions consists of four components or facets. These four components include the population, interventions, outcomes related to the problem statement and the study designs that are suitable for addressing it (Higgins & Green, 2008:59; Khan et al., 2003:118).

### **Step 2: Identifying relevant literature**

The search for studies should be broad and a clearly defined search strategy that specifies data sources and keywords for searching should be developed and documented. Multiple resources should preferably be searched bearing in mind the budget and the manpower constraints (Higgins & Green, 2008:65). Resources include:

- electronic databases
- hand-searching
- checking reference lists
- checking other reviews
- print versions of electronic databases
- identifying unpublished studies and
- evidence on adverse effects

Most systematic reviews, specifically Cochrane reviews, include only randomised or quasi-randomised trials, while others are less restrictive (Higgins & Green, 2008:68). The type of design to include also relies on the questions posed, and the types of study designs employed to answer certain research questions.

The first stage for checking the results of a search includes assessing titles and abstracts to determine whether each article meet pre-determine eligibility criteria (Higgins & Green, 2008:69). The latter should flow directly from the review questions and the reasons for inclusion/exclusion of studies should be recorded (Khan et al., 2003:119).

Reviewers must decide if more than one of them will assess the records retrieved from electronic databases. There is evidence that using at least two reviewers has an important effect on reducing the possibility that relevant reports will be discarded (Khan et al., 2003:119). Once the screening process has been completed, the full text of the citations considered relevant for the review, are retrieved (Higgins & Green, 2008:69).

Upon retrieval of the relevant articles, the predetermined inclusion and exclusion criteria are again applied to the full reference of all the studies to aid final selection. A blinded process is followed where the reviewers independently review the articles. It is recommended that disagreements regarding inclusion or exclusion of articles be resolved by discussion or a third reviewer is requested to participate (Higgins & Green, 2008:69).

Potential problems in systematic reviews and meta-analysis should be guarded against. Bias could include English language bias, database bias, citation bias, multiple publication bias and bias in provision of data. Critical investigation for the presence of such biases in sensitivity and funnel analyses is therefore advised and should form an important part of meta-analyses if appropriate (Higgins & Green, 2008:80).

### **Step 3: Quality assessment of studies**

Quality assessment of individual studies that are summarized in systematic reviews is essential to limit bias in conducting the review, increase insight into potential comparisons and direct interpretations of findings. Factors that warrant assessment are those related to applicability of findings (external validity or generalizability), validity of individual studies, and certain design characteristics that affect

interpretation of results (Higgins & Green, 2008:79). Assessment of study quality is relevant to every step of a systematic review.

Internal validity is the extent to which the design and conduct of a study are likely to have prevented systematic error (bias). In studies of the effects of health care, the main types of bias arise from systematic differences in the groups that are compared (selection bias), the care that is provided, exposure to other factors apart from the intervention of interest (performance bias) withdrawals or exclusion of people entered into the study (attrition bias) or how outcomes are assessed (detection bias) (Higgins & Green, 2008:80).

External validity is the extent to which results provide a correct basis for generalizations to other circumstances including patient characteristics, treatment regimens, settings and modalities of outcomes (Higgins & Green, 2008:79).

Study design is very important and determines the validity of the observed effects, for example, our confidence that results of a study are likely to approximate to the 'truth' for the participants or patients studied depends on the soundness of its design (Khan et al., 2003:120).

The Cochrane Collaboration's recommended tool for assessing risk of bias is neither a scale nor a checklist. It is a domain-based evaluation (Cochrane 'risk of bias' tool), in which critical assessments are made separately for different domains, namely, sequence generation, allocation, concealment, blinding, incomplete data, selective outcome reporting and other sources of bias (Higgins & Green, 2008:83).

**Step 4: Data and analysis**

The data collection and extraction form is the link between the primary, which is the individual journal article and what is reported by the reviewer. Sufficient time, thought and planning should be invested in the design of these forms. Key components of these forms include information regarding study references and reviewers, verification of study eligibility and study characteristics including methods, participants, intervention and outcomes (Higgins & Green, 2008:91). The data collection form should be designed bearing in mind the specific review questions and planned analyses at all times. A blinded data extraction form for the authors, the journal and the results when assessing quality, has been proposed. Although there is some evidence that blinded assessments of trial quality may be more reliable and different from assessments that are not blinded, blinding is difficult to achieve, is time consuming and might not substantially alter the results of a review (Higgins & Green, 2008:91).

Data synthesis involves collecting and summarizing the results of the included primary studies. Synthesis can be narrative or descriptive i.e. non-quantitative. Narrative synthesis uses subjective rather than statistical methods for reviews, where meta-analysis is either not feasible or not sensible. For narrative reviews, care should be taken not to introduce bias by inappropriately stressing the results of one or certain studies over others. It is sometimes possible to complement a descriptive synthesis with a quantitative summary (Higgins & Green, 2008:97).

Using statistical techniques to obtain a quantitative synthesis is referred to as meta-analysis and results are often displayed graphically, typically using forest and funnel plots. The value meta-analysis can add to a review depends on the contexts in which it is used. Reasons for possibly including a meta-analysis in a review are to:

- increase power,
- improve precision,
- answer questions not posed by the individual studies

- to settle controversies arising from conflicting studies or
- to generate new hypothesis.

Well conducted meta-analysis allows for an objective appraisal of the evidence. It provides for a precise estimate of treatment effect, and may explain heterogeneity between the results of individual studies. Opinions will often differ on the correct method for performing a particular meta-analysis. In this regard the strength of the findings for different assumptions about the data and the methods that were used can be inspected through a sensitivity analysis.

### **Step 5: Interpreting the results**

It can be reasoned that the results of a systematic review or meta-analysis should stand alone, but in fact many readers turn to the discussions and conclusions for help when interpreting the results. Discussions and conclusions about the following issues may help readers to make decisions:

- The strength of the evidence
- The applicability of the results
- Other information e.g. considerations of costs and current practice
- Clarifications of any important trade-offs between the expected benefits, harms and costs of the intervention.

This section of the systematic review should be able to help people understand the implications of the evidence in relation to practical decisions. It should consider that the purpose of a systematic review is to present information, rather than to offer advice. Important limitations of the systematic review should also be emphasized here and placed in context when interpreting the findings (Higgins & Green, 2008:167).

The Cochrane Collaboration and the Cochrane Handbook for Systematic Reviews of Intervention focus particularly on systematic reviews of randomised controlled trials

(RCTs) because these are likely to provide more reliable information than other sources of evidence on differential effects of alternative forms of healthcare (Kunz, 2003:18). Systematic reviews of other types of evidence can also help those wanting to make better decisions about healthcare, particularly forms of care where RCT have never been done. Furthermore RCTs are particularly suited to question effectiveness, but may be less suitable for considerations of safety or adverse effects. The basic principles of reviewing research are the same, whatever the type of evidence that is being reviewed (Higgins & Green, 2008:16). For the purpose of this study, the Cochrane Handbook for Systematic Reviews of Interventions version 5, Updated September 2006 and 2008 was used.

### **2.3 OVERVIEW OF HAND HYGIENE**

Hand hygiene is the primary measure to reduce infection (WHO, 2005:5). According to Magiorakos, Leens, Douvot, May-Michelangeli, Reichardt and Gastmeister et al. (2010:1), hand hygiene is the most effective way to stop the spread of microorganisms and to prevent health-care associated infections (HAI). Substantiated further by Jumaa (2005:3), hand hygiene is the most effective measure for interrupting the transmission of microorganisms that cause infection both in community and healthcare settings.

Hand washing requires the application of plain soap and water to wash hands (CDC, 2002:3). These provisions and requirements are problematic in settings without access to running water. In such settings, the availability of an alcohol-based hand rub is critical to promote effective hand hygiene practices (WHO, 2005:23). Pickering, Boehm, Mwanjali and Davis (2010:270) indicates that the correct use of hand sanitizer does not require water, takes less time than hand washing and does not require drying of hands with potentially contaminated surfaces. According to Pickering et al. (2010:270), a range of efficacy tests for hand sanitizer have been performed on hands artificially contaminated with bacteria and viruses. These studies have demonstrated hand sanitizer to be as, or more effective, than hand washing soap and water.

The introduction of alcohol-based hand rub has led to an increase in hand hygiene compliance among healthcare workers and decreased healthcare-associated infections (WHO, 2005:26). According to Allegranzi and Pittet (2009:312), the introduction of alcohol-based hand rubs and continuous educational programmes are key factors to overcoming infrastructure barriers and to build solid knowledge improvement. Support by healthcare administrators and commitment by national and local government are essential to make hand hygiene an institutional and national priority for patient safety and to ensure long-term sustainability of promotional programmes (Allegranzi & Pittet, 2009:313). The question that arises is if home-based hand hygiene can reduce communicable infection?

The importance of hand hygiene in the control of infection cannot be over emphasised and improving hand hygiene remains a challenge for infection control practitioners in healthcare institutions and in the community (Jumaa, 2005:3,4). No single intervention is adequate to bring about change in behaviour. In fact, for hand hygiene practices to be changed and results to be sustainable, multimodal approaches and complex interventions have been shown to be necessary, (Magiorakos et al. 2010:1).

The World Health Organization (WHO), introduced the “Clean Care is Safer Care” campaign in 2005. Since then, more than 120 countries have pledged to improve hand hygiene as a keystone of their national and subnational healthcare-associated infection prevention programme. In 2005, the WHO’s World Alliance for Patient Safety, launched the First Global Patient Safety Challenge, Clean Care is Safer Care, which targeted the prevention of HAI. Subsequently, in 2009 the WHO launched the SAVE LIVES: Clean Your Hands initiative, highlighting the importance of hand hygiene and providing guidelines and toolkits for the best implementation of hand hygiene (Magiorakos et al., 2010:1).

Germany embarked on a national campaign to improve hand hygiene on 1 January 2008. The campaign is designed as a multi-modal campaign based on the WHO implementation strategy. Reichardt, Königer, Bunte-Schönberger, Van der Linden, Mönch and Schwab et al. (2013:511), reported the implementation of a national campaign using the WHO multi-modal intervention strategy which led to improved hand hygiene compliance and hand rub availability in participating settings.

## **2.4 HISTORY OF HAND HYGIENE**

The word hygiene is derived from the name Hygeia, the Greek goddess of healing and in modern terms hygiene usually refers to cleanliness and especially to any practice which leads to the absence or reduction of harmful agents (Jumaa, 2005:4). Although hand washing has been considered a measure of personal hygiene for centuries, the specific link between hand washing and the spread of infectious diseases has been reported only during the last 200 years (Jumaa, 2005:4). Hand washing with soap and water has been a measure of personal hygiene for generations (CDC, 2002:2). The concept of cleansing hands with an antiseptic agent emerged in the early 19th century. In 1822, a French pharmacist demonstrated that solutions containing chlorides of lime or soda could eradicate the foul odours associated with human corpses and that such solutions could be used as disinfectants and antiseptics. In 1925 it was proposed that physicians and other persons attending to patients with contagious diseases would benefit from moistening their hands with liquid chloride solutions (CDC, 2002:1).

William McKinley, the 25<sup>th</sup> president of the United States of America died on September 14 1901 from gangrene caused by a bullet wound. He was shot on September 6, 1901. Specialists were summoned. As yet unknown to the doctors, gangrene was growing on the walls of his stomach and toxins were passing into his blood. Precautions against infections were admittedly difficult and negligently handled (Leech, 1959:np). Another similar case where anti-septic measures were not taken is reported by Brown (1978:np). The 20<sup>th</sup> president of the United States of America, James A. Garfield was shot by an assassin three months after election.



Doctors probed the wound with dirty, unsterilized fingers and instruments, attempting to find the location of the bullet. However, blood poisoning and infection set in. Puss-filled abscesses spread all over his body as infection raged. Unfortunately for Garfield most American doctors of the day did not believe in anti-sepsis measures or the need for cleanliness to prevent infection (Brown, 1978:np).

Hand hygiene is a topic of considerable attention ever since Semmelweiss stressed the importance of hand washing in 1947 (Messina, Brodell, Brodell & Mostow, 2008:1043). The early studies of Semmelweiss (1840) and Holmes (1843) are considered the seminal studies for the importance of hand washing to reduce cross-contamination (Twomey, 2006:1). In 1846, Semmelweiss reported a reduction in the number of deaths from puerperal infection as a result of the implementation of a hand hygiene programme (Petty, 2009:250). In 1847 Ignaz Semmelweiss first demonstrated that good hand disinfection was able to prevent puerperal fever and evidence continues to show that hand hygiene is the simplest, most effective way to prevent cross-transmission of micro-organisms and healthcare-associated infections (HAI) (Twomey, 2006:1). Holmes described ways to control cross-contamination but was ignored at the time (Twomey, 2006:1). Although hand washing has been considered a measure of personal hygiene for centuries, the specific link between hand washing and the spread of infection was only reported during the last 200 years (Jumaa, 2005:4).

The establishment of hand washing as an intervention to prevent infection did not occur for many years and formal written guidelines on hand washing practices in hospitals were published by CDC in 1975 and 1985. In 1988 and 1995 guidelines for hand washing and hand antisepsis were published by the Association for Professionals in Infection Control (APIC). In 1995 and 1996 the Healthcare Infection Control Practices Advisory Committee (HICPAC) recommended that either antimicrobial soap or a waterless antiseptic agent be used for cleaning hands upon leaving the rooms of patients (CDC, 2002:2).

## **2.5 DEFINITIONS OF HAND HYGIENE**

Hand hygiene includes a variety of action related concepts which may be used in specific settings. The World Health Organization (WHO, 2005:np) defines hand hygiene as any action for hand cleaning and the primary measure to reduce infection. Substantiated further, WHO (2009:2) refers to hand hygiene practices as antiseptic hand washing, antiseptic hand rubbing, hand antisepsis, hand care, hand washing, hand cleansing, hand disinfection, hygienic hand antisepsis, hygienic hand rub and hygienic hand wash.

According to Jumaa (2005:4) hand washing refers to washing hands with non-antimicrobial soap while, antiseptic hand wash refers to washing hands with water and soap or another detergent containing an antiseptic agent. In addition, antiseptic hand rub refers to rubbing hands with an antiseptic hand rub and surgical hand antisepsis is referred to preoperative antiseptic hand wash or hand rub performed by surgical personnel.

The CDC (2002:7) refers to hand hygiene either as hand washing, antiseptic hand wash, and alcohol-based hand rub, or surgical hand hygiene/antisepsis

## **2.6 HAND HYGIENE PRACTICES**

According to the Centres for Disease Control and Prevention (CDC) hand hygiene applies to either hand washing, antiseptic hand wash, antiseptic hand rub or surgical hand antisepsis (CDC, 2002:3). The two major hand hygiene methods are alcohol-based hand rub and soap and water (WHO, 2009:28). Studies have shown that the use of alcohol-based hand rub increased the killing rates of various bacteria compared to the use of soap and water (CDC, 2002:2).

Studies done by Schweon, Edmonds, Kirk, Rowland and Acosta (2013:39) showed that alcohol-based hand rub reduces hand contamination during routine patient care

more effectively than hand washing with soap and water. Usually hands that are visibly dirty must be washed with soap and water, while alcohol-based hand rub is applied to visibly clean hands. The latter may also be indicated where there is no water available (CDC, 2002:2).

Alcohol-based hand rub is an alcohol-containing preparation of 60% to 95% ethanol or isopropanol designed for application to the hands to reduce the number of viable micro-organisms (CDC, 2002:8). Alcohol has excellent in vitro germicidal activity against gram-positive and gram-negative vegetative bacteria and when used against several viruses (CDC, 2002:8). Alcohol-based hand rub that do not require water, are a benefit for agitated parents and busy caregivers in hospitals and communities. Alcohol-based hand rub rapidly destroys most bacteria and viruses. Products that contain emollients tend to be gentler on the hands than soap and water (Sandora, Taveras, Shih, Resnick, Lee & Ross-Degnan et al., 2005:587).

The introduction of alcohol-based hand rub has led to an increase in hand hygiene compliance among health care workers and a decrease in healthcare associated infections (WHO, 2005:14). This in turn has resulted in saved lives and reduced morbidity (WHO, 2005:14). Alcohol-based hand rub can prevent the transfer of healthcare associated pathogens. In one study, gram-negative bacilli were transferred from a colonized patient's skin to a piece of catheter material via the hands of nurses in only 17% of experiments after the use of an alcohol-based antiseptic hand rub (WHO, 2005:14). In contrast, transfer of organisms occurred in 92% of experiments after hand washing with plain soap and water (CDC, 2002:11). This experimental model indicates that when hands of health care workers (HCW) are heavily colonised, an antiseptic hand rub using an alcohol-based hand rub can prevent pathogen transmission more effectively than hand washing with plain soap and water (CDC, 2002:11). In all but two of the trials that compared alcohol-based solutions with antimicrobial soap, the alcohol reduced bacterial counts on hands more than the washing of hands with soap (CDC, 2002:11).

Failure to apply infection control measures favours the spread of pathogens (WHO, 2005:12). The prevention of the spread of infections is important during outbreaks, and health-care settings can act as multipliers of disease, with an impact on both hospital and community health.

Lee, Salomon, Friedman and Hibberd et al. (2005: 852) performed an observational, prospective cohort study to determine transmission rates for respiratory and gastro intestinal infection illnesses within families with at least one child between six months and five years of age. They concluded that alcohol-based gel use was associated with reduced respiratory illness transmission in the home. According to Sandora et al. (2005:587-588), an increasing body of literature suggests that regular use of alcohol-based hand rub can reduce transmission of infections in hospitals and other health care settings.

The adoption of alcohol-based hand rub is considered the gold standard for hand hygiene in most clinical situations. The recommendations promoted by CDC and WHO and embraced by many national hand hygiene guidelines, is based on evidence of better microbiology efficacy, less time required to achieve the desired effect, point of patient care accessibility and a better skin tolerance profile (Allegranzi & Pittet, 2009:312).

In 2006, a prospective study in two dental offices, it was demonstrated that the use of daily hand hygiene protocol using alcohol-based hand rub is less costly, less time-consuming than traditional hand washing and easier to use (Messina et al., 2008:1048). Messina et al. (2008:1048) also found that alcohol-based hand rub is with fewer adverse skin events and reasonable cost compared with other hand hygiene products. CDC (2002: 12) through best evidence available, support the use of alcohol-based hand rub for preventing infection. The WHO Guidelines on Hand Hygiene in Health Care have been conceived to catalyse hand hygiene improvement in any setting regardless of resources available and cultural background.

According to Allegranzi and Pittet (2009:312), there is a strong emphasis in the guidelines and implementation tools on the availability of alcohol-based hand rub as key factor for hand hygiene improvement. In addition, the procurement and cost of these products, especially in developing countries, challenges the recommendation's feasibility. Global sales of commercially produced, alcohol-based hand rub in 2007 were high with an overall 16.3% increase compared to 2003 (Allegranzi & Pittet, 2009).

In Hong Kong a clustered randomized controlled trial of a hand hygiene intervention involving pocket-sized containers of alcohol-based hand rub was done. The result indicated an increased adherence to hand rubbing and a reduction in the incidence of serious infections in long-term care facilities (Yeung, Tam & Wong, 2011:67).

According to Plante-Jenkins and Belu (2009:111), alcohol-based hand rub have been available since 1997 at Trillium Health Centre, one of Canada's largest community hospitals. In 2008 the Ministry of Health and Long-Term Care's Provincial Infectious Disease Advisory Committee issued guidelines recommending the use of alcohol-based hand rub as the preferred method of hand hygiene. Following this implementation a study was done to demonstrate that alcohol-based hand rub is effective at reducing bacteria present on the hands of healthcare providers at the Trillium Health Centre (Plante-Jenkins & Belu, 2009:112). Visual and written feedback of the results indicated that 99% of healthcare provider's preferred alcohol-based hand rub. Alcohol-based hand rub is economical and versatile and the challenge has improved healthcare providers' confidence in alcohol-based effectiveness (Plante-Jenkins & Belu, 2009:114).

## **2.7 COMMUNICABLE DISEASES IN CHILDREN**

Every year diarrhoea and acute respiratory–tract infections cause the deaths of more than 3.5 million children under five years worldwide (Farrer, 2010:12). According to Lee et al. (2014:852) 7.5 million children younger than five years were enrolled in child care in the United States in the year 2013. These numbers continue to increase as women enter the workforce in greater numbers as the number of single-parent homes escalate. In turn, the widespread use of child care facilities has influenced the epidemiology of infectious diseases in the community (Lee et al., 2014:852).

Concentrations of young children in crèches are at an extremely high risk of being affected by the transfer of infections among each other. Transmission rates are high because children readily exchange secretions. Furthermore, at this vulnerable developmental stage of life children are susceptible to the transfer of secretions via contaminated hands of caregivers and objects. Consequently, transmission of these infections within child care settings, are enhanced. Children with potentially communicable infections may be excluded from child care to prevent further spread of infections (Lee et al., 2014 852).

Infections that are acquired in child care are readily transmitted to family members in the home where organisms are spread primarily via contaminated hands (Sandora et al., 2005:587). According to Farrer (2010:12), respiratory-tract infections are easily transmitted when contaminated secretions from an infected individual are deposited on the fingers, which then come into contact with the hands or mucous membranes of the nose or mouth of a susceptible person. The virus which causes the common cold can remain viable on human skin for up to two hours. Viral spread from contact with a contaminated surface is another mechanism of transmission. Rhinoviruses that are estimated to cause up to half of all colds per year, may survive for 2 hours to 7 days on surfaces and the influenza virus for one to two days (Farrer, 2010:12).

According to Luby, Agboatwalla and Feiken (2005:225) diarrhoeal diseases remain one of the top three killers of children in the world. Diarrhoea is a serious global public health problem and the WHO estimates that over 2.2 million deaths due to diarrhoeal infections occur annually, especially among children less than five years of age (WHO, 2002). In developing countries, diarrhoeal diseases are estimated to cause approximately two million deaths among children under 5 years of age each year (Kosek, Bern & Guerrant, 2003:1421). These deaths are preventable. Microorganisms that cause diarrhoea are most often found in stools and these microorganisms may cause disease when they gain entry into the body through the mouth (Farrer, 2010:12). Entry into the mouth can be facilitated by hands that have been in contact with stools, from contaminated water, unwashed raw foods, poorly cooked or reheated foods, unwashed eating utensils and contaminated clothes (Farrer, 2010:12). Rotaviruses are persistent on surfaces from 6 to 60 days (Farrer, 2010:14).

It has been estimated that the universal adoption of hand washing with soap would save more than a million of these lives per year (Curtis & Cairncross, 2003:275). Healthcare professionals face daunting challenges in personal hand hygiene and environmental sanitation (Sandora et al., 2005:587). A review of hand hygiene by the International Scientific Forum on Home Hygiene (IFH) in 2007 concluded that a significant reduction in the infectious disease burden could be achieved by giving greater attention to good hand hygiene in the home and community. The review highlights the need for more education about the importance of hand hygiene including guidance on how to choose and apply the best hand hygiene methods (CDC, 2009:np).

## **2.8 HAND HYGIENE IN SOUTH AFRICA**

In Africa, more than 38% of the population has no access to a safe water supply, a higher proportion than in any other region of the world (Draft White Paper on Water Services, Republic of South Africa, 2002:np). In South Africa, at the dawn of democracy, there were 12 million people without adequate water and 20 million

people without adequate sanitation services. Nevertheless, South Africa has made great strides in reducing the gross inequality in water supply since 1995 (Duse et al., 2003:np). South Africa was the first country to launch the water, sanitation and hygiene for all campaign (WASH) as a national campaign (UNICEF, South Africa, 2010:np). The objectives of WASH in South Africa are to promote hand washing to such an extent that it results in a decrease in water borne disease and an increase in the awareness of the benefits of good sanitation to consumers. Hand washing saves lives (UNICEF, South Africa, 2010:np).

A comprehensive family hygiene campaign in peri-urban Cape Town were conducted and concluded that hygiene education alone resulted in meaningful reduction in gastrointestinal and respiratory illness in children across communities. However, families with hygiene education plus consistent use of provided hygiene products had greater reduction (Cole et al., 2012:109).

## **2.9 IMPLEMENTED STRATEGIES IN THE COMMUNITY AND HEALTHCARE OF SUCCESSFUL HAND HYGIENE**

Successful hand hygiene depends on the implementation of strategies. Strategies may include:

- governmental support,
- the use of indicators for hand hygiene benchmarking,
- developing national surveillance systems for auditing alcohol-based hand rub consumption,
- ensuring seamless coordination of processes between health regions in countries with regionalised healthcare systems,
- implementing the WHO My Five Moments for Hand Hygiene, and
- auditing of hand hygiene compliance (Magiorakos et al., 2010:1)

The newly developed 'My Five Moments for Hand Hygiene' has emerged from the WHO Guidelines on Hand Hygiene in Health Care to add value to hand hygiene



improvement strategies (WHO, 2006:np). Sax, Allegranzi, Uckay, Larson, Boyce and Pittet (2007:13) recommend that My Five Moments for Hand Hygiene should occur

- before patient contact,
- before an aseptic task,
- after body fluid exposure risk,
- after patient contact and
- after contact with patient surroundings

According to Reichardt et al. (2013:513), the introduction of the WHO Five Moments model is also the key element in the German hand hygiene campaign. In England, Wales and Australia this model is an integral part of many national campaigns.

In Belgium, three multimodal, country-wide hand hygiene campaigns were organised from 2005-2009. The main foci of the campaigns were to improve the use of alcohol-based hand rub and to measure participants compliance with hand hygiene before and after each patient's intervention. Each of the three national hand hygiene campaigns resulted in a significant increase in hand hygiene compliance of healthcare workers and also a higher consumption of alcohol-based hand rub. Compliance with hand hygiene, measured by direct observation, increased significantly from 49% to 69% during the first campaign, from 53% to 69% during the second campaign and from 58% to 69% during the third campaign (Magiorakos et al., 2010:2).

## **2.10 ROLE OF HAND HYGIENE IN HEALTHCARE ASSOCIATED INFECTION PREVENTION**

According to Allegranzi and Pittet (2009:305), healthcare workers' hands are the most common vehicle for transmission of healthcare-associated pathogens from patient to patient within the healthcare environment. According to Sax et al. (2007:9),

hand hygiene is a core element of patient safety for the prevention of healthcare associated infections.

The WHO's first global patient challenge 'Clean Care is Safer Care' has expanded educational and promotional tools, developed initially for the Swiss national hand hygiene campaign, for worldwide participation. The concept of "My five moments for hand hygiene" as explained in paragraph 2.8 should be applied for patient safety.

### **2.11 FACTORS INFLUENCING HAND HYGIENE COMPLIANCE**

Hand hygiene is the leading measure for preventing the spread of antimicrobial resistance and reducing healthcare-associated infections (HCAIs), but healthcare worker compliance with optimal practices remains low in most settings (Allegranzi & Pittet, 2009:305).

According to Allegranzi and Pittet (2009:306), factors which influence hand hygiene compliance, include the following:

- Lack of appropriate infrastructure: no infection control measures in place; no washing facilities, such as running water; no or inadequate equipment to enable hand hygiene performance such as broken basins and taps that are out of order.
- Cultural background: in the Xhosa culture animals are slaughtered without the slaughterer washing their hands. One knife for traditional circumcisions is frequently used for multiple boys without disinfection and without washing their hands.
- Under staffing and overcrowding: personnel are exhausted, under paid and under pressure to deliver nursing care to high volumes of patients without washing their hands.
- Wearing of gowns: sometimes personnel wash their hands but dry them on their gowns instead of using disposable hand towels.
- Rings or gloves: healthcare professionals are not allowed to wear rings since bacteria accumulate under the rings that are then transferred to patients.

Personnel surmise that if they wear gloves, they do not have to wash their hands. Hands sweat inside the gloves and this provides warm and humid conditions for bacteria to multiply. Gloves tear and germs can be transferred to hands even though gloves are worn.

- Negligence: healthcare staff do not routinely disinfect their hands between patients.

Various reasons exist for this type of behaviour. Individual factors include, perception and knowledge of the transmission risks, social pressure, HCWs conviction of their self-efficacy, the evaluation of perceived benefits against the existing barriers, the intention to perform the hand hygiene action and touching a patient (taking a pulse or blood pressure) or having contact with an inanimate object in the patient's surroundings. These contacts do not necessarily trigger an intrinsic need to cleanse hands although they do involve the risk of cross-transmission. According to behavioural theories, this is the component of hand hygiene most likely to be omitted by busy HCWs and it has been repeatedly confirmed by field observations (Allegranzi & Pittet, 2009:306).

## **2.12 IMPORTANCE OF HAND HYGIENE IN A COMMUNITY SETTING**

The most critical times to wash your hands are inter alia after using the toilet, after cleaning a child's bottom, before handling food whether it be eating or preparing food, before giving medicine, before inserting contact lenses or before dressing wounds. At home you should wash your hands more often if you have an ill family member (Farrer, 2010:13).

According to Braimoh and Ubdeabor (2013:507) hand hygiene in the community has been acknowledged as an important measure to prevent and control diseases and can significantly reduce the burden of disease, in particular among children in developing countries. Braimoh and Ubdeabor (2013:510) further reported that the provision of alcohol-based hand rub may further help to solve common problems

associated with hand washing. According to Hübner, Hübner and Kramer (2013:523), campaigns that enforce the use of alcohol-based hand disinfectant can have a sustainable effect on compliance with hand hygiene in non-clinical settings.

### **2.13 RELEVANCE TO THE TOPIC**

Systematic reviews make considerable efforts to address the potential for bias and selective influences in conducting and reporting in the review. Systematic reviews are needed to efficiently integrate valid information and provide a basis for rational decision making (Higgins & Green, 2006:15). High-quality systematic reviews can define the boundaries of what is known and unknown, and may help healthcare professionals to practice evidence based healthcare. It is unusual for single studies to provide definitive answers to clinical questions, but systematic reviews can help practitioners solve specific clinical problems. By critically examining primary studies, systematic reviews can also improve understanding of inconsistencies among diverse pieces of research evidence (Higgins & Green, 2006:15).

### **2.14 CONCLUSION**

Alcohol-based hand rub which does not require water, rapidly destroy most bacteria and viruses, and ABHR products tend to be gentler on the hands than soap and water (Sandora et al., 2005:587). Systematic reviews helps investigators to summarize existing data, refine hypotheses, estimate sample size, and help define future research agendas. Therefore, investigating the effect of the use of alcohol-based hand rub in the preventing of diarrhea and respiratory-tract infection among children in community settings through conducting a systematic review may inform current hand hygiene practices in the community.

## **CHAPTER 3: RESEARCH METHODS**

### **3.1 INTRODUCTION**

A research design is the blueprint for conducting a study. It maximizes control over factors that could interfere with the validity of the findings. The research design guides the researcher in planning and implementing the study in a way that is most likely to achieve the intended goal (Burns & Grove, 2009:218).

### **3.2 RESEARCH AIM**

The research purpose is a clear, concise statement of the specific goal or aim of the study that is generated from the research problem (Burns & Grove, 2006:69).

The aim of the study was to systematically appraise evidence on the effect of alcohol-based hand rub compared with other interventions in the prevention of diarrhoea and respiratory infections among children in community settings.

### **3.3 OBJECTIVES**

The objectives set for this study are as follows:

- To identify studies that compared hand rub versus other interventions for the prevention of diarrhoea and respiratory-tract infection.
- To synthesize results of studies and compare hand rub over other interventions for the prevention of diarrhoea and acute respiratory-tract infection.
- To evaluate the methodological quality of the included studies.

### **3.4 CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW**

#### **3.4.1 Types of studies**

This review considered all published randomized controlled trials and quasi-experimental designs published from January 1990 to July 2014.

#### **3.4.2 Types of participants**

The systematic review included studies on children in community settings between the ages of 0 and 5 years.

#### **3.4.3 Types of outcome measures**

##### **3.4.3.1 *Primary outcomes***

- Incidence of diarrhoea
- Incidence of respiratory-tract infection

##### **3.4.3.2 *Secondary outcomes***

Secondary outcomes include mortality, due to respiratory-infection or diarrhoea, admission to hospital and duration of hospital stay.

### **3.5 SEARCH STRATEGY FOR IDENTIFICATION OF STUDIES**

#### **3.5.1 Electronic search strategy**

A comprehensive search for relevant studies was conducted on the following databases: EMBASE, MEDLINE, CINAHL, Google Scholar and Cochrane Central Register of Controlled Trials (CENTRAL).

### **3.5.2 Searching other resources**

The reference list of all relevant articles and textbooks were searched for additional studies. Unpublished data previously presented at international and scientific meetings was also included in the review. Proceedings of international conferences and others re pediatrics on diarrhoea and respiratory infection among children were searched for relevant articles. Subject experts were contacted.

### **3.5.3 Search terms**

The following MESH terms were used to conduct the search: randomized, randomization, alcohol hand rub, diarrhoea, respiratory tract infection, caregivers, children, pre-school and day care.

## **3.6 DATA COLLECTION AND ANALYSIS**

### **3.6.1 Selection of studies**

The two reviewers, Joelynn Steyn (JS) and Oswell Khondowe (OK) first read the titles from the research results and identified potential studies for inclusion. The reviewers then read the abstracts of the potential titles. Eligibility criteria were used to screen abstracts. Full-text articles were retrieved for the studies that were identified as relevant to the study. The studies were thoroughly assessed including the methodological quality to select the studies for inclusion. The process was performed independently by JS and OK. Studies that were considered were; randomised controlled trials on alcohol-based hand rub, diarrhea and/or acute respiratory infection, on children aged between 0-5 years of age, in community and day care centres. The reviewers resolved any disagreements through discussion. Prof Ethelwynn Stellenberg (ES) was available were consensus was not reached.

### **3.6.2 Data extraction and management**

A standard data extraction form was used from Cochrane Collaboration and was modified by JS with the supervision of OK. For eligible studies, the two reviewers extracted the data using the agreed form. Discrepancies were resolved through discussion. Data was entered into Review Manager© software (RevMan, 2011) and checked for accuracy.

### **3.6.3 Assessment of risk of bias in included studies**

To limit bias in this review, the reviewers individually assessed the trials' methodological quality using the Cochrane risk of bias tool (The Cochrane Collaboration, 2012:7,8). Disagreements were resolved by discussion. No authors were contacted.

#### **3.6.3.1 *Random sequence generation: checking for possible selection of bias***

The reviewers extracted data for each study including the method used to generate allocation sequence, in sufficient detail to allow an assessment of whether it might produce comparable groups. .

- Low risk of bias meaning any truly random process, for example, the random number table, computer random number generator, shuffling cards or envelopes.
- High risk of bias meaning any non-random process, such as odd or even date of birth, hospital or clinic record number.
- Unclear risk of bias such as insufficient information to permit either 'High risk' or 'Low risk'.

#### **3.6.3.2 *Allocation concealment: checking for possible selection bias***

The reviewers described each included study, the method that was used to conceal allocation to intervention prior to assignment and assessed whether intervention



allocation could have been foreseen before or during recruitment, or whether it was changed after assignment. The categories included:

- Low risk of bias such as telephone or central randomisation or consecutively numbered sealed opaque envelopes.
- High risk of bias such as open random allocation, unsealed or non-opaque envelopes, alternation or date of birth.
- Unclear risk of bias such as insufficient information to permit either 'Low risk' or 'High risk'.

### **3.6.3.3 Blinding**

(i) *Blinding of participants and personnel: checking possible performance bias*

Blinding of those receiving and providing care is useful in protecting against performance bias. When participants are aware of the groups they are allocated to in a study, they tend to report more adverse effects relating to the intervention they are allocated to, leading to biased results. Blinding was used as a criterion for validity.

The reviewer questioned who was blinded by using the following questions.

- Were the recipients of care unaware of their assigned intervention?
- Were those providing care unaware of the assigned intervention?

The methods were assessed as:

- Low risk of bias, for example, blinding of key study personnel.
- High risk of bias, for example, the outcome or outcome measurements likely to be influenced by lack of blinding.
- Unclear risk such as insufficient information to permit either 'Low risk' or 'High risk'.

Blinding of participants and personnel was assessed separately from blinding of outcome assessors.

(ii) *Blinding of outcome assessment, checking for possible detection bias*

Detection bias refers to systematic differences between the comparison groups in outcome assessment (Deeks et al., 2006:82). Blinding of outcome assessors to the intervention allocation reduces detection bias.

We assessed the methods as:

- Low risk of bias such as blinding of key study personnel.
- High risk of bias, for example, the outcome or outcome measurements likely to be influenced by lacking of blinding.
- Unclear risk such as insufficient information to permit either 'Low risk' or 'High risk'.

Blinding of participants and personnel was assessed separately from blinding of outcome assessors.

**3.6.3.4 *Incomplete outcome data: checking for possible attrition bias due to the amount, nature and handling of incomplete outcome data***

Attrition bias refers to systematic differences between the comparisons groups in the loss of participants from the study (Deeks et al., 2006:82). The approach to handling losses has great potential for biasing the results and reporting inadequacies which may cloud this problem, for instance, if the number of dropouts and withdrawals are not reported. Reported follow-up was used as a validity criterion.

The reviewers assessed methods for:

- Low risk of bias, for example, no missing outcome data or missing outcome data balanced groups.
- High risk of bias, such as numbers or reasons for missing data imbalanced across groups or 'as treated' analysis done with a substantial departure from intervention received, from that assigned at randomization;
- Unclear risk of bias, for example, insufficient information to permit either 'Low risk' or 'High risk'.

### **3.6.3.5 Selection reporting: checking for reporting bias**

Publication bias was investigated by preparation of the funnel plot, of which signs of asymmetry were examined. If asymmetry was noticed, reasons other than publication bias were considered.

The method was assessed as:

- Low risk of bias, is where it was clear that all the study's pre-specified outcomes and all expected outcomes of interest to the review were reported
- High risk of bias, for instance, where not all the study's pre-specified outcomes were reported; one or more reported outcomes were not pre-specified; outcomes of interest were reported incompletely and thus not used; studies that fail to include results of key outcomes that would have been expected to have been reported.
- Unclear risk of bias such as insufficient evidence to permit either 'Low risk' or 'High risk'.

### **3.6.3.6 Other bias: checking for bias due to problems not covered by (3.6.3.1- 3.6.3.6) and overall risk of bias**

The reviewers described any important concerns they had about other possible source of bias. Explicit judgements were made about studies that were at high risk of bias, according to the criteria. Regarding subsections 3.6.3.1 to 3.6.3.6 above, the authors assessed the likely magnitude and direction of the bias and whether it might impact on the findings. The impact of the level of bias was explored through undertaking sensitivity analyses.

'Low risk', 'High risk' or 'Unclear' as follows:

- Low risk of bias, such as the study appeared to be free of other risk of bias.
- High risk of bias, for example the study had a potential source of bias related to the specific study design or other problems.
- Unclear risk, for instance, insufficient information was present to permit either 'Low risk' or 'High risk'.

### **3.7 MEASURES OF TREATMENT EFFECT**

For binary data, we presented results as summary risk ratio with 95% confidence intervals. For continuous data, the mean differences were used. All outcomes were measured in the same way between trials.

### **3.8 UNIT OF ANALYSIS ISSUES**

The unit of analysis includes individuals or communities, families and day care centres.

### **3.9 DEALING WITH MISSING DATA**

The reviewers did not encounter missing data and hence the authors of the studies were not contacted.

### **3.10 ASSESSMENT OF HETEROGENEITY**

The Cochrane Handbook for Systematic Reviews of Intervention (2006:136) refers to heterogeneity as any kind of variability amongst studies in a systematic review. More specifically, clinical heterogeneity is described as variability in participants, interventions and outcomes studied. Statistical heterogeneity refers to the variability in the treatment effects being evaluated in different trials. A consequence of clinical and methodological diversity among studies manifests itself as treatment effects being more different from each other than what would be expected in random error or “change” alone (Cochrane Handbook for Systematic Reviews of Interventions 4.2.6. 2006:136). Statistical heterogeneity was assessed in each meta-analysis using  $I^2$ . It assisted in assessing whether observed differences in results are compatible with chance alone.

### **3.11 DATA SYNTHESIS**

Burns and Grove (2009:695) states that the aim of “data synthesis” is to reduce, organise and give meaning to data. Burns and Grove (2009:463) states that a confirmatory data analysis is performed to confirm expectations regarding the data that are expressed as hypothesis, questions or objectives. Statistical analysis was carried out using the Review Manager software (RevMan, 2011). Random-effect analysis was used for combining data as there was considerable heterogeneity across studies. Results were presented as average treatment effects with their 95% confidence intervals and estimates of  $I^2$ .

### **3.12 SUBGROUP ANALYSIS AND INVESTIGATION OF HETEROGENEITY**

Subgroup analysis was done in subsets of the studies according to the type of intervention used, such as alcohol hand rub versus placebo. It was considered whether an overall summary was meaningful, and if it was, random effect analysis was used to produce it. Other features such as duration of use of the alcohol hand rub and the specific type of alcohol hand rub was also sub grouped.

### **3.13 SENSITIVITY ANALYSIS**

A sensitivity analysis was performed by including four studies with adequate sequence generation, allocation concealment and attrition rate (Corea, Pinto, Salas, Camacho, Rondon & Quintero, 2012:476-484; Sandora, Taveras, Shih, Resnick, Lee, Ross-Degnan & Goldmann, 2005:588-594; Larson, Ferng, Wong-McCloughlin, Wang, Haber & Morse, 2010:178-191; Butz, Larson, Fosarelli & Yolken, 1990:347-353). There were no differences in the overall direction of findings. Funnel plots were excluded as the number of trials was less than ten as recommended by Higgins and Green (2006:214).

### **3.14 VALIDITY AND RELIABILITY**

The following measures were introduced to ensure validity and reliability:

- Explicit inclusion and exclusion criteria were specified and a thorough search for studies was done.
- Electronic searches were performed on different databases.
- A data extraction tool was used.
- Review Manager© (RevMan, version 5) was used for statistical analysis. This software was developed by Cochrane Collaboration and is available at no cost.
- Two independent reviewers performed research tasks.

### **3.15 ETHICAL CONSIDERATIONS**

In a systematic review no actual participants are recruited, but available studies on the topic are consulted. A systematic review was proposed and the reviewer was permitted to proceed with a systematic review as part of the requirements towards a master's in nursing degree. As systematic reviews do not use data of actual patients, ethical approval for studies involving human subjects was not required. However, a research committee in the Division of Nursing at Stellenbosch University reviewed and accepted the protocol.

### **3.16 DISSEMINATION OF RESULTS**

The thesis was compiled and submitted to Stellenbosch University. Results will be presented at a conference and published in a peer reviewed journal.

### **3.17 LIMITATION**

Foreign language literature was not used due to time constraints and limited access.

### **3.18 CONCLUSION**

This chapter discussed steps followed and methods used to conduct the review. In the next chapter, the results of the research process will be presented and interpreted.

## CHAPTER 4: RESULTS

### 4.1 INTRODUCTION

In this chapter the results are analysed and presented. Data analysis is performed to reduce, organise and provide meaning to the data (Burns & Grove, 2007:41). This results section has been structured according to the framework stipulated in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins & Green, 2006:50). All appropriate data was entered into Review Manager© (version 5, Cochrane Collaboration) for analysis.

### 4.2 RESULTS OF THE RESEARCH

The searches were performed in June 2014. A search was performed in PubMed, Cochrane library, Cochrane Database of Systematic Reviews and Scopus (Table 4.1). The following citations were identified: 3 in Cochrane Database of Systematic Reviews, 6 in PubMed, 9 in Africa-Wide, 42 in Scopus, 42 in CINAHL, 100 in Academic Search Premier. The reference list of identified publications was also screened for other publications that might have been relevant to this review. Figure 4.1 illustrates the study selection process in a flow diagram.

**Table 4.1: Summary of search**

Summary of search	Database	Search results
<b>Electronic database</b>	Cochrane	3
	Pubmed	6
	Africa Wide	9
	Scopus	42
	CINAHL	42
	Search Premier	100



**Table 4.2: Search string**

<b>Database</b>	<b>Search string</b>
<b>Cochrane</b>	Alcohol-based hand rub OR waterless hand sanitizer AND prevent AND diarrhoea OR respiratory tract infection AND child.
<b>Scopus</b>	Alcohol-based hand rub OR waterless hand sanitizer AND prevent AND diarrhoea OR respiratory tract infection AND child.
<b>Pubmed</b>	Alcohol-based hand rub OR waterless hand sanitizer AND prevent AND diarrhoea OR respiratory tract infection AND child.
<b>CINAHL</b>	Alcohol-based hand rub OR waterless hand sanitizer AND prevent AND diarrhoea OR respiratory tract infection AND child.
<b>Africa Wide</b>	Alcohol-based hand rub OR waterless hand sanitizer AND prevent AND diarrhoea OR respiratory tract infection AND child.
<b>Search premier</b>	Alcohol-based hand rub OR waterless hand sanitizer AND prevent AND diarrhoea OR respiratory tract infection AND child.

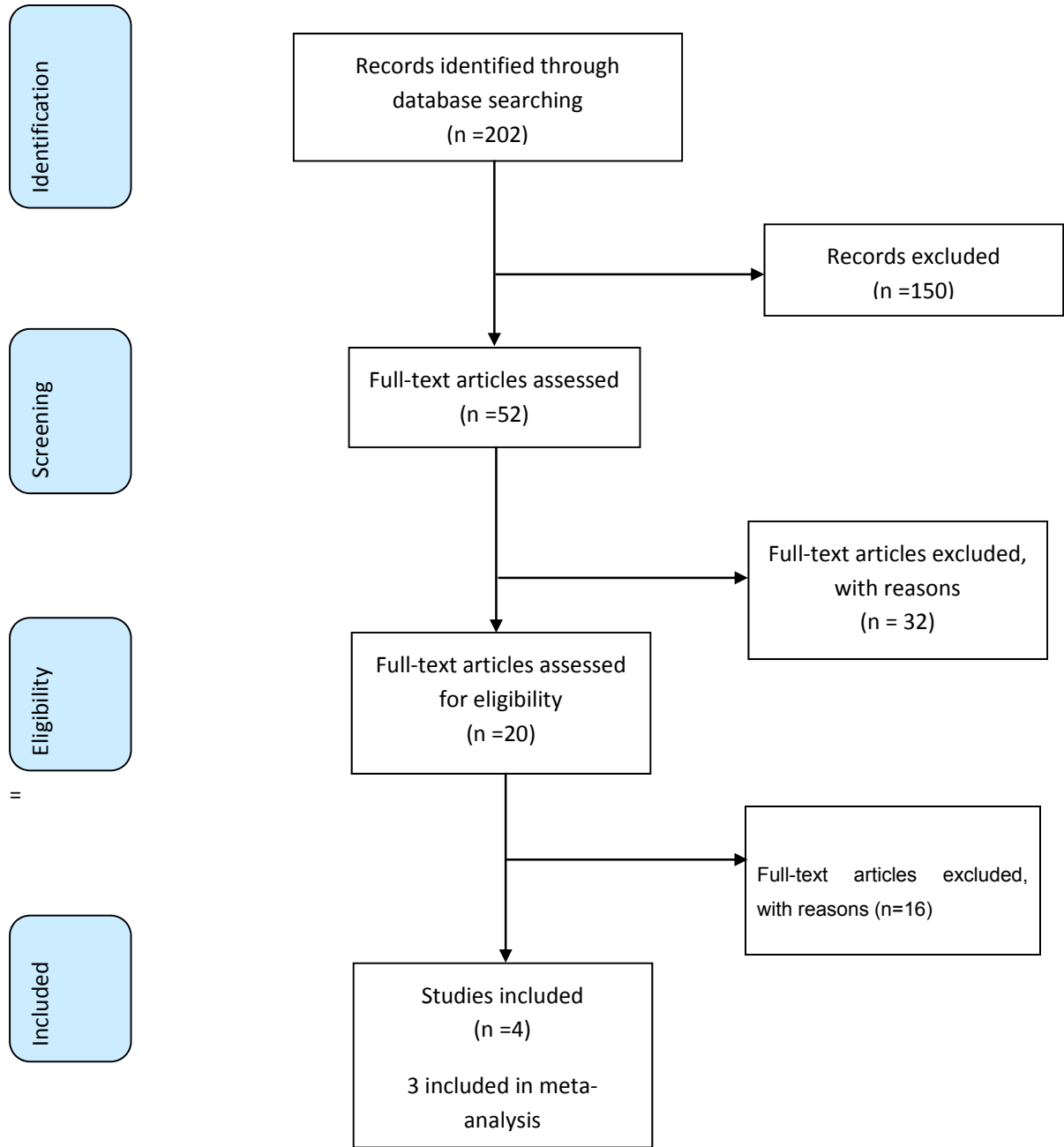


Figure 4.1: Flow Diagram describing selection of articles

### Description of the flow chart selection using inclusion and exclusion criteria

Potentially relevant citations were identified and screened for retrieval (n=202). Irrelevant studies (n=150) were then excluded after reading the titles. A total of (n=52) studies were retrieved for further evaluation. Studies that did not report on alcohol-based hand rub, diarrhoea and acute respiratory tract infection on children, the reviews, editorials, duplicates and comments (n=32) were excluded after reading the abstracts. The full text of studies with potential for inclusion in the reviews were retrieved for closer examination (n=20). A total of 16 studies were excluded due to methodological issues and use of waterless disinfectant scrub (Table 4.7). Studies included in the review were four in total after critical appraisal of methodological quality. A flow diagram (Figure 4.1) illustrates the study selection.

Below is the table with citations of the included studies.

**Table 4.3: Included studies**

Study ID	Citation
<b>Butz, 1990</b>	Butz, A. M., Larson, E., Fosarelli, P. & Yolken, R. 1990. Occurrence of infectious symptoms in children in day care houses. <i>American journal of infection control</i> , 18(6):347-353.
<b>Larson, 2010</b>	Larson, E.J., Ferng, Y., Wong-McLoughlin, J., Wang, S., Haber, M. & Morse, S. 2010. Impact of non-pharmaceutical interventions on URIs and Influenza in crowded, urban households. <i>Association of School of Public Health</i> , 125:178-191.
<b>Sandora, 2005</b>	Sandora, T.J., Taveras, M.E., Shih, M., Resnick, E.A., Lee, G.M., Ross-Degnan, D. & Goldmann, D.A. 2005. A randomised, controlled trial of a multifaceted intervention including alcohol-based hand sanitizer and hand -hygiene education to reduce illness transmission in the home. <i>Pediatrics</i> , 116:587.
<b>Corea, 2012</b>	Correa, J.C., Pinto, D., Salas, I., Camacho, J.C., Rondòn, M. & Quintero, J. 2012. A cluster –randomized controlled trial of handrubs for prevention of infectious diseases among children in Columbia. <i>Rev Panam Salud Publica</i> , 31(6):476-484.

### 4.3 CHARACTERISTICS OF INCLUDED STUDIES

The characteristics of included studies are discussed below according to the study design used, the participants, the sample size and the settings where the trials were conducted. Table 4.4 summarizes the characteristics of the included studies. It

provides data on the characteristics of the studies that were included in this systematic review. Four studies were included in this review: Butz et al. (1990); Larson et al. (2010); Sandora et al. (2005) and Correa et al. (2012). The review included internationally published studies in English. Eligible studies were from the United States of America (Maryland, New York, Massachusetts and Colombia). The studies were all randomized but one has a cross-over design, one block, two were cluster and one randomised controlled trial. The sample size for included studies ranged from 114 to 383 children and 292 to 509 were families. All the studies were done in the community, either a school or day care.

**Table 4.4: Table of characteristics of included studies**

<b>Author/Year</b>	<b>Country</b>	<b>Participants</b>	<b>Sample size (n)</b>	<b>Methods</b>
<b>Butz 1990</b>	Maryland, <b>USA</b>	Family day care homes, by frequent and intimate exposure among susceptible hosts, with diaper changing as the highest-risk procedure	114	Randomised controlled trial
<b>Larson 2010</b>	Upper Manhattan, <b>USA</b>	At least three people living in the household, with at least one being a preschool or elementary school child; speaking English or Spanish; having a telephone; being willing to complete system assessment and having bimonthly home visits; and not routinely using alcohol-based hand sanitizer.	509.	Block randomised

<b>Sandora 2005</b>	Massachusetts neighbourhoods (Boston, Brookline, Cambridge) <b>USA</b>	The family had at least 1 child between 6 months and 5 years of age enrolled in out-of-home child care (The oldest child who met these criteria was define as the index child)  The index child was enrolled in out- of – home child care with at least 5 other children for 25 hours per week. The family planned to reside in the area and keep the index child enrolled in the centre for the duration of the study.  The family had access to a telephone. The primary home caregiver could speak English or Spanish.	292 family units	Cluster randomised, controlled trial
<b>Correa 2012</b>	Colombia	Eligible childcare centres were either “community homes” or preschools licensed to care for 12 or more children 1-5 years of age for 8 hours a day, 5 times per week, and where availability of tap water was limited.	1727	Cluster-randomised control trial

#### 4.3.1 Study design

Two studies were cluster-randomised control trials (Corea et al., 2012; Sandora et al., 2005). One was block randomised (Larson et al., 2010). One was a randomised controlled trial (Butz et al., 1990).

### **4.3.2 Participants**

Participants were children from day care centres and elementary schools (Cornea et al., 2012; Butz et al., 1990) and in 2 trials they were based at homes.

### **4.3.3 Sample size and settings**

The total number of participants combined from four studies was 2744 children rub (Corea et al., 2012; Larson et al., 2010; Butz et al., 1990). Sandora et al (2005) reported on 292 family units. The trials were conducted in four states in USA and one in South-America.

### **4.3.4 Outcome measures**

Diarrhoea and respiratory tract infection was reported in three studies (Corea, 2012; Butz, 1990; Sandora, 2005). In Larson (2010) there was no detectable benefit of alcohol-based hand rub but symptoms of respiratory-tract infection were significantly more likely reported and no household member had symptoms of respiratory-tract infection.

### **4.3.5 Interventions**

All four studies used alcohol-based hand rub (Corea, 2012; Sandora, 2005; Larson, 2010; Butz, 1990). Only two studies mentioned the percentage of alcohol used in the hand rub (Butz, 1990; Sandora, 2005).

**Table 4.5: Description of interventions**

<b>Study Author, Year, study no.</b>	<b>Intervention</b>	<b>Comparison</b>
<b>Butz 1990</b>	The intervention included four components, 1). A hand washing educational program. 2). Use of vinyl gloves 3). Use of disposable diaper changing pads 4) use of alcohol-based hand rinse by the day care provider.	The control homes received no educational intervention but received biweekly nurse visits for symptom collection.
<b>Larson 2010</b>	2). Hand sanitizer group received the same educational materials and hand sanitizer and a container to be carried by individual members to work and school. 3). The hand sanitizer and face mask groups which received the same interventions as well as face masks with instruction for both caretaker and ill person to wear them when an influenza-like illness occurred in any household member.	Households were block randomised into one of three groups: 1) education group, which received written Spanish or English-language educational materials regarding the prevention and treatment of URIs and influenza.
<b>Sandora 2005</b>	Received a supply of alcohol-based hand sanitizer to use in the home during a 5 month study period. They also received biweekly hand hygiene educational material at home for 5 months	Control group did not receive hand sanitizer or material related to hand hygiene, they instead received biweekly educational material about healthy diet. Control group were asked not to use hand sanitizer during the study period.
<b>Correa 2012</b>	For centres assigned to the intervention arm, alcohol-based hand rub and training on proper use were provided to staff and children.	Centres assigned to the control were simply told to continue their current practices, placebo not provided.

Table 4.5 is a detailed summary of the interventions. All the studies made use of hand sanitizer. Most of the studies provided education with their intervention.

**Table 4.6: Intervention schedule**

<b>Study Author, Year, Study No.</b>	<b>Intervention Schedule/Duration</b>	<b>Loss to Follow-up</b>
<b>Butz 1990</b>	The intervention program consisted of in-home instruction to day care providers by the investigators during the first four home visits. The intervention instruction included modes of transmission of pathogens in the home, indications for hand washing, and the use of the vinyl and disposable diaper changing pads at each change. Providers were instructed to dispose of the gloves, disposable pads, and diapers in plastic bags. Between hand washes, when the providers were unable to wash their hands with soap and water, they were instructed to use an alcohol-based hand rinse.	6 children
<b>Larson 2010</b>	Participants were provided with a two-month supply of hand sanitizer and / or face masks, and new supplies were delivered to the household at least once every two months. Throughout the 19 months data collection period, the Project manager accompanied the RA's on random home visits and made random calls to households participants for ongoing quality monitoring.	56 households
<b>Sandora 2005</b>	Received a supply of alcohol-based hand sanitizer to use in the home during a 5 month study period. They also received biweekly hand hygiene educational material at home for 5 months. Control group did not receive hand sanitizer or material related to hand hygiene, they instead received biweekly educational material about healthy diet. Control group were asked not to use hand sanitizer during the study period. No placebo for hand sanitizer was provided	Intervention group- lost to follow (3), discontinued intervention (12)  Control group lost to follow-(8), discontinued intervention (11)
<b>Correa 2012</b>	Proper use of alcohol-based hand rub was ensured 1). Pre-trial alcohol-based hand rub use workshop that followed recommended hand hygiene teaching techniques and instructed teachers to add alcohol-based hand rub to routine hand hygiene and give preference	Intervention: 1 centre closed (14). Withdraw from centre (132)



to hand wash if hands were visibly soiled 2). Location of visual reminders of alcohol-based hand rub technique in bathrooms and next to dispensers 3). Provision of monthly 30 minute alcohol-based hand rub technique refresher workshop.	children) Control: 1 centre closed (5). Withdraw from centre (118 children).
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Table 4.6 is a description of the intervention schedule. All the studies above had different approaches in their intervention and comparison group. Their loss to follow up also differed. The duration of all the studies differed. Detailed information of designs are presented in each study report.

#### 4.4 EXCLUDED STUDIES

A total of 33 studies were excluded after retrieving full texts. Articles, duplicates, reviews, or studies that were irrelevant were discarded. Table 4.7 consists of articles excluded and the reasons are provided.

**Table 4.7: Excluded studies**

Study ID	Reason for Exclusion
Allison 2008	Review.
Apisarnthanarak 2009	Focus was on influenza.
Bailey 2013	Review.
Bloomfield 2007	This is a review.
Bloomfield 2013	It is a review.
Cimiotti 2000	Hospital setting.
Cole 2012	Review article.

Coronado 2012	<i>Report on pesticide exposure.</i>
Curtis 2008	Study on hospital acquired infections.
Ejemot-Nwadiaro 2012	Hand washing.
Gore 2001	They used a product called "clean hands" contains surfactants which include allantoin and benzalkonium chloride.
Hammond 2000	Use instant hand sanitizer with Aloe.
Jefferson 2009	Review article.
Kotch 1994	Use a waterless disinfectant scrub.
Larson 2006	It is a review.
Lau 2012	Report on influenza.
Lee 2004	Students.
Lee 2005	Observational, prospective cohort study.
Lee 2005	Not community setting.
Lee 2010	Review.
Luby 2010	Does not use alcohol, but uses organic acids to reduce the pH of skin.
Miller 2009	Retrospective study.
Pandejpong 2012	Influenza.
Peel 2005	On behavioural determinants.
Pickering 2010	No experimental group.
Rabie 2006	Hand washing.
Schweon 2013	Long- term care facility, not community setting.
Stebbins 2011	Influenza.
Uhari 1999	Use of an alcohol-based oily disinfectant.
Vessey 2007	Participants were children older than 5
Warren-Gash 2012	Report on influenza.
Wong 2014	It is a systematic review on influenza.
Zomer 2013	Ongoing study.

#### 4.5 RISK OF BIAS IN INCLUDED STUDIES

**Table 4.8: Risk of bias in included studies**

	Sequence Generation	Allocation Concealment	Blinding	Incomplete Outcome Data	Selective Outcome Reporting	Other Potential Sourced
<b>Butz 1990</b>	Y	Y	Y	N	Y	U
<b>Correa 2012</b>	Y	N	N	N	Y	U
<b>Larson 2014</b>	Y	N	N	N	Y	U
<b>Sandora 2014</b>	Y	Y	Y	N	Y	U

**Key: Y-Yes: Low risk of bias**

**N-No: High risk of bias**

**U-Unclear: Unclear risk of bias**

Table 4.8 describes the risk of bias. All the articles included showed an incomplete data outcome and that are a high risk. Other potential sources of bias were unclear in all the articles.

#### 4.6 INCIDENCE OF DIARRHOEA

Only three studies reported on diarrhea (Butz et al., 1990; Sandora et al., 2005; Corea et al., 2012). In the Sandora et al. (2005) study, child days of diarrhoea were less in the intervention groups when compared to their controls (Table 4.9).

#### 4.7 INCIDENCE OF ACUTE RESPIRATORY INFECTIONS

Table 4.9 and 4.10 provides information on the main findings of the included studies. Not all studies showed a reduction in diarrhoea and respiratory-tract infection but all studies showed that alcohol-based hand rub is the choice in schools and day cares. Larson et al. (2010) showed no detectable benefit of hand sanitizer or face masks

over targeted education on the overall rates of URIs. Correa (2012), Butz (1990) and Sandora (2005) all showed a reduction in diarrhoea. Butz (1990) showed that diarrhoea and vomiting were significantly reduced in intervention families, whereas respiratory symptoms were not significantly reduced. Larson (2010) showed that there was no detectable benefit of hand sanitizer or face masks over targeted education on overall rates of URIs. Sandora (2005) showed that diarrhoea is significantly lower in the intervention compared to the control families and showed no significance in respiratory illnesses between the groups. Corea et al. (2012) showed that there were no differences in diarrhoea and respiratory-tract infection in the first three months. There was, however, a significant reduction in the three to six months (Table 4.9 and Table 4.10).

**Table 4.9: Incidence of diarrhoea (child days)**

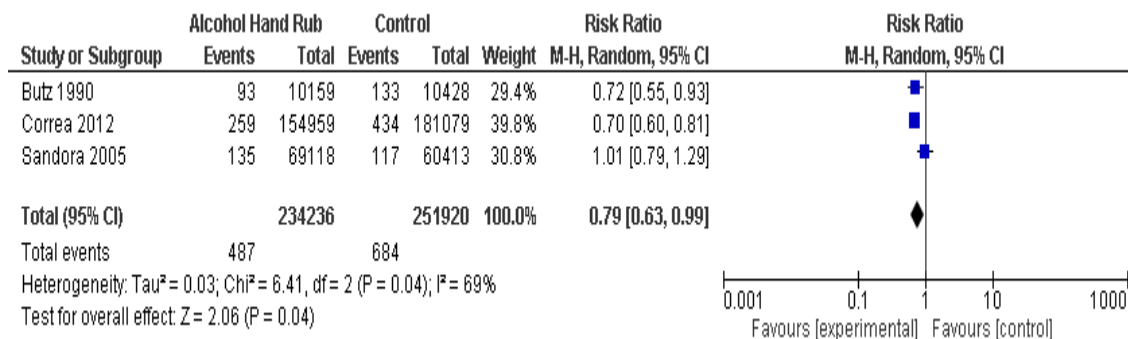
	Intervention		Control	
	n	days	n	days
Butz 1990	93	10 159	133	10 428
Correa 2012	259	154 959	434	181 079
Sandora 2005	135	69 118	117	60 413

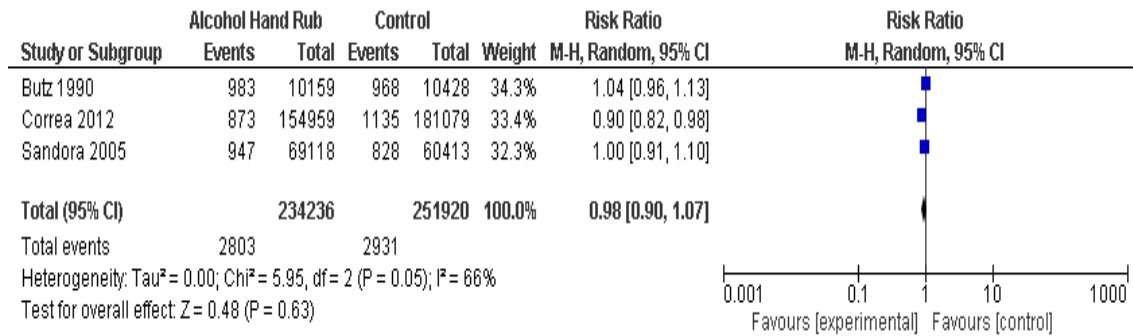
**Table 4.10: Incidence of acute respiratory infections**

	Intervention		Control	
	n	days	n	days
Corea et al., 2012	873	154 959 (child days)	1135	181 079
Sandora et al., 2005	947	69 118	828	60 413
Butz et al., 1990	983	10159	968	10428

#### 4.8 META-ANALYSES

In Figure 4.2, the result on the effect of alcohol hand rub was pooled from three studies. The risk of alcohol hand rub versus control for the prevention of diarrhoea was significantly reduced (RR 0.79, 95% CI 0.63 to 0.99,  $I^2=69%$ ,  $p=0.04$ ). Statistical heterogeneity was observed ( $I^2=69$ ,  $p=0.04$  for chi). Heterogeneity was substantial as indicated by the p-value of 0.04.

**Figure 4.2: Alcohol hand rub versus control for the prevention of diarrhoea**



**Figure 4.3: Alcohol hand rub versus control for the prevention of acute respiratory infections**

The data from the three studies showed no significant difference on alcohol hand rub versus control for the prevention of respiratory-tract infections. The results indicated a relative ratio of almost 1 (RR 0.98, 95% CI 0.90 to 1.07,  $p=0.63$ ). Heterogeneity across the studies ( $I^2=66%$ ,  $p=0.05$  for chi) was substantial.

#### 4.5 CONCLUSION

This chapter described the analysis for this review. Results were presented narratively, in tabular format and as forest plots. The research objectives were addressed;

- To identify studies comparing hand rub versus other interventions for the prevention of diarrhoea and acute respiratory-tract infection.
- To synthesize results of studies that compare hand rub over other interventions for the prevention of diarrhoea and acute respiratory-tract infection.
- To evaluate the methodological quality of studies included in the review

The next chapter covers the conclusion and a summary of the main results.

## CHAPTER 5: DISCUSSION AND RECOMMENDATIONS

### 5.1 SUMMARY OF RESULTS

Four studies were included in this review of which three were included in the meta-analysis. Four of the studies were conducted in USA but in different states and one in South America. All the studies used the intervention, alcohol-based hand rub. The statistical evidence from this review shows a reduction in diarrhoea and other interventions such as education and hand washing but not in respiratory-tract infection after caregivers or children used alcohol-based hand rub.

#### 5.1.1 Primary outcomes

The statistical evidence from this review shows a reduction in diarrhoea. The risk of alcohol hand rub versus control for the prevention of diarrhoea was significantly reduced (RR 0.79, 95% CI 0.63 to 0.99,  $I^2=69%$ ,  $p=0.04$ ). This evidence may be related to education in hand washing (Butz, 1990:347). Statistical heterogeneity was substantial ( $I^2=69$ ,  $p=0.04$  for chi). Hand rub did not reduce the incidence of respiratory-tract infection in children (RR0.98, 95% CI0.90 to 1.07,  $p=0.63$ ). Heterogeneity across the studies was substantial ( $I^2=66%$ .  $p=0.05$  for chi). The results should, however, be interpreted with caution due to the limited number of studies done in the community with alcohol-based hand rub used by caregivers.

#### 5.1.2 Secondary outcomes

In terms of the secondary outcomes of this review, it was not possible to conduct an analysis since no mortality, admission to hospital and duration of hospital stay incidents were reported in the included studies. Future studies should consider these outcomes.

### **5.1.3 Limitations of the study**

The limited number of studies in this review, makes it difficult to make strong conclusions on findings and provide sufficient evidence to guide future research.

#### **5.1.3.1 Other limitations**

Only a few studies were conducted in the communities on alcohol-based hand rub and used by caregivers. Interventions varied between studies and that resulted in increased heterogeneity. Further research is definitely needed to provide further evidence that could guide ongoing research on the use of alcohol-based hand rub used by caregivers in the community.

## **5.2 OVERALL COMPLETENESS AND APPLICABILITY OF EVIDENCE**

The attrition rate was mostly low in the studies and where data was available dropouts or missing data were analysed on the intention to treat analysis (ITT). The included studies were too limited to give a strong conclusion on the applicability of evidence.

## **5.3 QUALITY OF THE EVIDENCE**

Two of the included studies lacked methodological rigor (Corea et al., 2012; Larson et al., 2010). On assessment of methodological quality, a Cochrane tool was employed. Dropouts and missing data in the studies were not sufficiently addressed and therefore attrition bias was high. The authors adequately reported on the primary outcomes but not on secondary outcomes. The studies were all randomized controlled trials. Two were cluster (Butz et al., 1990 & Correa et al., 2012) and one a randomised controlled trial review (Sandora et al., 2005). A low risk of bias was indicated in two of the studies (Butz et al., 1990; Sandora et al., 2005). Two studies indicated high risk (Larson et al., 2010 & Correa et al., 2012) for allocation concealment.



#### **5.4 POTENTIAL BIASES IN THE REVIEW PROCESS**

The search study was restricted to studies written in English. The exclusion of other languages could be a basis of bias in the review. To reduce biases in the review, the methods from the Cochrane handbook for systematic reviews were used as a guide (Higgins & Green, 2006:79). To assess the risk of bias, a standardised data extraction form was used. The data was thoroughly reviewed by two reviewers to identify studies for inclusion. No results of one study have been inappropriately stressed above other studies in an attempt to minimise bias.

#### **5.5 AGREEMENTS AND DISAGREEMENTS WITH OTHER STUDIES OR REVIEWS**

The statistical evidence from this review shows a reduction in diarrhoea but not in respiratory-tract infection after caregivers or children using alcohol-based hand rub (Butz et al., 1990:347-353; Larson et al., 2010:178-191; Sandora et al., 2005:587-594 & Correa et al., 2012:476-483). Warren-Gash, et al (2012) conducted a systematic review to review evidence that improving hand hygiene reduces primary and secondary transmission of influenza and acute respiratory tract infections in community settings. Unlike our findings, there was high-quality evidence of a small reduction in respiratory infection in childcare settings. A Cochrane systematic review reported on hand washing for preventing diarrhoea (Ejemot et al., 2008). Hand washing resulted in a 39% reduction in diarrhoea in children in institutions in high-income countries (IRR 0.61, 95% CI 0.40 to 0.92; 2 trials) and a 32% reduction in such episodes in children living in communities in low- or middle-income countries (IRR 0.68, 95% CI 0.52 to 0.90; 4 trials). No evidence was reported on the secondary outcomes, mortality, admission to hospital and duration of hospital stay.

#### **5.6 AUTHORS' CONCLUSIONS**

##### **5.6.1 Implications for practice**

There is low evidence that the use of alcohol-based hand rub can reduce diarrhea in children. The evidence suggests that alcohol-based hand rub does not reduce

respiratory-tract infections in children. Results of this review should be interpreted with caution. Considering the high incidence of mortality as a result of diarrhoea in poor resourced communities, alcohol-based hand rub could reduce the incidence of diarrhoea and may be considered for national public health policies should more evidence support these findings.

### **5.6.2 Implications for research**

Further research is needed on alcohol-based hand rub in the prevention of diarrhoea and respiratory-tract infection among children in community settings. Randomised controlled trials using double-blinding and placebo with large populations especially in low resource settings would be beneficial to answer the research questions. Studies need to be conducted of high methodological quality. Conducting the studies in Africa could address the high burden of paediatric morbidity and mortality experienced in these countries. There is also a need to investigate the cost-effectiveness of alcohol-based hand rub versus other hand hygiene interventions.

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## APPENDICES

### Appendix A: Data Extraction Form

#### 1.1 Source

<b>Study ID</b>	
<b>Reviewer</b>	
<b>Author, year</b>	
<b>Journal</b>	
<b>Title</b>	
<b>Country</b>	

#### 1.2 Eligibility

<b>RCT</b>	
<b>Quasi-experimental</b>	
<b>Published study</b>	

#### 1.3 Types of participants

<b>Adult carers</b>	
<b>Children in communities</b>	

#### 1.4 Types of intervention

<b>Alcohol – based hand rubs</b>	
--	--

#### 1.5 Types of outcomes

<b>Incidence of diarrhoea</b>	
<b>Incidence of respiratory- tract infection</b>	
<b>Mortality</b>	
<b>Admission to hospital</b>	
<b>Duration of hospital stay</b>	
<b>Any other outcomes of the study</b>	

#### 1.6 Lost to follow up

<b>Equation</b>	
-----------------	--

**1.7 Other reasons for exclusion**


**2. Methodology**

**2.1 Study design**

<b>RCT</b>	
<b>Quasi experimental designs</b>	
<b>Comparative studies published</b>	

**2.2 Study duration**

<b>Month &amp; Year</b>	
-------------------------	--

## 2.3 Eligibility criteria


### Methodological quality/Risk of bias assessment (table 4.8)

(Answer the domain-question with a “Yes” signifying low risk of bias, “No” signifying high risk of bias, and “Unclear” signifying either lack of information or unknown risk of bias).

### 2.4 Cochrane Collaboration “Risk of Bias” Tool

Entry	Judgement	Description
Adequate sequence generation?		
Allocation concealment?		
Blinding of participants and personnel		
Blinding of outcome		

<b>assessors?</b>		
<b>Incomplete outcome data addressed</b>		
<b>Free of selective outcome reporting?</b>		
<b>Free of bias</b>		

## 2.5 Participants

<b>Total number</b>	
<b>Total number analysed</b>	
<b>Setting</b>	
<b>Age</b>	
<b>Country</b>	
<b>Co-morbidity</b>	
<b>Date of study</b>	

## 2.6 Interventions

<b>Experimental group</b>	
<b>Control group</b>	

**2.7 Outcome relevant to this review**

	<b>Yes</b>	<b>No</b>
<b>Incidence of diarrhoea</b>		
<b>Incidence of respiratory-tract infections</b>		
<b>Mortality</b>		
<b>Admission to hospital</b>		
<b>Duration of hospital stay</b>		
<b>Any other outcome from studies</b>		

**3. Results**

<b>Number of participants</b>		
	<b>Randomized</b>	<b>Analysed</b>
<b>Experimental</b>		
<b>Control</b>		
<b>Total</b>		

**3.1 Summary data for each intervention group**

<b>Incidence of diarrhoea</b>	<b>Event</b>	<b>No event</b>	<b>Total</b>
<b>Experimental group</b>			
<b>Control group</b>			

<b>Incidence of respiratory tract infections</b>	<b>Event</b>	<b>No event</b>	<b>Total</b>
<b>Experimental group</b>			
<b>Control group</b>			

<b>Mortality</b>	<b>Event</b>	<b>No event</b>	<b>Total</b>
<b>Experimental group</b>			
<b>Control group</b>			

<b>Admission to hospital</b>	<b>Event</b>	<b>No event</b>	<b>Total</b>
<b>Experimental group</b>			
<b>Control group</b>			

<b>Duration of hospital stay</b>	<b>Event</b>	<b>No event</b>	<b>Total</b>
<b>Experimental group</b>			
<b>Control group</b>			

<b>Any other outcomes from studies</b>	<b>Event</b>	<b>No event</b>	<b>Total</b>
<b>Experimental group</b>			
<b>Control group</b>			

**3.2 Continuous Data**

<b>Outcome</b>	<b>E-group (mean ± SD)</b>	<b>C-group (mean ± SD)</b>	<b>WMD</b>	<b>CI 95%</b>	<b>P=value</b>

**3.3 Estimate of effect with confidence interval/P=value**

<b>Incidence of diarrhoea</b>	<b>RR</b>	<b>CI 95%</b>	<b>P=vale</b>
<b>Experimental</b>			
<b>Control group</b>			

<b>Incidence of respiratory –tract infections</b>	<b>RR</b>	<b>CI 95%</b>	<b>P=value</b>
<b>Experimental group</b>			
<b>Control group</b>			



<b>Mortality</b>	<b>RR</b>	<b>CI 95%</b>	<b>P=</b> value
<b>Experimental group</b>			
<b>Control group</b>			

<b>Admission to hospital</b>	<b>RR</b>	<b>CI 95%</b>	<b>P=</b> value
<b>Experimental group</b>			
<b>Control group</b>			

<b>Duration of hospital stay</b>	<b>RR</b>	<b>CI 95%</b>	<b>P=</b> value
<b>Experimental group</b>			
<b>Control group</b>			

<b>Any other outcomes from studies</b>	<b>RR</b>	<b>CI 95%</b>	<b>P=</b> value
<b>Experimental group</b>			
<b>Control group</b>			

### 3.4 Sub analysis


### 3.5 Miscellaneous

<b>Key conclusions</b>	
<b>Other comments from authors</b>	
<b>Reference to other relevant studies</b>	
<b>Correspondence required</b>	
<b>Comments from reviewers</b>	

## Appendix B: Certificate of editing

Mary A. Cohen  
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*Editing and proof reading for academics*

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The above-named student's thesis titled "*Alcohol-based hand rub in the prevention of diarrhoea and respiratory-tract infection among children in community settings: A systematic review,*" was edited for grammar, spelling, syntax and referencing.



## Appendix C: Certificate of technical formatting



To whom it may concern

This letter serves as confirmation that I, Lize Vorster, performed the technical formatting of Joelynn Geraldine Rachelle Steyn's thesis. Technical formatting entails complying with the Stellenbosch University technical requirements.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Lize Vorster', is written over a simple line drawing of a pen nib.

Lize Vorster

Language Practitioner

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