

**The effectiveness of surgical face masks in the operating room:
A systematic review**

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By

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ABBREVIATIONS

ADA	American Dietetic Association
AORN	Association of periOperative Registered Nurses
BMC	Bio Medical Central
EBP	Evidence–Based Practice
CASP	Critical Appraisal Skills Programme
CDC	Centre for Disease Control and Prevention
CRD	Centre for Reviews and Dissemination
FDA	Food and Drug Administration
HCPRDU	Health Care Practice Research and Development Unit
NHS	National Health Service
NIOSH	National Institute for Occupational Safety and Health
OHR	Ottawa Hospital Research
OSHA	Occupational Safety and Health Administration
RCT'S	Randomised Critical Trials
WHO	World Health Organisation

ABSTRACT

Surgical face masks have been designed to protect health care professionals from the splashes of the patients' blood or body fluids and also to minimise the transmission of oro- and nasopharyngeal bacteria from the surgical team to the patient's wounds, thereby decreasing the likelihood of postoperative surgical site infections during a surgical procedure. However, there are several ways in which surgical face masks could potentially contribute to contamination of the wound during a surgical procedure in the operating room.

The objectives of this study were to explore and describe the effectiveness of surgical face masks as a protective barrier during a surgical procedure in the operating room in the public hospitals in the North West Province, South Africa and to formulate recommendations regarding surgical face masks worn by health care professionals during a surgical procedure in the operating rooms.

A systematic review was conducted, followed by a quantitative, explorative, descriptive and contextual approach. The motivation for a systematic review was to search evidence on surgical face mask efficiency. A search strategy was conducted in February and March 2012 and the total initial search was 9,933 research articles. Screening of articles on effectiveness of surgical face masks during a surgical procedure was done. After six months the search was updated and the final sample of six relevant articles (n=6) was obtained. Studies that met the inclusion criteria were critically appraised based on the scores using standardised critical appraisal tools. The findings of this research project were synthesised and evaluated in order to come to conclusions. Conclusions were integrated and synthesised as the basis of developing a clear overview of the best quality empirical evidence about effectiveness of surgical face masks during a surgical procedure in the operating room.

Recommendations were formulated for the nursing practice, education and research focussing on wearing a surgical face mask during a surgical procedure in the operating room.

Reviewer's conclusion: From the limited results it is unclear whether wearing surgical face masks during a surgical procedure in the operating room serve as a protective device for both surgical team and the patient. There is a need for further research.

Key words: effective, efficient, surgical face masks, operating room, theatre, surgical procedure, health care professionals.

OPSOMMING

Chirurgiese gesigmaskers is ontwerp om werkers in die gesondheidsorg van die spatsels van die pasiënte se bloed of liggaamsvloeistowwe te beskerm en ook die oordrag van oro- en nasofaringeale bakterieë van die chirurgiese span na die pasiënt se wonde te verminder, en daardeur ook die vermindering van die waarskynlikheid van post-operatiewe chirurgiese area-infeksies gedurende 'n chirurgiese prosedure te weeg te bring. Daar is egter verskeie maniere waarop chirurgiese gesigmaskers moontlik kan bydra tot besoedeling van die wond gedurende 'n chirurgiese prosedure in die operasiekamer.

Die doelwitte van hierdie studie was om die doeltreffendheid van chirurgiese gesigmaskers as 'n beskermende versperring gedurende chirurgiese prosedures in die operasiekamers in openbare hospitale in die Noordwes Provinsie, Suid-Afrika, te verken en te beskryf en aanbevelings ten opsigte van die chirurgiese maskers wat deur professionele gesondheidsorg werkers gedurende die chirurgiese prosedures in die operasiekamers gedra word, te formuleer.

'N sistematiese oorsig is volgens 'n kwantitatiewe, verkennende, beskrywende en kontekstuele benadering gedoen. Die motivering vir 'n sistematiese oorsig was om bewyse te soek aangaande chirurgiese gesigmasker doeltreffendheid. 'n Soekstrategie is uitgevoer in Februarie en Maart 2012 en die totale aanvanklike teks was 9,933. Sifting van artikels oor die doeltreffendheid van chirurgiese gesigmaskers gedurende 'n chirurgiese prosedure is gedoen. Na ses maande is die soektog opgedateer en is die finale steekproef van ses relevante artikels ($n = 6$) verkry. Studies wat aan die insluitingskriteria voldoen het, is krities beoordeel op grond van die tellings met behulp van gestandaardiseerde kritiese evaluering gereedskap. Die bevindinge van hierdie navorsingsprojek is gesintetiseer en geëvalueer ten einde tot gevolgtrekkings te kom. Gevolgtrekkings is geïntegreer en gesintetiseer as die basis van die ontwikkeling van 'n duidelike oorsig van die beste gehalte empiriese bewyse oor die doeltreffendheid van chirurgiese gesigmaskers gedurende 'n chirurgiese prosedure in die operasiekamer.

Aanbevelings is geformuleer vir die verpleegpraktyk, onderrig en navorsing deur op die dra van 'n chirurgiese gesigmasker gedurende 'n chirurgiese prosedure in die operasiekamer te fokus.

Evalueerder se gevolgtrekking: Van die beperkte resultate is dit onduidelik of die dra van chirurgiese gesigmaskers gedurende 'n chirurgiese prosedure in die operasiekamer dien as

'n beskermende apparaat vir beide die chirurgiese span en die pasiënt. Daar is 'n behoefte aan verdere navorsing.

Sleutelwoorde: effektief, doeltreffend, chirurgiese gesigmaskers, operasiekamer, teater, chirurgiese prosedure, werkers in die gesondheidsorg.

DECLARATION

I hereby declare that this research study entitled “The effectiveness of surgical face masks in the operating room: A systematic review” is my own work and it has never been submitted for any examination or degree at any other university. I also declare that all sources used in this study are acknowledged in the reference list.

Full name: Nontsokolo Sylvia Makeleni

Date: November 2012

Signed: _____

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CHAPTER ONE

OVERVIEW OF THE STUDY

1. 1 INTRODUCTION

In this study a systematic review was conducted with the aim of critically appraising and synthesising the best available existing evidence about the effectiveness of surgical face masks during a surgical procedure in the operating room. The focus of this study is related to the theoretical framework of the model for evidenced-based clinical decision making (Phillips, 2007:8). This model incorporates the four components that should be taken into consideration during decision making for the best clinical practice: such as the patient's preferences, clinical status and circumstances, evidence from research and health care resources. In this study the researcher was able to identify the areas of uncertainty and also to refine those areas into questions that are both specific and researchable (Oermann *et al.*, 2009:36).

As such, the systematic review will serve as a good starting point when the surgical team, that can also be referred to as health care professionals in the operating room (whether scrubbed or not scrubbed), is looking for evidence that will guide them in clinical decision making, focusing on the research question “what is the effectiveness of surgical face masks as a protective measure during a surgical procedure in the operating room?” (Oermann *et al.*, 2009:36). The Evidence-Based Practice (EBP) (Phillips, 2007:26) was explained in this systematic review aiming at empowering surgical teams to be able to evaluate the strength of the EBP. The outcome of the systematic review will be published and made accessible to clinical practitioners in order to improve knowledge regarding surgical masking.

1.2 BACKGROUND

The use of surgical face masks has been a standard practice in the operating room since the beginning of the century (Davis *et al.*, 2007:455). It has been integral in the surgical team's apparel like head gear, eye wear, gloves, aprons and shoe covers, commonly referred to as personal protective equipment (Phillips, 2007:267; Romney, 2001:254; Cantrell, 2008:36; Lipp & Edwards, 2005:24). These authors further recommended that surgical face masks during a surgical procedure in the operating rooms should be maintained because it serves as a barrier between the surgical team and the patient.

According to Li *et al.*, (2005:61) a nanoparticle-coated face mask has been developed for the protection of the surgical team against some infections and its protective effect is only maintained when the surface layer of the mask is dry. If the mask surface is contaminated with infectious agents, the micro organisms may be able to penetrate the protective layers with the droplets and therefore replacement with a clean surgical face mask is necessary (Belkin, 2006:656). Cantrell (2008:36) reported that the immediate replacement of a surgical face mask is not done as expected e.g. after every surgical procedure due to various reasons. In addition, Philips (2007:270) recommends that during removal of a surgical mask after the procedure, the surgical team should not touch the filter section by hand. The reason is that the inside of the surgical mask is covered with droplets from the mouth and nose which can result in the contamination of the wearer's hands.

The Occupational Safety and Health Administration's (OSHA's) final rule (Belkin, 2006:656) on occupational exposure to blood-borne pathogens identified that the surgical mask can be used together with a face shield and eye shields to serve as personal protective equipment in exposure situations. Li *et al.*, 2005:59 reported the findings of a study conducted to assess the antimicrobial activity of nanoparticle-coated face masks. The results revealed that *Escherichia coli* and *Staphylococcus aureus*, attached to the surface of nanoparticle-treated masks were completely killed.

Researchers (Phillips, 2007:267; Romney, 2001:254; Cantrell, 2008:36; Lipp & Edwards, 2005:24) recommended that the wearing of surgical face masks during a surgical procedure in the operating room should be maintained. The Association of periOperative Registered Nurses (AORN) of 1981, as indicated in Phillips (2007:270) reported that the surgical team does not conform to the correct wearing of surgical masks because the strings are crossed over the head. Crossing the strings of the mask over the head and cheeks allows the sides of the mask to form a gap and permits non-filtered air to escape through venting. Many of the surgical team tie the bottom of the mask too loose so that one can see their chins, mouth and nose when looking at their profile (Rothrock, 2007:78). It has also been observed by the researcher (an operating theatre trained nurse) that surgical teams in the operating rooms in public health care facilities in the North West Province, South Africa, do not comply with the wearing of surgical face masks or do not apply surgical masks correctly during a surgical procedure.

As Lipp and Edwards (2005:267) have identified below, it is not only the wearing of surgical face masks alone that is important to protect the surgical team but also the correct surgical

masking techniques. Lipp and Edwards (2005:267) have identified various factors resulting in the incorrect use of a surgical face mask during surgery which can be summarised as follows:

- insufficient tension on the string of the mask causing venting, which refers to leakage of air from the side of the surgical face mask;
- wicking as a method of conveying liquid via capillary action, possibly contributing to the passage of bacteria;
- wiggling, referring to a friction of the mask against the face which causes the dispersal of the skin scales from the face;
- wearing of the surgical face mask incorrectly, which implies exposure of the nose and/ or mouth; and also
- removing the surgical face mask incorrectly, by grasped by the filter section of the mask resulting to contamination of wounds (also confirmed by Cantrell, 2008:40).

These factors might indicate that the effectiveness of a surgical face mask might be more complex than when expected, as it is not only the fabrication thereof that is important but also the correct application of the surgical face mask by the surgical team.

As discussed in this paragraph, international studies indicated the complexity surrounding the effectiveness of surgical face masks in the operating room. Grinshpun *et al.*, (2009:594) confirmed that both the Food and Drug Administration (FDA) and National Institute for Occupational Safety and Health (NIOSH) in the United State of America (USA) stated that surgical face masks are not subject to filter certification tests to qualify for their efficiency. Rather, the manufacturer should demonstrate the filter performance and facial fit characteristics for surgical face masks to be considered an effective protective device. According to Oberg and Brosseau (2008:281) none of the surgical face masks exhibited adequate filter performance and facial fit characteristics thus resulting to unclear impact regarding the effectiveness of surgical masks in the operating room during clean surgical procedures.

Although surgical face masks have been used for more than a century, there is still a controversy about their effectiveness as to whether they provide protection for the surgical team from the patient or whether they protect the patient from the surgical team during a surgical procedure in the operating room. The practice of wearing face masks is believed to minimise the transmission of oro-pharyngeal and naso-pharyngeal bacteria from the surgical team to the patient's wound (Bahli, 2009:166).

It has been recommended that the wearing of surgical face masks be preserved as it serves as a protective measure for the surgical team, as well as others by preventing potentially infectious splashes from reaching the lower face (Davis *et al.*, 2007:455). Surgical face masks do not only provide a barrier for airborne organisms but also a protection of the surgical team against blood and body fluid splashes during a surgical procedure (Bahli, 2009:166). However, a contradictory argument arises that the wearing of surgical face masks may create a false sense of security with regard to protection (Lipp & Edwards, 2005:254; Davis *et al.*, 2007:455).

1.3 PROBLEM STATEMENT

Studies on surgical face masks with regard to its effectiveness have been conducted and recommended surgical face masks to protect both the surgical team and the patients (Lipp & Edwards, 2005:254; Davis *et al.*, 2007:455). Yet, the mere presence of surgical face masks may be insufficient for optimal protection. The researcher concluded that on the one side, the wearing of surgical face masks is part of traditional operating room apparel that might protect both the surgical team and the patient. On the other side, international literature indicated that surgical face masks are protective only when it is worn and applied correctly. In addition the researcher experienced that in a level three public hospital in the North West Province, the members of surgical team employed in the operating rooms either wear surgical face masks but apply it incorrectly or do not wear surgical face masks at all. This prompted the researcher to ask what the effectiveness of surgical masking is during a surgical procedure in an operating room in order to influence the policy to enhance the correct utilisation thereof. No systematic review was found regarding the effectiveness of surgical masking during a surgical procedure in the operating room.

1.4 RESEARCH QUESTION

From the information expounded above, the research question is formulated as: "What evidence is available regarding the effectiveness of surgical face masks as a protective device during a surgical procedure in the operating room?"

1.5 RESEARCH AIM

The overall aim of this study is to establish the effectiveness of surgical face masks worn during surgical procedures in the operating room. The researcher wants to submit the research findings to the public hospitals in the North West Province's operating rooms in order to enhance the correct application and wearing of surgical face masks during a surgical procedure in the operating room.

1.6 RESEARCH OBJECTIVES

In order to obtain the above-mentioned aim, the following objectives are stipulated:

- to explore and describe the effectiveness of surgical face masks during a surgical procedure in the operating room; and
- to formulate recommendations to enhance the correct application and wearing of surgical face masks during a surgical procedure in the operating room.

1.7 PARADIGMATIC PERSPECTIVE

A paradigmatic perspective is the view that one takes of reality and it serves as the driving force behind choices and actions (Tackett, 1997:1). The philosophical viewpoint or world view forms the basis of a paradigmatic perspective. When conducting the study, a researcher should be consistent with his or her view (the researcher of this study will be referred to as "her") by developing and revealing certain assumptions that are integrated in a philosophical basis, framework or the study design (Burns & Grove, 2009:39). The paradigmatic perspective will be discussed as the meta-theoretical assumptions, central theoretical argument, and the theoretical and methodological assumptions.

1.7.1 Meta-theoretical assumptions

According to Mouton and Marais (2011:192) meta-theoretical assumptions originate from philosophy, are non-epistemic statements that cannot be tested and that concerns human, environment, health and nursing. The researcher's meta-theoretical assumption is a combination of a Christian worldview (Tackett, 1997:1) in combination of a holistic worldview (Lazlo, s.a.:1). A Christian worldview implies that God is the creator of all and that the Bible is the ultimate source of truth. A holistic worldview takes the collective and integral subjectivity of systems into consideration and implies that subjects cannot be found separate from the environment and others.

For the researcher to be able to reflect her meta-theoretical beliefs, these concepts should be considered interrelated to each other.

1.7.1.1 View of man:

The researcher's view of man is a combination of the words in Genesis 1:23 and that of holism. Genesis 1:23 (Good News Bible, 2009:4) states that "God created human beings making them to be like Himself". To the researcher this implies that man is a unique creation, with dignity, own rights and should be given due respect for being God's creature.

In addition to man being a God-created being, man is an integral and complex system and is therefore also a holistic being. The concept "holistic being" refers to considering man as a whole in his physiological, psychological, social and spiritual wellbeing (Freshwater & Manslin-Prothero, 2005:278).

The physiological wellbeing of man refers to the body, its parts and how it functions (Oxford Dictionary, 2009:326). The psychological wellbeing means the state of mind and how it works (Oxford Dictionary, 1996:252). Social wellbeing refers to people's welfare (Oxford Dictionary, 2009:420). Finally, spiritual wellbeing refers to religious beliefs (Oxford Dictionary, 2009:427) of a human being with regard to God and worshipping.

In this study the patient and the members of the operating team are created by God and should be treated with dignity and respect. In addition, the patient and members of the operating team are holistic beings and their physiological, psychological, social and spiritual wellbeing should be promoted. The correct wearing of the appropriate surgical face masks in the operating room during a surgical procedure is essential to protect both the patient and the operating team and therefore promote their wellbeing and enhance their respect.

1.7.1.2 View of nursing

In addition to the researcher's Christian worldview and holism, the researcher agrees with the World Health Organisation's (WHO's) definition of nursing. Nursing, in accordance with the WHO (2012), is the collaborative and autonomous care rendered to patients (individuals of all ages, families, groups, communities), whether these patients are sick or well and in all settings. This care entails the promotion of health, the prevention of illness, the care of the ill and disabled, and dying.

Applied to this study, nursing refers to all the care rendered by the nurse as part of the operating team towards the patient in order to promote the patient's health and prevent infection by wearing surgical face masks as part of the theatre apparel in the correct manner during a surgical procedure in the operating room. Although the patient undergoes surgery, nursing entails to prevent infection during and after surgery and to promote healing whether

the patient is ill, disabled or dying.

1.7.1.3 View of health

The researcher's view of health is in congruence with the WHO (2001:8) and correlates with a holistic worldview. In accordance with the WHO health is "...a state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity". In addition, the researcher adds spiritual wellbeing to her view of health, as spiritual wellbeing is interrelated with the physical, mental and social wellbeing of both the members of the surgical team and the patient.

The view of health applied to this research is the wellbeing of both the patient and the members of the surgical team with regard to their physiological, mental, social and spiritual wellbeing. Health does not imply that the patient or the members of the surgical team do not suffer from any disease or infirmity. Wearing of the correct surgical face masks during a surgical procedure in the operating room can impact on both the patient and the members of the surgical team's health (Phillips, 2007:270)

1.7.1.4 View of the environment

According to Christian worldview the researcher declares that the environment is created by God and should be treated with respect. In addition, from a holistic worldview, the environment is a complex context that is continuously and interrelated in interaction with human beings and can be influenced by each other WHO (2001:8). The environment might have a positive e.g. no postoperative wound infection reports or negative impact on human life e.g. contracting airborne diseases. Finally, the environment is a view of the collectiveness of systems rather than the isolation of objectives.

In this study the environment is the complex context of the operating theatre and all the interrelated activities that are conducted within this environment. This entails that the operating theatre is only one context of all the activities conducted within a level-3 public hospital in the North West Province. Both the patient and the surgical team interact within the environment. The surgical team can have direct impact on the operating room environment with regard to infection control. Therefore, the wearing of surgical face masks by the surgical team during a surgical procedure is conducted within the operating room to prevent infection.

1.7.2 Theoretical assumptions and definitions

The theoretical assumptions include the theoretical assumption, the central theoretical argument and the conceptual definitions of the main concepts applicable to this study.

1.7.2.1 Theoretical assumption

The Evidence-Based Practice (EBP) framework forms the theoretical assumption in this research and will be described in the following paragraphs.

Brink (2006:14) defined EBP medicine as the integration of best research evidence with clinical expertise and patient values. According to Rothrock (2007:5) and Phillips (2007:26) the medical model has used traditional meaning that the beliefs are being passed down from generation to generation in order to determine the foundation of practice. In the twenty-first century EBP is in the forefront of contemporary discussions of nursing research and nursing practice.

The surgical team can view EBP as a problem-solving method that involves identifying a clinical problem, searching the literature, evaluating the evidence from multiple studies, and deciding on the most appropriate intervention (Rothrock, 2007:5). The surgical team should always question why they are doing something in a particular way and determine if it is truly effective (Phillips, 2007:26). In addition, behaviours should be continually evaluated for usefulness as opposed to ritualism because many practices may no longer be necessary as they are not supported by evidence e.g. wearing a surgical face mask in the operating rooms during a surgical procedure (Phillips, 2007:26).

According to Rothrock (2007:8), evidence-based clinical decision making that was developed by the Association of periOperative Registered Nurses (AORN) should incorporate the following components:

- patient's preference;
- clinical status and circumstances;
- evidence from research; and
- health care resources.

A brief application of these components will follow shortly. The peri-operative nurse's clinical expertise (which includes preoperative, intra-operative and postoperative phases), together with the integration of the four components mentioned above, uses clinical skills and past experiences to design nursing care. The evidence-based model provided below (Rothrock

2007:8) is used to illustrate the interrelationship between the four components within the evidence-based model.

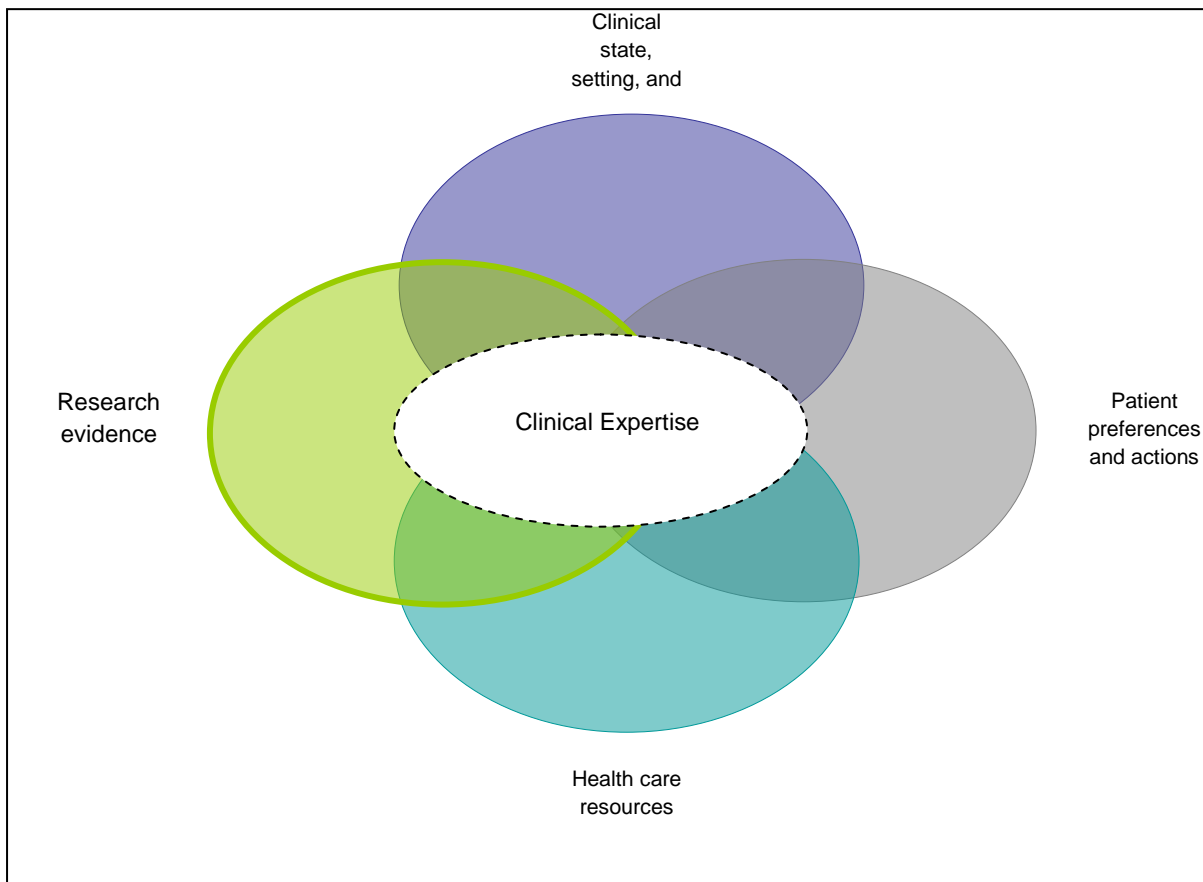


Figure 1.1 The components within the evidence-based model (Rothrock, 2007:8)

The components of the evidence-based model are described below.

(i) Patient's preference:

A patient's unique concerns and expectations must be integrated into clinical decision making in order to serve the patient effectively. In this study a systematic review has been conducted on the effectiveness of surgical face masks as a protective device during surgical procedures in operating rooms by selecting literature that best explains preferences and experiences of patients under study.

(ii) Clinical status and circumstances:

Evidence-based decision making should be made in relation to best practice in the operating rooms. EBP will revolve around the patient and the surgical team's clinical state and the environmental circumstances, of which both can have positive and negative effects on the

health of the individual. If the information given to the surgical team about the effectiveness of surgical face masks is evidence-based, the outcome will be that of critical thinking which can be translated into best practice in the operating room.

(iii) Evidence from research:

In order to set up for a systemic review for EBP in clinical decision making for patient care delivery, interaction of processes should be established (Rothrock, 2007:8; Phillips, 2007:26) such as:

- **measuring** the patient's outcome and quality clinical indicators;
- **establishing** best practices which involves clinical problem analysis, via review nursing theory, research, literature and expert opinion;
- **implementing** via educating health care workers and patients about EBP and providing feedback on it; and
- **performance reporting.**

The aim of EBP is to empower the surgical team to realise its meaning and be able to translate the research evidence into daily practice.

(iv) Health care resources:

The AORN recommended practices for peri-operative nursing concerning aseptic techniques and technical aspects of nursing practice directed toward providing safety in the peri-operative environment. According to Phillips (2007:20), the guidelines and recommended practices of other agencies should be used, e.g. those of the Centre for Disease Control and prevention (CDC). Coordination efforts by all agencies will promote safe environments for the patients and the surgical teams in the operating rooms thus minimising health problems (Phillips, 2007:21).

1.7.2.2 Central theoretical argument

There is contradictory information from the literature with regard to the effectiveness of surgical face masks worn during surgical procedures in the operating room. Furthermore, wearing a surgical face mask during a surgical procedure in the operating room is viewed as an effective protective measure. On the other hand, it is dependent on the correct application of surgical face masks in order to be effective. The results from a systematic review that can provide the best available evidence of the effectiveness of surgical face masks as a protective device during a surgical procedure in the operating room. It can also assist the

researcher to formulate recommendations. The recommendations formulated can be submitted to the operating rooms of level-3 public hospitals in the North West Province in order to enhance the wearing and correct application of surgical face masks during surgical procedures in the operating room.

1.7.2.3 Conceptual definitions

The following concepts are central to this study and are listed below in Table 1.1. Column A refers to the concepts that need to be defined, Column B portrays the concepts defined in everyday use and Column C contains the conceptual definitions as it will be used in this study.

Table 1.1 Conceptual definitions applied to this study

A	B: Definitions used everyday	C: Conceptual definition applied to this study
Effectiveness	A measure of the accuracy or success of a diagnostic or therapeutic technique when carried out in an average clinical environment. (Freshwater & Maslin-Prothero, 2005:199).	Production of an effect that protects a patient and health care workers from contracting air and blood borne infections.
Surgical masking	Wearing a mask to cover the nose and mouth and conforms to facial contours, upper strings are tied at the back of the head and lower strings are tied behind the neck (Phillips, 2007:271).	Wearing a mask to protect the sterile team from blood borne pathogens that may splash or spray the nose or mouth.
Surgical procedure	Invasive incision into the body tissue or minimally invasive entrance into a body cavity for either therapeutic or diagnostic purposes during which protective reflexes or self-care abilities are potentially compromised (Phillips, 2007:1).	Surgical intervention for correction of defects, alteration of the form, restoration of function, diagnosis and/or treatment and palliation.
Operating rooms	The areas where surgical procedures are performed under strict sterile techniques (Phillips, 2007:198).	A room in a hospital equipped for the performance of surgical procedures/ operations and where great care is taken to keep the operating rooms aseptic.

Personal protective equipment	Attire worn by the surgical team that does not allow blood or other potential injurious material to reach the inner clothing, skin or eyes during a surgical procedure (Phillips, 2007:257).	Refers to protective clothing, helmets, goggles or other garments e.g. mask, designed to protect the wearer's body from injury through blunt and sharp objects, electrical hazards and infection, job related occupational safety and health purposes.
Blood borne disease	An infectious disease resulting from a penetrating injury (e.g. needle prick, cut) or a splash (e.g. into the eye, onto the mucous membranes) with fluid contaminated with blood or body fluids e.g. Hepatitis, Human Immunodeficiency Virus (HIV) and other blood borne pathogens (Phillips, 2007:227).	An infectious disease where blood borne pathogens have transmitted through breaks in the skin or direct contact with mucous membranes e.g. Hepatitis and Human Immunodeficiency Virus (HIV).

1.7.3 Methodological assumptions

The methodological assumptions of this study are derived from the model for nursing research (Botes, 1995:5). In this model there are three interrelated orders that propose the nursing activities e.g. nursing practice, nursing science and the paradigmatic perspectives (philosophy) which will be discussed below:

The first order: focuses on the nursing practice to improve the health of the patient/community and forms part of the empirical world (reality). Research problems are derived from the empirical world and for this study the researcher focussed on the effectiveness of surgical face masks within the operating room environment by following the functional approach to research.

The second order: entails nursing as a science which is developed through research and generation of theory to enable the professional nurses to take an active part in the health care system. On this level the researcher conducts a study after identifying the problem within the framework of the study determinants and the researcher's assumptions. The results of the study are applied to nursing practice in order to enhance development of scientific knowledge on the surgical team within the nursing profession (Botes, 1995:6). In this study the effectiveness of surgical face masks during a surgical procedure in the

operating room was explored and described within public hospitals of the North West Province in South Africa in order to formulate recommendations for surgical masking during a surgical procedure in the operating room.

The third order: entails the meta-theoretical assumptions that influence the methodological approach used. In this study the methods used are in line with the theoretical and meta-theoretical assumptions. As stated in 1.6.1, the researcher's meta-theoretical assumptions are a combination of a Christian and a holistic worldview.

1.8 RESEARCH DESIGN

In this study a systemic review was conducted, the aim of which was to explore the best available evidence of the effectiveness of surgical face masks during a surgical procedure in the operating room (Phillips, 2007:270). The method of the systematic review will be explained in detail in chapter 2.

In this study only quantitative studies are included, a quantitative systematic review process was followed. Although no particular design is considered to be more valuable than the other, the best design is always the one that is most appropriate to the research problem and the purpose (Brink, 2006:119). The research design is not only a quantitative systematic review, but is also explorative, descriptive and contextual in nature.

Polit and Beck (2008:20) refer to exploration as an attempt to understand the phenomenon under study better. The evidence regarding the effectiveness of surgical face masks as the protective device during a surgical procedure in the operating room was explored and then described. After the exploration follows the description and this entails to synthesise information critically in order to get the best available existing evidence and give a clear overview of the situation as it naturally happens. A systematic review was conducted in order to describe and elucidate the effectiveness of surgical face masks as a protective device during a surgical procedure in the operating rooms (Burns & Grove, 2009:28, Brink, 2006:120).

Brink (2006:64) state that the researcher has theoretical and methodological beliefs about the nature and structure of the problem under study. A systematic review was conducted to enable the researcher to summarise the best quality empirical evidence of benefits of surgical face masks during a surgical procedure in the operating room within public hospitals in the North West Province, South Africa. Data collection, critical appraisal and data analysis was done. This could facilitate education of and updating by the surgical team by increasing

their ability in order to translate research evidence into clinical decision making, and optimising the health care outcomes in order to practice as a safe and effective surgical team (Condon & Sinha, 2009:51).

1.9 RESEARCH METHOD

The research method in this study refers to the research plan. This research plan has been drafted according to the steps of the systematic review as stipulated by the Centre for Reviews and Dissemination (CRD) (2009:15). Refer to Figure 1.2 below for an outline of these steps which can be translated into the research method.

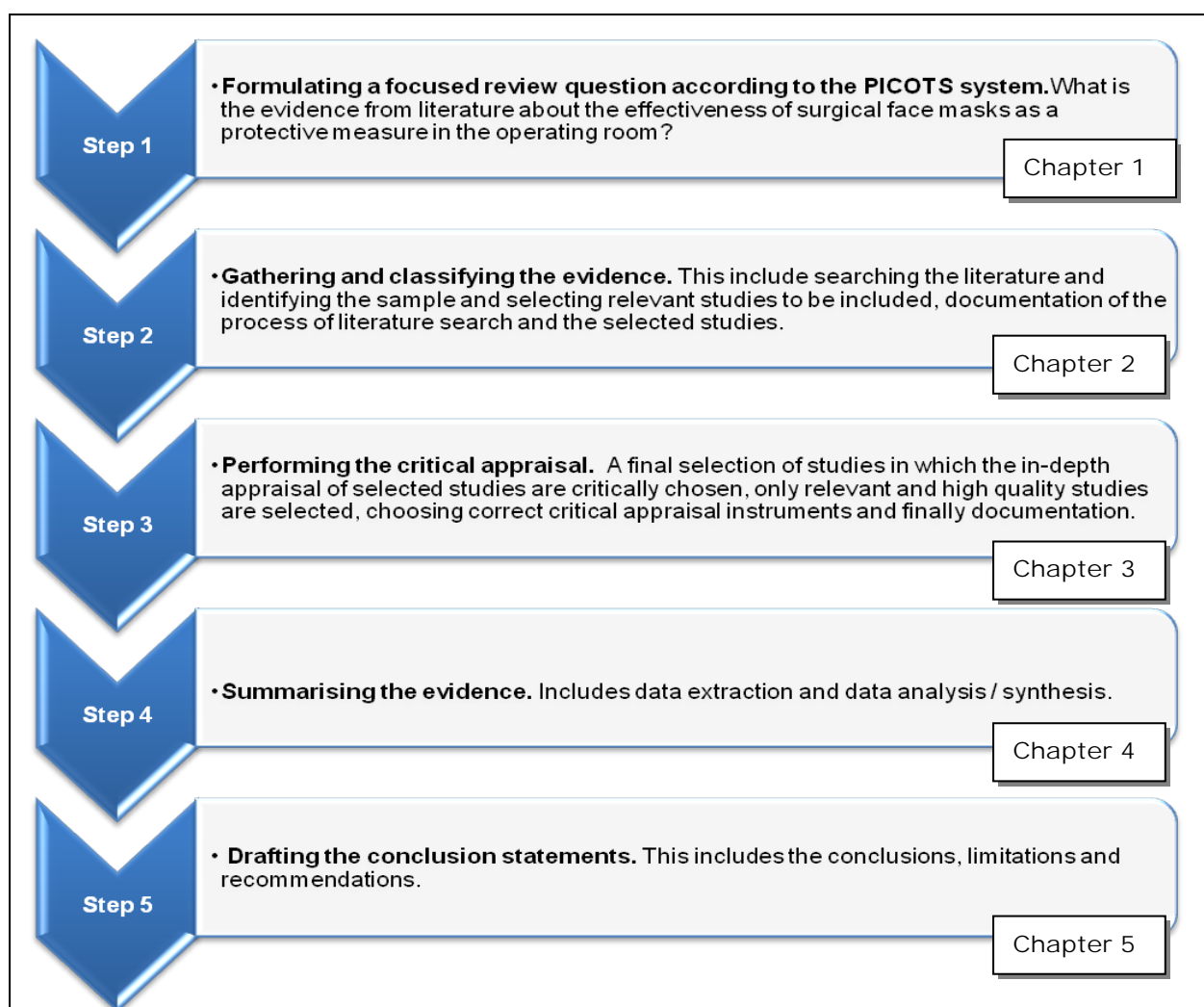


Figure 1.2 Steps of the systematic review process (adapted from ADA, 2008:6-65; Magarey, 2001:377) applied to this research

Now that the reader has been introduced to the five steps in the systematic review process which will be followed closely throughout this study, the following paragraphs will pay

attention to the steps applied to data collection and analysis.

1.9.1 Data collection

Under data collection follows the information on the population, sampling and sample. As this study is a systematic review, the steps in data collection are combined with the steps of the systematic review process.

With regard to the population, sampling and sample, the first three steps in the systematic review are described below.

Step 1: Formulating a focussed review question

In a systematic review, asking a focussed research question which is based on practical needs is of importance because it will assist the researcher to be able to approach the research in a focussed and systematic manner which in turn will have an effective impact on the nursing practice. In this study the systemic review question is: what evidence exists about the effectiveness of surgical masking as a protective measure during a surgical procedure in the operative rooms? A focussed question in the evidence analysis must include the elements used in the PICOT(S) format (ADA, 2008:19). The PICOT(S) is an acronym where each letter has a meaning, namely, (P) refers to population with a specific problem, (I) to an intervention, (C), to comparison intervention and (O) to outcomes, (T) to time frame and (S) to setting.

Step 2: Gathering and clarifying the evidence:

After the formulation of a good question that focuses on the best evidence analysis, identifying the best available, most relevant research begins (ADA, 2008:19). During this process several actions are involved such as to plan a search strategy. A well planned search strategy should be developed, identifying the current best evidence relevant to the question. The search and document adjustment should be according to the search strategy and should follow several iterations of searches such as:

- List inclusion and exclusion criteria: articles should be systematically defined, meaning that the inclusion and exclusion criteria will be used in defining the search strategy and also for filtering the identified research reports. Articles accepted for evidence analysis must be peer-reviewed and published in a juried publication (ADA, 2008:20).

- Identify search words: During this process specific factors that were not included in the actual question may be defined and be used as additional terms in identified relevant pieces of search (ADA, 2008:20)
- Identifying databases to search: In order to be able to identify a sample, multiple sources are used such as:
 - Electronic databases: Including MEDLINE, CINAHL, EBSCO, ProQuest, Psychinfo, and Cochrane.
 - Manual searching: e.g. reading of journals, reference lists from relevant studies, relevant data and abstracts from literature relevant to the research topic (CRD, 2009:17-18).
 - Grey literature (contains unpublished papers, reports and conference abstracts). Information can be obtained by contacting the authors for authenticity (CRD, 2009: 17-18). Internet sources e.g. Google and Google scholar can ensure whether the relevant studies have been identified.

At this stage, special considerations focus on the number and type of sources found in the initial search, inclusion and exclusion criteria, additional searches and adjustments that have been made to the search strategy. Titles and abstracts are reviewed, meaning that the filtering procedure is followed to determine whether the research article matches with the inclusion criteria and is relevant to the question under study. Gathering of all remaining papers or electronic copies of all research articles after citation and abstract review should be done. The list of citations should not be too long or too short in order to be able to address the question (ADA, 2008:21). Librarians should be requested to assist during literature search because their involvement helps in the expansion of search (Kitchenham, 2004:7).

Changes made to the search plan and the number of sources identified in each search should be documented for future reference. The research question should be clearly stated and recorded and the date of the literature review conducted should also be stated for evidence analysis. The inclusion criteria e.g. the PICOTS, sample size, language, and other factors should be determined by the researcher. Only research that meets the criteria should be accepted for evidence analysis (ADA, 2008:21). List of excluded articles should be recorded and reasons for excluding these articles from evidence analysis should be stated e.g. sample size too small. The search vocabulary, electronic databases (number of articles

reviewed included and excluded in the search) should be defined and properly documented (ADA, 2008:24-27).

Step 3: Performing the critical appraisal

Critical appraisal is the last step of sampling and should be accurate in order to give a true reflection of the best available evidence. During this phase, the relevant research articles are critically reviewed, and low quality studies are excluded. At the end, of the critical appraisal, a conclusion statement is written in order to get an answer to the research question and also the grading of the strength of the evidence (ADA, 2008:34). Critical appraisal should be accurate and reveal hierarchical levels of evidence which are derived from various types of methods in the systematic review (ADA, 2008:34).

The levels of studies (ADA, 2008:87) can be graded as follows:

- Grade 1: Good evidence derived from good design that answers the research question.
- Grade 2: Fair evidence derived from good design but there is inconsistency with results due to inadequate sample size, being biased, etc.
- Grade 3: Limited or poor evidence derived from studies that have weak design and fail to answer the research question.
- Grade 4: Applies to conclusion in studies by the opinion experts based on their clinical expertise.
- Grade 5: Evidence is not assignable, meaning that evidence is not available to directly support the conclusion.

Appropriate tools that fit into the design should be used in order to appraise the research study, thus strengthening the validity and reliability of the study (CRD, 2009:44). A second independent reviewer should be involved to enhance objectivity and reliability during the process of critical appraisal (Magarey, 2001:379). Disagreements among reviewers might be due to various reasons e.g. misinterpretation or lack of experience, or consensus could not be reached on what to include or exclude in the study (CRD, 2009:24). Documentation of quality appraisal of each relevant study could be done electronically (CRD, 2009:25). A list of studies excluded throughout the critical appraisal process should be compiled.

The data analysis plan in the systematic review refers to steps 4 and 5 of the systematic review process. These two steps will now be described.

Step 4: Summarising the evidence

Data extraction is determined by the type of research question and the type of studies that are accessible. Data extraction refers to "...the process by which researchers obtain the necessary information about the study characteristics and findings from the studies included" (CRD, 2009:28). The researcher extracts data that will answer the research question e.g. studies with high quality or a high score (ADA, 2008:51-52). The information that will be included on the spread sheet is as follows:

- General information: Name of the researcher, date of the study, and publication (date and year), and author(s).
- Study characteristics: Aim and objectives of the study, study design and inclusion and exclusion criteria of the study.
- Participants' characteristics: Name, gender, ethnicity, socioeconomic status.
- Setting and intervention: Place where the study/intervention was conducted, description of intervention and control.
- Outcome/results: Unit analysis, method used, results of each measurement tool and the limitations and implications to nursing practice (ADA, 2008:54, CRD, 2009:30-31).

According to CRD (2009:45), data analysis involves synthesis and summarising the outcomes within the systematic review. Synthesised outcomes enhance the identification of consistent versus inconsistent findings in the study in order to include studies with reliable conclusions only. After data has been analysed in systematic reviews, a summary is given in the form of text and tables for interpretation of characteristics included in the study and outcomes of the study (ADA, 2008:56).

Step 5: Drafting the conclusion statements

Written conclusion statements must be clear, and must be based on the review studies and be related to the review question. Sometimes the evidence does not support the review question (ADA, 2008:59). This should be taken into account in the conclusion because unbalanced reporting could be provided by the researcher e.g. only reporting the positive results.

According to Burns and Grove (2009:39-40), limitations refer to weaknesses of a study and the two types are:

- **Theoretical limitations:** include weaknesses in the study framework e.g. unclear defined concepts within the study framework.
- **Methodological limitations:** include weaknesses in the study design, sampling, measurement, etc. and can be due to inclusion of poor quality primary studies, poor appraisal technique and poor rigour during literature search.

The final action requires the formulation of recommendations concerning policies should be specific, indicate whether future research is required, be based on evidence and the review question and be arranged in hierarchical order of importance (CDR, 2009:82).

1.10 MEASURES TO ENHANCE RIGOUR

Rigour is striving for excellence in research and involves discipline, scrupulous adherence to detailed and strict accuracy (Burns & Grove, 2009:34). Validity (internal and external) and reliability are considered to be very important throughout the research process. The term validity refers to the extent to which the instrument actually reflects the abstract concept being examined (Burns & Grove, 2009:43). Internal validity refers to the extent to which the effects detected in the study are true reflections of reality rather than the results of extraneous variables (Burns & Grove, 2009:222). External validity refers to the extent to which the study findings can be generalised beyond the sample used in the study (Burns & Grove, 2009:225).

Reliability is concerned with how consistently the measurement technique measures a concept (Burns & Grove, 2009:43). An appraisal tool used during the critical appraisal process should be consistent, meaning that it should give the same results when used by

different independent reviewers (Burns & Grove, 2009:740). Inconsistency of the appraisal tool affects reliability of the research process and can be due to lack of knowledge and skills of the reviewer to critically interpret the designs (CRD, 2009:34; Scott *et al.*, 2007:685). When conducting systematic reviews, high quality studies should be ensured and team work of at least two reviewers are required in order to compare the findings throughout the steps of the study, thus preventing errors and being biased (CRD, 2009:4). In order to maintained rigour in all types of reviews, the problem, aims and objectives of the study should be clearly defined.

1.11 ETHICAL CONSIDERATIONS

As a systematic review was conducted no humans were used as participants, therefore no consent was needed. However, there are ethical issues that were taken into consideration, for example, during a critical appraisal of the studies, the researcher's responsibility was to conduct a study in an honest way (Rossouw, 2005:40). In this study honesty was maintained by upholding integrity throughout the research process. The researcher kept an audit of all actions to be reviewed by the study supervisor at any time. The researcher adhered to the ethical guidelines of the ethics committee of the North-West University. Special reference was granted to the prevention of plagiarism by giving credit to the authors' view points when necessary and providing a list of references of all studies used in this study. The results obtained from the systematic review should be shared with other scientists and the public in a manner that is understandable.

1.12 SUMMARY

Chapter 1 entails an overview of the process of research. The study began with the introduction then it outlined a background that indicated the problem and the need for a systematic review. A research question, the aim and the objectives of the study were stated. The researcher's paradigmatic perspective was outlined, focusing on the meta-theoretical assumptions. The theoretical framework which includes the central theoretical argument and the conceptual definitions of the main concepts applicable to this study were used for clarification. The methodological assumptions based on the three orders and the research design regarding explorative, descriptive and contextual were explained. The research method based on the specific steps of the systemic review was outlined in Figure 1.2. Rigour considering reliability and validity was maintained throughout the study. Ethical considerations were declared.

CHAPTER 2

SYSTEMATIC REVIEW AS THE RESEARCH METHOD

2.1 INTRODUCTION

In this chapter the methodology of the systematic review will be explained according to the specific steps. These steps are: 1) a focussed review question, 2) clarifying the evidence (plan the search strategy, conduct literature and search and documentation of the study), 3) performing a critical appraisal (critical appraisal tools, documentation of the critical appraisal), 4) data extraction, data analysis/synthesis, results, setting and intervention, and 5) drafting the conclusion statements (including conclusions, limitations, and recommendations). Regarding the flow of the study, the research objectives are stipulated for the reader, namely, to explore and describe the effectiveness of surgical face masks during a surgical procedure in the operating room.

2.2 RESEARCH METHODOLOGY

Systematic reviews represent a rigorous and transparent approach of synthesising scientific evidence that minimises bias (Lichtenstein *et al.*, 2009:1). This approach is used to summarise the available data and also serves as a useful tool for identifying the state of science including knowledge gaps and associated research needs, supporting development of science-based recommendations and guidelines, and serving as the foundation for updates of the new data (Lichtenstein *et al.*, 2009:1). Systematic review highlights the usefulness of bringing together a summary of reviews on more than one review on an important topic, with questions that are clearly formulated, weighing pieces of evidence and integrating information in order to draw conclusions about the state of evidence and following the steps of the systematic review (Smith *et al.*, 2011:1).

There are various reasons for conducting systematic reviews, amongst others: to collect data of high-quality from relevant studies, to rigorously synthesise and be able to provide a comprehensive picture of the current best available evidence (Burns & Grove, 2009:28). Evidence-based practice done through systematic review can be utilised effectively in the nursing profession as protocols and policies regarding the effectiveness of surgical face

masks as a protective device in the operating room and these can serve as guidelines for appropriate decision making during the implementation of nursing care. However, evidence-based practice derived from systematic reviews cannot affect change within the nursing practice. Instead, collaborative efforts of translating evidence to practice through an evidence-based practice model, is necessary (Burns & Grove, 2009:635; Phillips, 2007:26: Rothrock, 2007:8).

2.2.1 Research design

The research design is described and motivated below.

2.2.1.1 Quantitative design: This study used quantitative designs which include a sample and use of scoring of levels as evidence (Polit & Beck, 2006:508; Burns & Grove, 2009:40). This design is considered to be more valuable and appropriate to the research problem in as far as a surgical mask is a protective device, that it should be worn and applied correctly, that the researcher's experience is important, and that the surgical team do not wear surgical face masks and do not apply them correctly. Only RCTs / quantitative studies were included as effectiveness of masks was searched for. The researcher will consider exploration, description and contextualisation as the best ways of applying a quantitative design.

2.2.1.2 Explorative: Polit and Beck (2006:20) refer to exploration as an attempt to understand the phenomenon being studied better. In this study, exploration was done because the researcher has limited knowledge about the effectiveness of surgical face masks as protective devices during surgical procedures in the operating room with regard to the type of mask, correct application, and the correct wearing procedure.

2.2.1.3 Descriptive: This study is descriptive as the information gathered was initially explored and critically synthesized in order to get the best available existing evidence and to give a clear overview of the effectiveness of surgical face masks as a protective device during surgical procedures in the operating room by means of a systematic review (Burns & Grove, 2009:28; Brink (2006:120). Knowledge about the effectiveness of surgical face masks in the operating room following a systematic review could assist the researcher to identify what frequently happens in the operating room and give meaning to each problem.

2.2.1.4 Contextual: This study is contextual in nature since the findings are valid and specific, a population was identified, a sample selected, data collected, a design chosen and results were analysed. Brink (2006:64) confirmed that the researcher has theoretical and methodological beliefs about the nature and structure of the problem being studied. A systematic review might enable the researcher to summarise the best quality empirical evidence of the benefits of surgical face masks during surgical procedures in the operating room. This could facilitate education and updating of the knowledge of health care professionals by increasing their ability in order to translate research evidence into clinical decision making, thus optimising the health care outcomes in order to practice as safe and effective health care workers (Condon & Sinha, 2009:51).

2.3 SYSTEMATIC REVIEW

In this study, a systematic review was used to identify and appraise articles that discuss surgical masking in the operating room in order to explore, describe and rigorously repeat the research results regarding the effectiveness of surgical face masks as a protective device during surgical procedures in the operating room.

2.3.1 Steps of the Systematic Review

When a systematic review is used as a research design, a research methodology should include a well-planned review protocol and should clearly state specific steps within the process of the systematic review (CRD, 2009:15). The specific steps of a systematic review are as follows:

2.3.1.1 Step1: *Formulating a focussed review question*

With a systematic review, asking a focused research question which is based on practical needs is of great importance because it will assist the researcher to be able to approach the research in a focussed and systematic manner. This in turn has the most effective impact on the nursing practice. In this study the systemic review question is: what the evidence about the effectiveness of surgical face masks as a protective device in the operative room? A focused question in the evidence analysis must include the elements used in the PICOTS format (ADA, 2008:19) which were: (P) refers to population with a specific problem, (I) intervention, (C) comparison intervention, (O) outcomes, (T) time frame, and (S) setting.

2.3.1.2 Step 2: Gathering and clarifying the evidence

After formulation of a focused question which includes identifying the best available evidence and selection of the most relevant studies (ADA, 2008:19), several actions are involved during this process, such as:

2.3.1.2.1. Plan the search strategy

The search strategy should be well-planned in order to identify the current best evidence relevant to the question. The search engines used should be well-documented for easy reference and when a need of adjustment arises, it should be done in accordance with the search strategy and should follow several iterations of searches such as:

- List inclusion and exclusion criteria: Articles should be systematically defined, meaning that the inclusion and exclusion criteria will be used in defining the search strategy and also for filtering the identified research reports. Articles accepted for evidence analysis must be peer-reviewed and published in a juried publication (ADA, 2008:20).
- Identify search words: During this process, specific factors that were not included in the actual question may be defined and be used as additional terms in identifying relevant pieces of search (ADA, 2008:20).
- Identifying databases to search: In order to be able to identify a sample, multiple sources can be used such as :
 - Electronic search engines: Includes MEDLINE, CINAHL, EBSCOhost, ProQuest, Psychinfo, and Cochrane, etcetera.
 - Manual searching: e.g. reading of journals, reference lists from relevant studies, relevant data and abstracts from literature relevant to the research topic (CRD, 2009:17-18).
 - Grey literature (contains unpublished papers, reports and conference abstracts) information can be obtained by contacting the authors for authenticity (CRD, 2009: 17-18). Internet sources e.g. Google and Google scholar to ensure that the relevant studies have been identified.

2.3.1.2.2 Conduct literature search

At this stage the focus should be laid on various aspects of research such as the initial search (the type and number of databases found, additional searches and specific adjustments made). The titles, abstracts and authors are reviewed in accordance with to the keywords to ascertain whether they match with the question under study. All articles collected either electronically or manually are reviewed and citations are compared with the abstracts, meaning that the filtering procedure is followed to determine whether the research article matches with the inclusion criteria and is relevant to the question under study. The inclusion and exclusion criteria should be reflected (ADA, 2009:21). Access to the databases requires the assistance of a librarian in order to search for relevant literature (Kitchenham, 2004:7).

2.3.1.2.3 Documentation of the search study selection

Documentation of all activities should be done continuously as these records will be kept for future reference. The research question should be clearly stated, the review date, the number and names of sources during the initial search and changes made in the search plan should be clearly defined. The researcher should determine the most important factors regarding the inclusion and exclusion criteria and reasons thereof, and be well-documented. The selected studies should be only those that meet the inclusion criteria and which are deemed to be relevant to the study and be accepted for evidence analysis (ADA, 2008:21). The list of excluded articles and reasons should be reflected, for example, that the size of the sample was either too big or too small (ADA, 2008:24-27).

2.3.1.3 Step 3: Performing the critical appraisal

This is the last step of sampling and should be accurate in order to give a true reflection of the best available evidence. During this phase, the relevant research articles are critically reviewed, and low-quality studies are excluded. At the end, a conclusion statement is written in order to get an answer to the research question, as well as to grade the strength of the evidence (ADA, 2008:34). A critical appraisal should be accurate and reveal hierarchical levels of evidence, which are derived from various types of methods in the systematic review (ADA, 2008:34).

2.3.1.3.1 *The grading of the level of studies (ADA, 2008:87)*

- **Grade 1:** Good evidence derived from a good design that answers the research question.
- **Grade 2:** Fair evidence derived from a good design, but there is inconsistency in results due to an inadequate sample size, being biased, etc.
- **Grade 3:** Limited or poor evidence derived from studies that have a weak design and that fail to answer the research question.
- **Grade 4:** Applies to studies involving conclusions by experts whose opinion is based on their clinical expertise.
- **Grade 5:** The evidence is not assignable, meaning that evidence is not available to directly support the conclusion.

2.3.1.3.2 *Critical appraisal tools*

The researcher should ensure that appropriate tools that fit into the design are used in order to correctly appraise the articles, thus strengthening the validity and reliability of the study (CRD, 2009:44). To enhance objectivity and reliability during this process, a second independent reviewer should be involved (Magarey, 2001:379). Disagreements among reviewers might be due to various reasons, for example, misinterpretation or lack of experience. Consensus should be reached on what to include in, or exclude from, the study (CRD, 2009:24).

2.3.1.3.3 *Critical appraisal tools used in the study*

The critical appraisal tools are divided into randomised controlled trials and nonrandomised control trials.

Randomised Controlled Trials

- **CASP: Critical Appraisal Skills Programme - Randomised Critical Trials (RCT) and Critical Appraisal Tools (CAT),** issued by: Public Health Resource Unit, National Health Service (NHS) England.
- **CASP: COHORT STUDIES:** is a methodological checklist which provides key criteria relevant to cohort studies. Issued by Public Health Resource Unit, NHS. England

Non randomised Controlled Trials

- The TREND (Transparent Reporting of Evaluations with Non-randomised Designs) statement. Issued by: Centre for Disease Control and Prevention (CDC), United States of America.
- A scoring system for *mixed methods research and mixed studies reviews* (qualitative/quantitative experimental, quantitative observational and mixed methods at the time). Issued by Pluye *et al.* (2009:529-546).
- *The Preferred Reporting Items for Systematic Reviews and Meta Analyses (PRISMA)* (statement that provides evidence based minimum set of items for reporting systematic reviews and meta-analyses). Issued by Ottawa Hospital Research Institution (OHRI), Canada.

2.3.1.3.4 Documentation of the critical appraisal

After critical appraisal, the documentation of the appraisal of each relevant study and reasons should be done electronically (CRD, 2009:25). All studies excluded throughout the critical appraisal process should be clearly defined and reasons for exclusion should be clearly stated. Documentation can be done either electronically or follow the traditional way that is "paper and pencil".

2.3.1.4 Step 4: Summarising the evidence

This includes data extraction and data analysis/synthesis, which will be outlined as follows.

2.3.1.4.1 Data extraction

Data extraction refers to "...the process by which researchers obtain the necessary information about the study characteristics and findings from the studies included" (CRD, 2009:28). This process is determined by the type of the research question and the types of studies that are accessible. The researcher extracts data that will answer the research question, for example, studies with a high quality or high score (ADA, 2008:51-52). The information that will be included in the spread sheet is as follows:

i) General information: Name of the researcher, date of the study and publication (date and year), and author(s).

ii) Study characteristics: Aim and objectives of the study, study design, and inclusion and exclusion criteria of the study.

iii) Participants' characteristics: Name, gender, ethnicity, and socio-economic status.

iv) Setting and intervention: Place where the study/interventions were conducted, description of interventions, and control.

v) Outcome of data/results: This includes unit assessment/analysis, measurement tool/method used, results of each measurement tool/study analysis, the limitations of, and implications for, nursing practice (ADA, 2008:54; CRD, 2009:30-31). The research question and the types of studies that were used will determine how and which data should be extracted. It is recommended that before data can be categorised, thorough data extraction be done and be properly saved (CRD, 2009: 28-29).

2.3.1.4.2 Data analysis/synthesis

Data analysis involves synthesis and a summary of the outcomes within the systematic review (CRD, 2009:45). Synthesised outcomes enhance identification of consistent versus inconsistent findings in the study in order to include only the studies found to have reliable conclusions. In systematic reviews, analysis of data is done, and then a summary is to be given in the form of text and tables for the interpretation of characteristics of the included studies and outcomes of the study (ADA, 2008:56).

2.3.1.5 Step 5. Drafting the conclusion statements (including conclusions, limitations, and recommendations)

In the systemic review, conclusions are done in the final step (step number 5) and they involve the writing of conclusion statements. Conclusions must be clear, specific, related to the review question and be based on the review studies. Interpreting and reporting the results should provide a balanced report that means that the reviewer should mention both negative and positive results (ADA, 2008:75).

According to Burns and Grove (2009:39-40), limitations refer to weaknesses of a study threats to the rigour which could be caused by the inclusion of poor quality primary studies or incomplete appraisal techniques. Limitations can be divided into:

- Theoretical limitations which include weaknesses in the study framework, for example, unclear defined concepts within the study framework (Burns & Grove, 2009:40).
- Methodological limitations which include weaknesses in the study design, sampling, measurement, etc. and can be due to inclusion of poor-quality primary studies, poor appraisal techniques, and poor rigour during the literature search (Burns & Grove, 2009:40).

Recommendations regarding policies should be specific, arranged in hierarchical order of importance and should be based on evidence. The most important recommendations should indicate whether future research is required (CDR, 2009:82).

2.4 CRITIQUE AGAINST SYSTEMATIC REVIEWS

A systematic review of reviews provides reassurance that the conclusions of individual reviews are consistent or not. The quality of individual reviews may be assessed, so that evidence from the best quality reviews can be highlighted and brought together in a single document, providing definitive summaries that could be used to inform clinical practice (Smith *et al.*, 2011:2). Various challenges have been recognised when preparing systematic reviews of individual studies. These challenges are as follows:

2.4.1 Review selection

Before commencing with the systematic review of reviews a review team should be established and include at least one person with methodological expertise in conducting systematic reviews and at least one person with expertise on the topic under review. The review strategy is developed in order to identify reviews relevant to the topic and potential importance to answering the research question (Smith *et al.*, 2011:5).

2.4.2 Meta-analysis in systematic review of reviews

A major challenge in conducting systematic reviews is meta-analysis of included reviews, which are themselves meta-analyses (Smith *et al.*, 2011:9). When doing this, it is important not to use data from primary sources more than once because that would lead to a risk of producing misleading estimation. To overcome this challenge, analysis of each source included in the review and subsequent combination of the results of the individual included studies should be done (Smith *et al.*, 2011:9). In this research the focus remains on the steps of a systematic review and therefore the researcher will declare the steps conducted to the reader in the realisation of data collection and data analysis.

2.5 SUMMARY

This chapter provided an overview of the systematic review as a methodology. The systemic review process was outlined in accordance with the specific steps of the systematic review which include: step number one which involves the formulating of a focused review question which is followed by step two where gathering and classifying of the evidence, which include identifying relevant studies for inclusion through literature search, selection of studies and sampling procedure, are done. Step 3 involves performing a critical appraisal of selected studies and step four is about summarising the evidence which include data extraction and data analysis/synthesis and the last step (step 5) involves the drafting of the conclusion statements which include conclusions, limitations and recommendations. Chapter 3 which is Step 3 of the systematic review involves the realisation and findings of the research and will be discussed next.

CHAPTER 3

REALISATION AND FINDINGS OF THE RESEARCH

3.1 INTRODUCTION

In this chapter an overview and realisation of the systematic review conducted will be explained according to three of the five steps of the systematic review. These steps are: 1) a focused review question, 2) identifying relevant studies for inclusion (sampling procedure), and 3) performing the critical appraisal.

3.2 REALISATION OF STEP 1: THE REVIEW QUESTION

The steps of the systematic review were directed by the research question and objectives, and are listed as follows:

Research question:	Research objective:
What is the evidence about the effectiveness of surgical face masking as a protective measure in the operating room?	Explore and describe the evidence of the effectiveness of surgical face masking during a surgical procedure in the operating room.

3.2.1 Formulating a focused review question

The review question was approved and refined with the assistance of the research supervisor as well as the peer reviewer. The PICOT(S) (ADA, 2008:16) format was followed to ensure that a well-structured question is used. The components (in accordance with PICOT/PICOTS) of the research question are outlined in table 3.1

Table 3.1 Elements of the research question (PICOTS)

P =Population with a specific problem	Health care professionals
I =Intervention	Face masking
C =Comparison	Wearing versus not wearing a face mask
O =Outcomes	Evidence of effectiveness
T =Time frame	Time period of studies: from 2000 until recent
S =Setting	The operating rooms (South Africa, public sector).

In this study, a focused question is stated to gather the evidence about the effectiveness of surgical masking in the operating room which will only be answered by choosing the best research design during data collection.

3.3 STEP 2: GATHERING AND CLASSIFYING THE EVIDENCE

In step 2, the gathering and classification of the evidence are described in detail below.

3.3.1 Identifying relevant studies for inclusion (sampling procedure):

During this step the researcher identified relevant studies according to specific inclusion and exclusion criteria. These criteria are listed below.

3.3.1.1 Inclusion criteria

The sample included all studies that met the following requirements:

- Research studies related to effectiveness, wearing a mask, not wearing a mask, operating room, and health care professionals.
- Studies published since 2000 to ensure more recent results.
- Studies written in English as the researcher is proficient in English only.

3.3.1.2 Exclusion criteria

The sample excluded all studies that met the following requirements:

- Studies that are irrelevant regarding the topic such as:
 - i) Studies not specific to surgical masking.
 - ii) Studies regarding wearing surgical masking outside the theatre/operating room environment.
- Non-research reports (see table 3.4)
- Duplicate studies.
- Qualitative studies as the focus will remain on quantitative studies for a systematic review and not an integrated literature review.

A broad search was conducted to ensure that available studies were available, with the aim of including all studies that were relevant to the research question. Thereafter, filtering was done to ensure that all studies included were relevant.

3.3.2 Literature search conducted

A literature search was done on the topic, using a combination of keywords such as: “surgical mask” and “effect” or “efficient” or “use” and “operating room” or “theatre”. An advanced search was done in the categories of *All or Title, Abstract or Author Supplied Abstract or Keywords*. In databases where sufficient or relevant results were required, only selected keywords were used and where no sufficient or irrelevant results were obtained, a combination of keywords were used.

3.3.3 Multiple sources of literature

Multiple sources of literature such as different databases and catalogues were included in order to search relevant research studies. Published and unpublished literature for example grey literature was searched. A plotting table was designed to indicate the specific combination of keywords used in each database. Refer to Table 3.2 below.

Table 3.2 Sources of literature used in the search strategy

STUDIES PUBLISHED IN JOURNALS, THESES/DISSERTATIONS AND SYSTEMATIC REVIEWS			
		Electronic Databases	Type of literature included
International	1	EBSCOhost: Academic Search Premier, Cinahl, Health Source, Nursing Academic Edition, MasterFile Premier, Medline, PsycholInfo and Africanwide NiPAD	Journal articles
	2	Science Direct	Journal articles
	3	ProQuest	Theses and dissertations
	4	Scopus	Journal articles
	5	Cochrane	Systematic reviews of studies
National	1	Nexus (National Research foundation [NRF]).	In order to conduct and obtain all relevant search studies in these databases, an expert (librarian) was consulted for assistance because it was difficult to access these databases. All the above types of literature already mentioned, were used.
	2	Sabinet (SAePublications, SAe Catalogue).	

Studies not published in journals

Manual search	Search was done on grey literature such as discussion papers, report booklets, conference proceedings and unpublished research theses. A manual search was done to obtain articles from the Internet and to scan through references.
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From the above table it is clear that the literature search conducted covered the major databases both internationally and nationally.

3.3.4 Role of the librarian

In order to obtain all relevant articles, an experienced librarian from the Ferdinand Postma Library at the North-West University (Potchefstroom Campus) was consulted for assistance during the search strategy within the chosen data bases and also gave support with

selection of key words. Electronic national databases like Nexus (National Research Foundation) and Sabinet (SAePublications and SACatalogue –SACat) were not easy to access; therefore guidance was sought in this regard.

3.3.5 Documentation of the search strategy

The researcher started with the search strategy by accessing the search engines and electronic databases. Table 3.3 outlines the searches conducted, the selection of literature and the number of literature selected for critical appraisal.

Table 3.3 Summary of the results of the search

Summary of search	Databases	Initial search	Full text	Appraisal
Electronic databases:				
1. International	<ul style="list-style-type: none"> • EBSCOhost. 75 • Science Direct. 65 • ProQuest. 935 • Cochrane. 38 • Scopus. 301 			
2. National	<ul style="list-style-type: none"> • Sabinet (including SAe Publications, NWU.Catalogue (SACat). 8.284 • Nexus (NRF). 200 			
Internet	Google Scholar.	32	2	2
References	Reference search.	3	0	0
TOTAL		9.933	21	6

From the initial search of 9.933 documents, a total of 21 were selected through the process of elimination according to the search strategy. Another aspect of data collection entailed the purposive exclusion of literature as indicated by the exclusion criteria. See to Table 3.4 for an outline of the articles excluded.

Table 3.4 Articles excluded according to search engine including the reasons for exclusion

Search engines	Total initial search	Reasons for exclusion			Total excluded
		Irrelevant studies: not specific to surgical masking in the operating room	Duplicate studies	Non research reports / qualitative studies	
EBSCOhost	75	53	6	7	66
Science Direct	65	54	5	3	62
ProQuest	935	935	0	0	935
Cochrane	38	36	0	0	36
Scopus	301	277	16	3	296
Sabinet (including SAE Publications and SA Catalogue)	8,284	0	0	0	8,284
Nexus (NRF)	200	0	0	0	200
Google Scholar	32	30	0	0	30
Reference list (manual search)	3	3	0	0	3
Total	9.933	1.388	27	13	9.912

An effort was made in various ways to obtain some articles but all in vain. A record of articles that were unobtainable and reasons therefore are provided below. See Table 3.5 for an outline of unobtainable articles.

Table 3.5 Unobtainable articles

No	Source	Reference	Reason
1	EBSCOhost	Lahme, W.K. 2001. Surgical face mask for patients during anaesthesia. Hygienic necessity or dispensable ritual. <i>Anaesthetist</i> . 50: 846-851.	Require registration and not available through interlibrary loan services.
2	EBSCOhost	Sjørl, A & Kelbaek, H. 2002. Is use of surgical caps and masks obsolete during percutaneous heart catheterization? <i>Ugeskrift for Læger</i> , 164(12):1673-1675.	Publication in Danish.
3	Scopus	Anon. 1998. "Title unknown". <i>Operating room manager</i> , 11(1):12-13.	No author available
4	EBSCOhost	Mitchell, L. 2009. Does the wearing of surgical mask in procedural or operating rooms protect the patient and the wearer? <i>The journal of perioperative nursing in Australia</i> , 22(3), Summer.	Require registration

The search process included the critical appraisal of articles (included, excluded and unobtainable), and was followed by the filtering process in accordance with levels 1, 2, 3 and 4 in order to enhance the specification of the final sample, which is outlined in the next paragraph.

3.3.6 Levels used during the search

Filtering was done during the process of the final search, in order to obtain the final sample. Four levels of filtering during the search strategy were used as follows:

- Level 1: An initial search and scanning of titles and abstracts was done in order to select relevant studies.
- Level 2: Full text copies of all relevant studies were obtained.
- Level 3: Involves reading all obtained full texts in order to include or exclude articles for critical appraisal (step 3 of the systematic review).
- Level 4: Entails the critical appraisal of full text articles and data extraction of articles for inclusion (part of step 4 of the systematic review (the final sample)).

Below is Figure 3.1 that outlines the realisation of the search strategy, in accordance with levels 1, 2, and 3 in the form of a flow chart.

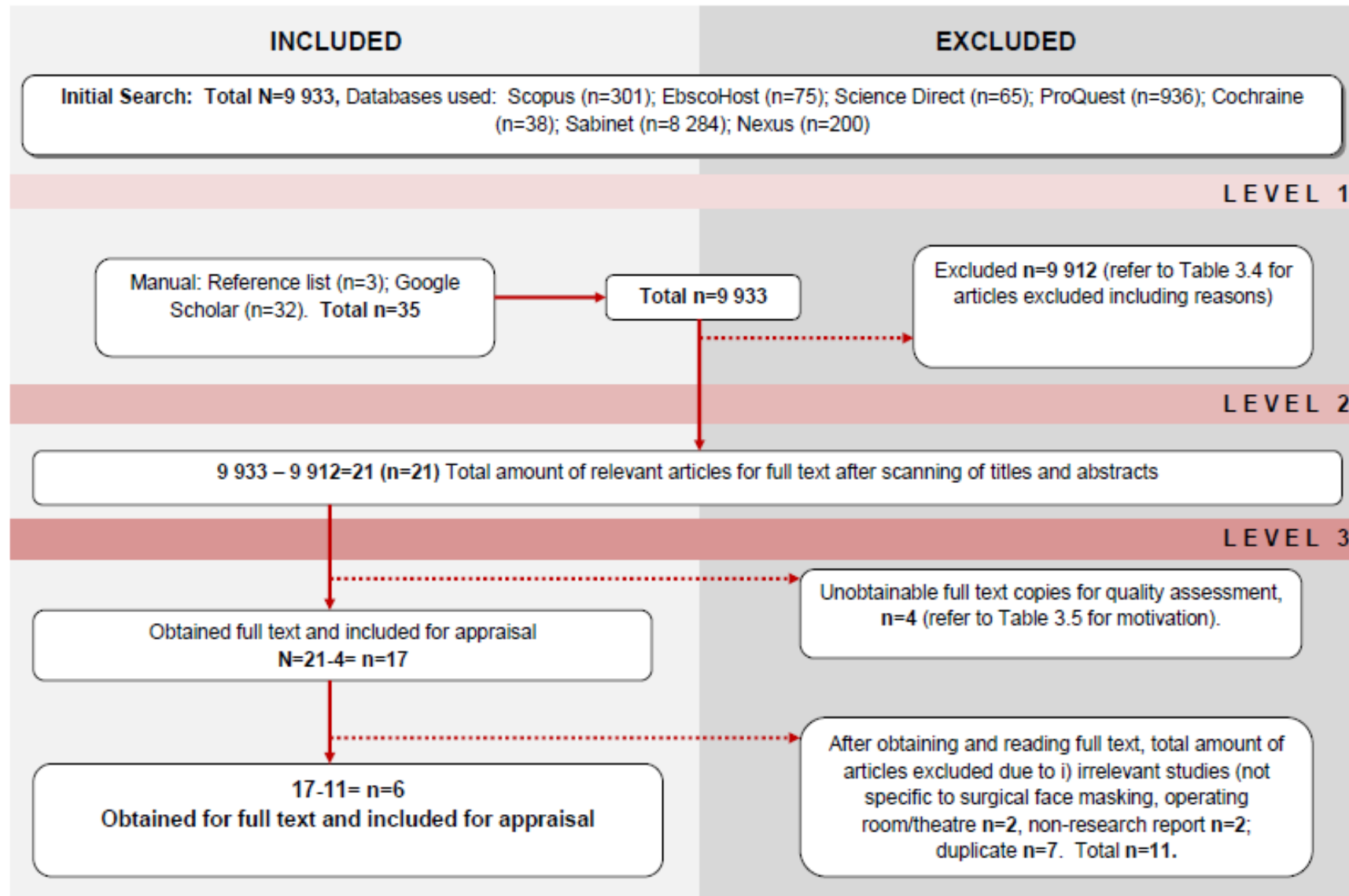


Figure 3.1 Realisation of the search strategy (research sample): Levels 1, 2 and 3 (CDR, 2009:2)

Furthermore, a critical appraisal and data extraction within the realisation of the search strategy was performed in order to ensure that a final sample was achieved.

Figure 3.2 below provides Level 4 (which contains critical appraisal and data extraction).

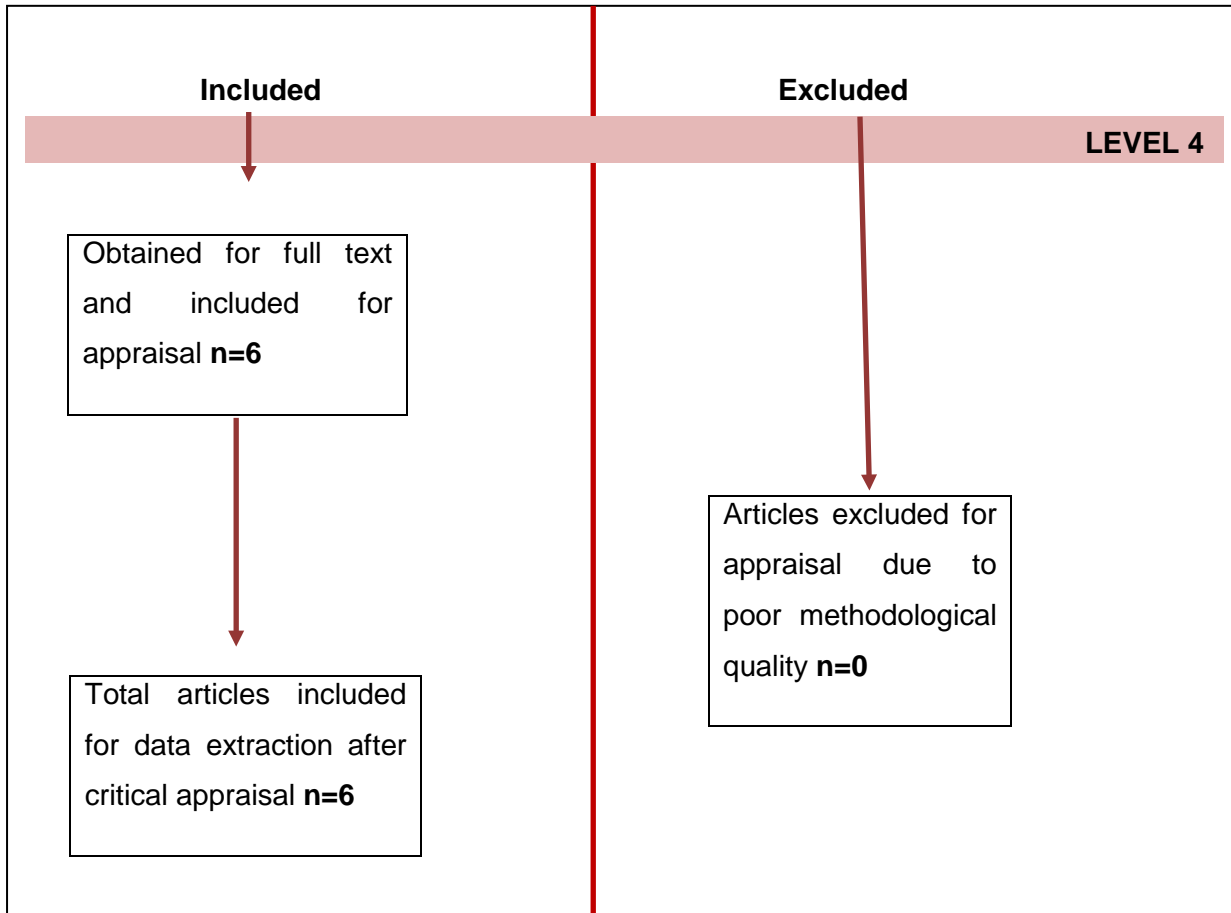


Figure 3.2 An overview of Level 4 in the critical appraisal and data extraction

In order to conduct an appropriate critical appraisal, full text articles were classified according to the type of the research design, and an appropriate appraisal tool that fits to the design was chosen in order to maintain internal validity (refer to paragraph 1.8).

3.3.7 Updating the search

Updating the search is a method of increasing the rigour (refer to paragraph 1.8). The entire updating of the search was done six months after the first search in order to ensure that no relevant data was missed.

3.4 STEP 3: PERFORMING THE CRITICAL APPRAISAL

Critical appraisal was performed to ensure that methodological quality and rigour for the inclusion of the final sample from where data was extracted, is maintained (ADA, 2008:41). During this step, the credibility and validity of the appraised studies were ascertained in order to determine whether the findings were evidence-based. The following objective and structured instruments were used during the critical appraisal process (refer also to 2.3.1.3.3):

- The evaluation tool for quantitative research studies (Long *et al.*, 2002).
- Critical appraisal instrument for reviews (CASP, 2006).
- Critical appraisal instrument for RCTs (CASP 2006).
- Critical appraisal instrument for cohort studies (CASP, 2006).
- BMC (Bio Medical Central) Medical Research (Development of AMSTAR) (Shea *et al.*, 2007) for quantitative studies.
- PRISMA statement checklist for systematic reviews (Moher *et al.*, 2009:6).

The above mentioned critical appraisal instruments have been chosen amongst others because they fit well into the design of the appraised samples, as motivated below:

- **The evaluation tool for quantitative research studies:** This instrument was used because the check list covers almost every item or topic that needs to be identified in any study. It was chosen because items regarding clinical applicability, and measures of statistical uncertainty of the study could be critically appraised.
- **Critical Appraisal Skills Programme (CASP) for RCTs:** This instrument was used because it was applicable to the research design of the sample. It contains systematic screening questions that can be easily answered e.g. Yes or No, thus these questions served as the guidelines during critical appraisal in the current study. Other examples of CASP used in this study are the Randomised Critical Trials (RCTs) and Case Control Study (CCS). These instruments consider the validity of the study, the results of the study and the impact on the nursing profession (Law *et al.*, 1998:2).

- **The tool for Cohort studies:** This instrument contains questions that served as guidelines during the critical appraisal of articles relevant to the current study. This instrument is in line with the Critical Appraisal Skills Programme (CASP).
- **Bio Medical Central (BMC) Medical Research (Development of AMSTAR):** This instrument was used as a guideline for the current study as it deals with the identification, literature review and appraisal of selected articles. It serves as the measurement instrument of methodological quality of systematic reviews (Shea *et al.*, 2007) in the event where quantitative studies are utilised.
- **PRISMA statement checklist**
This instrument served as the guideline during analysis to critically appraise and, finally, report on the findings of the study (Moher *et al.*, 2009:7) as applicable to systematic reviews.
- **PRISMA flow diagram**
The PRISMA flow diagram, a 27-item check list that could be used in various studies especially in systematic reviews.
- **Guidelines for critically review from quantitative studies:** This instrument was chosen because it uses simple basic terms that are easy to understand for a researcher. Broad terms that need to be considered are highlighted in this tool e.g. validity of the study, the results of the study and the impact on the nursing profession (Law *et al.*, 1998:2).

Although the systematic review was conducted by a single researcher, the critical appraisal was conducted by a review under the supervision of an experienced researcher who is experienced in conducting the systematic review. The researcher, in consultation with the supervisor, concluded that for the studies to be regarded rigorous and be included in data extraction, they should obtain 6/10 if CASP was used as a critical appraisal tool. Furthermore, studies were graded in accordance with definitions (Grade I–V) regarding the strength of evidence (ADA, 2008:62) outlined previously (refer to paragraph 2.3.1.3.1) Table 3.6 is provided to outline the articles for critical appraisal.

Table 3.6 Critical appraisal for sample (n = 6)

ARTICLES INCLUDED (n = 6)		RCTs n =6	
REFERENCE	DESIGN	RESEARCH METHODS	RIGOUR
ARTICLE NUMBER 1			
<p>Webster <i>et al.</i> (2010:169-173). “Use of face masks by non-scrubbed operating room staff: a randomized control trial.”</p>	<p>Study type: RCT.</p> <p>Setting: 17 Operating Theatres.</p> <p>Intervention: Group 1: Mask group (n=313). Group 2: No mask group (n=340).</p>	<p>Research Methods</p> <p>Sample: Computerised generated randomised schedule. Operation lists were randomised into two arms: mask group and no mask group.</p> <p>Data collection:</p> <ul style="list-style-type: none"> • Preoperative information included: • Composite Risk Index (e.g. patient’s physical status, length of surgery and wound classification). • Demographic data collected: age, gender, weight, body mass index (BMI), history of previous wound infection, smoking status and current co-morbidities, use of preoperative antibiotics prophylaxis, date and type of surgery, length in the operating room number of staff in the operating room, and whether the 	<p>Rigor</p> <p>Instrument used: CASP RCT</p> <ul style="list-style-type: none"> • The focused research question was stated and answered. • The outcomes of the study were clearly stated. • The design used was appropriate; the study and control groups were clearly defined. • Sample size was specified, the inclusion and exclusion criteria were used, allocation of participants occurred immediately before the session began. • Data was collected in the same way in both groups. • Data analysis was clear and the

		<p>wound was drained.</p> <p>Post-operative information included :</p> <ul style="list-style-type: none"> • Post-operative in-patient stay e.g. administration of post-operative antibiotics and length of pre-operative and post-operative hospital stay • Strategies used for surgical site surveillance after discharge included: • Routine follow-up (questionnaires) seeking information from patients admitted in the hospital about wound status, information from post-discharge follow-up clinics and where the information could not be found by any of these methods e.g. through phone calls made to the patient or to the general practitioner. <p>Data analysis: The following were used:</p> <ul style="list-style-type: none"> • Student's t-test and Chi-square (for baseline patient characteristics). • Standard deviation (to calculate the odds ratio of an outcome in the no mask group compared 	<p>blinding system was specific.</p> <ul style="list-style-type: none"> • The results of the study were clearly reported (mask group versus no mask group). • The ethical considerations were followed and clearly stated. <p>Conclusion: The study was well conducted, with precise and clear results.</p> <p>Rigour was good (10/10) and rated Grade I of evidence.</p> <p>Relevance to the study: Relevant because masked effectiveness during a surgical procedure was addressed.</p> <p style="text-align: center;">INCLUDED in the study.</p>
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		with the mask, with a 95% CI.	
ARTICLE NUMBER 2			
Romney (2001:47, 251-256). “Surgical face masks in the operating theatre: re-examining the evidence.”	<p>Study type: RCT.</p> <p>Setting: Operating Theatres (unspecified).</p> <p>Interventions: Performing masked versus unmasked surgical operations.</p>	<p>Sample: Randomised sampling (masked and unmasked operations)</p> <p>Data collection:</p> <ul style="list-style-type: none"> • Study 1: No masks were worn in approximately 1000 elective, general surgery cases and no control group. • Study 2: Randomised Control Trial. 41 women undergoing gynaecological and abdominal surgery (operating team masked or unmasked). • Study 3: in the delivery room patients were assigned to the experimental group, surgical team abandoned caps, masks and boots. • Study 4: 1537 masked operations and 1551 unmasked operations. • Study 5: Explored relationship between mask usage and bacteria shedding during cardiac catheterisation, masked position varied. randomly (30 cases) during each procedure • Study 6: Investigated whether oral bacteria dispersed by non-scrubbed, circulating staff (masked or unmasked) pose a risk to the 	<p>Instrument used: CASP RCT</p> <ul style="list-style-type: none"> • This study reflected a focused research question. • The overall objective of this study was clearly stated. • A clear and appropriate design and methods were used. • The sample (12 scientific studies) was retrieved for evidence. • Data was collected in the same way in all groups (studies). • It is unclear whether blinding of participants was used or not. • Follow-up clinical studies were done on effectiveness of wearing a mask during a surgical procedure. • The results of the studies conducted were precise and clear. • Conclusion: the study was fairly planned, conducted and reported medium rigour of 7/10 and rated Grade

		<p>patient on the operating table.</p> <ul style="list-style-type: none"> • Six (6) volunteers were asked to stand at a distance of one metre from the operating table and to speak loud or sing. • Settle plates were incubated and inspected for bacterial growth for 24 hours. <p>Data analysis:</p> <ul style="list-style-type: none"> • Studies 1, 2 and 3: Statistical analysis of data were not described. • Study 4: 47% (masked) and 35% (unmasked) by the two-tailed chi-square, • Study 5: No statistical relationship between the exact placement of mask (above or below the nose) and the colony count recovered. • Study 6: Method of data analysis was not fully explained. 	<p>IV evidence.</p> <p>Relevance to the study: Relevant because masked effectiveness during a surgical procedure was addressed.</p> <p>INCLUDED in the study.</p>
ARTICLE NUMBER 3			
<p>Lipp and Edwards (2005:21-38). “Disposable surgical face masks: A systematic review”.</p>	<p>Study type: RCT.</p> <p>Setting: Operating Theatres and in the laboratory.</p>	<p>Sample: Quasi-randomised control trials (scrubbed and unscrubbed operating team, masked and unmasked groups).</p>	<p>Instruments used: CASP RCT.</p> <ul style="list-style-type: none"> • This study did not answer the research question due to limited results from both studies. • The overall objectives of this study

	<p>Intervention: List was allocated to masked and unmasked group (scrubbed and unscrubbed members of the operating team).</p>	<p>Data collection:</p> <ul style="list-style-type: none"> • Study 1: 1,429 patients were randomly selected to undergo a clean surgery, clean contaminated and contaminated surgery and allocated to masked and unmasked staff for a period of one year. • Study 2: 41 patients were randomly selected to undergo clean gynaecological operations, carried out by masked and unmasked staff over a period of two months. <p>Data analysis:</p> <ul style="list-style-type: none"> • Study 1: No data analysis was done because nothing in the line of dropouts was reported. • Study 2: Data analysis was not done because the study was discontinued after a third case of post-operative infection in the unmasked group was diagnosed. 	<p>were clearly stated.</p> <ul style="list-style-type: none"> • Appropriate design and method was clearly stated. • The sample size was clearly stated and the overall strength of evidence in both studies during inclusion criteria revealed weakness. • In both studies data was insufficiently collected e.g: In study 1: The trial was larger than in study two, the design was rigorous and revealed results that did not favour wearing of surgical face masks therefore these were not statistically significant. In study 2: sampling was small and favoured wearing of surgical masks, was discontinued after seven weeks and resulted in difficulty in interpretation of results of the study. • The results extracted for this study were limited to clean surgery resulting in potential bias.
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			<ul style="list-style-type: none"> • Data analysis: neither of the studies analysed data and no blinding of participants (surgical team) and patients were stated in the study. • Ethical considerations: In the first study it was not clear whether consent was obtained from patients and staff whereas in study 2, consent was obtained from both staff and patients involved in the study. <p>Conclusion: The study was fairly planned, conducted and reported medium rigour of 7/10 and rated Grade IV of evidence.</p> <p>Relevance to the study: Relevant because masked effectiveness during a surgical procedure was addressed.</p> <p style="text-align: right;">INCLUDED in the study.</p>
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ARTICLE NUMBER 4

<p>Alwitry <i>et al.</i> (2002:975-972). “The use of surgical face masks during cataract surgery: Is it necessary?”</p>	<p>Study type: RCT (Prospective).</p> <p>Setting: Ophthalmic Operating Theatres (fitted with high efficiency particulate air [HEPA]).</p> <p>Intervention: Wearing a new mask and unmasked throughout the procedure.</p>	<p>Sample: Randomised sampling 109 cases to Group A (surgeons worn a new mask) and 112 Group B (surgeons worn no mask).</p> <p>Data collection:</p> <ul style="list-style-type: none"> • 118 cases were undertaken via temporal section control and 103 were done via superior approach on 15 randomly selected cases. • Six randomly selected cases were placed as background plates. • Duration of the procedure was noted. • The settle plates were incubated for 48 hours at 37 degrees Celsius in a 5% carbon dioxide incubator and were then read by a microbiologist. <p>Data analysis:</p> <ul style="list-style-type: none"> • In all statistical data analyses the X2 test was used (to compare the total counts of groups A and B and the Mann Whitney U-test was used to compare background plate counts with control plate counts. 	<p>Instruments used: Randomised critical trials (prospective).</p> <ul style="list-style-type: none"> • This study was clear concerning the research question. • The recruitment of the sample was clear, sample size was adequate and the inclusion and exclusion criteria were clear. • Ethical issues were taken into consideration. • Data collection methods were clearly described. • Data analysis was clearly stated and the research showed its value for further research and recommendations were clearly stated. <p>Conclusion: The study was well planned, conducted and reported with a medium rigour of 9/10 and rated Grade IV.</p>
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			<p>Relevance to the study: Relevant because effectiveness of surgical face masks was addressed. The study recommends routine wearing of surgical facemasks during a cataract surgery.</p> <p style="text-align: center;">INCLUDED in the study.</p>
ARTICLE NUMBER 5			
<p>Bahli (2009:166-170) “Does evidence based medicine support the effectiveness of Surgical facemasks in preventing post-operative wound infections in elective surgery?”</p>	<p>Study type: RCT.</p> <p>Setting: Operating Theatre (London, Unspecified).</p> <p>Intervention: Masked and no masked groups performing surgical procedures</p>	<p>Sample: Randomised sampling (unmasked and masked surgical team). Sample size in all four studies.</p> <p>Data collection: Masked and unmasked surgical teams (in 4 studies) were allocated to different operations and studies were evaluated according to the type and strength of efficacy evidence.</p> <p>Data analysis: Standard laboratory techniques were used for each study. Studies 3 and 4 (a p<value 0.05) were significant of a decrease in infection rate.</p>	<p>Instrument used: RCT Systematic Review</p> <ul style="list-style-type: none"> • A clearly focussed research question was stated in this study. • The overall objectives were clearly stated. • The design was clearly stated and the method was clearly stated. • The sample sizes were not clearly defined, thus the researches were biased. • In all studies data was collected in the same manner.

			<ul style="list-style-type: none"> • Of the 4 studies data analysis was not clear. • It is evident from these studies that a very limited research was done in this field and the applicability of the results is only limited to general and gynaecologic surgery. <p>Conclusion: This study was planned and well conducted. Rigour was 7/10 medium and with Grade II of evidence.</p> <p>Relevant to the study because evidence regarding the effectiveness of surgical masks during a surgical procedure was addressed.</p> <p style="text-align: right;">INCLUDED in the study.</p>
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ARTICLE NUMBER 6

<p>ARTICLE NO. 6 Cocciolone <i>et al.</i> (2004:439-441) “Surgical masks: Operative field contamination following visor to visor contact.”</p>	<p>Study type: RCT.</p> <p>Setting: Operating Theatre (Australia, unspecified).</p> <p>Intervention: Two operators (surgeon and assistant) Group 1 and Group 2 both didn't wear surgical visor masks.</p>	<p>Sample: Randomised sampling. Thirty (30) imitated operative procedures.</p> <p>Data collection:</p> <ul style="list-style-type: none"> • Two operators (surgeon and assistant) stood on either side of the operative field, donned a fresh surgical visor mask, performed a standardised scrub, and donned a sterile gown and gloves for each procedure which lasted for 20 minutes. • All procedures were performed over a standard blood agar plates array under a metal grid. • Normal conversation was maintained between operators throughout the procedure. • The degree of bacterial contamination was assessed by counting the colony-forming units (cfu.) that developed after 24 hours of incubation. <p>Data analysis:</p> <ul style="list-style-type: none"> • The SPSS 11.00 software and the one-tailed Mann-Whitney were used to compare the 	<p>Instrument used: RCT</p> <ul style="list-style-type: none"> • The research question and the objectives of this study were clearly stated. • The recruitment of the sample was not mentioned, the sample size was not clear and no inclusion and exclusion criteria were followed. • Ethical issues were not taken into consideration. • Data collection methods were clearly described. • Data analysis was clearly stated and the research showed its value for further research and recommendations were clearly stated. <p>Conclusion: The study was fairly planned, conducted and reported medium rigour of 7/10 and rated Grade II</p>
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		<p>colony counts between the groups as determined by the number of surgical visor mask clashes.</p>	<p>Relevance to the study: Relevant because effectiveness of surgical face masks (visor surgical masks) was addressed and concluded by highlighting factors the can affect the efficiency of a surgical mask.</p> <p>INCLUDED in the study.</p>
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3.5 SUMMARY

In Chapter 3 the researcher provided an overview of the realisation of the systematic review according to specific steps. The following aspects regarding these steps are summarised below and will give direction to the introduction to Chapter 4. Step number 1 was followed and a focussed research question was formulated according to the PICOTS acronym. In step number 2 evidence was gathered and classified until six (n=6) articles were selected as the final sample. This led to the final step, namely step number 3. Through declaring various critical appraisal tools, the researcher was able to evaluate the quality of these articles. In Chapter four the reader will be guided towards the analysis and synthesis of this evidence.

CHAPTER 4

FINDINGS OF THE STUDY

4.1 INTRODUCTION

In Chapter 4, two aspects of the systematic review are discussed. Firstly, the realisation of the extracted data, including the characteristics of the final sample was discussed. Secondly, the data synthesis which includes the summary of the research findings and the statements regarding the evidence founded was discussed.

4.2 SUMMARISING THE EVIDENCE

The summary of the research evidence entails two aspects in step number four of the systematic review, data extraction and data synthesis.

4.2.1 Step 4: Data extraction and synthesis

The characteristics of the final sample will be explained followed by an explanation of the data extraction.

4.2.1.1 *Characteristics of the final sample*

In this systematic review after a process of elimination, a total of six (6) RCT's were used. Of these six studies two (2) studies revealed good to strong evidence and were rated Grade I. The additional four (4) studies were fair to medium evidence and were rated Grade II. All of the six included studies regarding the effectiveness of surgical face masks during a surgical procedure in the operating room by health care professionals were addressed and revealed limited results whether wearing or not wearing surgical face masks had a benefit to both health care professional and the patient.

4.2.1.2 *Data extraction*

The data extracted from the selected studies is provided in Table 4.1 (below). In this Table an overview of the characteristics and findings of the studies from which data was extracted is formulated (ADA, 2008:52).

Table 4.1 Outline of data extraction of the included studies as final sample (n=6, all studies were randomised controlled trials)

Reference	Focus of the study	Overall results and bottom line findings	Findings relevant to the study
<p>Article number 1:</p> <p>Webster <i>et al.</i> (2010, 169-173).</p> <p>Use of mask by non-scrubbed operating room staff: a randomised control trial.</p>	<p>To assess the impact on surgical site infections (SSI) when non-scrubbed operating room staff did not wear surgical face masks.</p>	<ul style="list-style-type: none"> • 83 (10.2%) surgical site infections were recorded. • In the masked group 46/401 (11.5%) and in the non-masked group 37/410 (9.0%). The difference was not statistically significant. Odds ratio (OR) = 0.77, 95 % confidence interval (CI) = 0.49 to 1.21), p = 00.151. 	<p>Findings from this study regarding the effectiveness of surgical masks are that surgical site infections did not increase when non-scrubbed operating room personnel did not wear surgical face masks.</p>
<p>Article number 2:</p> <p>Romney (2001:251-256).</p> <p>Surgical face masks in the operating theatre: re-examining the evidence.</p>	<p>To evaluate the latest evidence for and against routine use of surgical face masks in the operating theatre.</p>	<ul style="list-style-type: none"> • The surgical site infection rate was compared between masked and non-masked groups. • The masked group was 4.7% and the non-masked group 3.5%. • The difference in rates was not statistically significant when using a chi-square test. 	<p>Based on this prospective randomised blinded trial it was concluded that wearing face masks have no effect on the rates of post-operative surgical infections.</p>

<p>Article number 3:</p> <p>Lipp and Edwards (2005:38).</p> <p>Disposable surgical face masks: A systematic review.</p>	<p>To identify and review all the relevant data in order to determine whether the disposable surgical face masks worn by the surgical team prevent wound infection in a clean wound.</p>	<ul style="list-style-type: none"> • Two randomised controlled trials were conducted in smaller trials there were a trend towards wearing masks being associated with fewer infections whereas in a larger trial it was found that there was no difference in infection rates between masked and unmasked groups. • Neither of the trials accounted for cluster and randomisation in the analysis. 	<p>From the limited results it is unclear whether wearing a surgical face mask results in any harm or benefit to the patient undergoing clean surgery. Both authors recommended further research to be conducted in order to determine conclusively the benefit of surgical face masks as a protective device.</p>
<p>Article number 4:</p> <p>Alwtry <i>et al.</i> (2012:975-977).</p> <p>The use of surgical face masks during cataract surgery: Is it necessary?</p>	<p>To assess whether face mask utilisation by the surgeon during cataract surgery had an effect on the bacterial load falling on to the operative site.</p>	<ul style="list-style-type: none"> • When surgical face masks were worn during cataract surgery, the results revealed statistically significant reduction in the volume of bacterial organisms falling on the operative site ($p < 0.001$). • The colony counts were significantly higher on the test plate when compared to the control plates thus indicating that the surgeon's proximity is indeed a causative increase of bacterial environmental load. 	<p>Findings from this study were that surgical masks were shown to have a significant effect on the volume of bacterial organisms falling on the operative site.</p>
<p>Article number 5: Bahli (2009:166-170).</p>	<p>To critically and systematically review the randomised control trials</p>	<ul style="list-style-type: none"> • There was a significance difference in the incidence of post-operative wound infection observed between masked 	<p>From the limited randomised control trials it is still not clear whether wearing surgical face masks is to the harm or</p>

<p>Does evidence-based medicine support the effectiveness of surgical facemasks in preventing wound infections in elective surgery?</p>	<p>regarding the effectiveness of surgical face masks to prevent post-operative wound infection in elective surgery.</p>	<p>groups and groups operating without masks (1.34, 95% CI, 0.58-3.07) and significant decrease in infection rate ($p < 0.05$).</p>	<p>benefit of the patient undergoing elective surgery.</p>
<p>Article number 6: Cocciolone <i>et al.</i> (2004:439-441). Surgical masks: operative field contamination following visor-to-visor contact.</p>	<p>To determine the potential for operative field contamination following surgical visor-mask clashes.</p>	<ul style="list-style-type: none"> The main colony forming units were significantly greater where surgical visor-mask clashes had occurred. 	<p>Surgical visor-mask clashes increase the risk of bacterial contamination of the operative field.</p>

4.2.1.3 Analysis strategy

In this study, six (6) quantitative studies were included and only one (1) focus question was used, namely "What is the evidence about the effectiveness of surgical face masks as a protective device in the operating room?" The findings from the included studies were analysed and compared. This comparison formed a summary after which conclusion statements were formulated (see paragraph 4.3). These statements were formulated as it is unclear whether wearing or not wearing of surgical face masks serve as a protective device during a surgical procedure in the operating room.

4.2.1.4 Summary of evidence

The following summaries of the evidence presented are formulated:

i) Overall summary statement

A summary of findings or evidence of included studies was conducted in order to reach a conclusion which was based on the focused research question "What is the evidence about the effectiveness of surgical face masks as a protective device in the operating room?" In this study the findings from included studies were unclear whether surgical face masks are effective as a protective device during a surgical procedure in the operating room.

ii) Comparison factors statements

In this study a comparison was made between masked and non-masked surgical teams in minimising the transmission of oro-pharyngeal and naso-pharyngeal bacteria from the health care professionals to the patient's wound during a surgical procedure. Findings from the included studies revealed the same results, namely that the wearing of surgical face masks during a surgical procedure is still unclear on whether it protects both patient and the health professionals. The authors recommended that further robust research was needed to determine conclusively the benefit of surgical face mask as a patient protective device (Lipp & Edwards, 2005:38).

Randomised controlled trials were used in all the included studies. Two (2) of the studies were appropriate and had strong evidence whilst four (4) studies had a medium evidence. In one of the four studies the sample size and the inclusion and the exclusion criteria were not stated and this resulted in uncertainty of the interpretation of the results whether surgical

visor-masks during a surgical procedure in the operating room can cause contamination of wounds or not.

Key words such as effectiveness, efficiency, surgical facemask, and operating room or theatre were used and defined as follows:

- Effectiveness: a measure of the accuracy or success of a diagnostic or therapeutic technique when carried out in an average clinical environment (Freshwater & Maslin-Prothero, 2005:199).
- Efficiency: the production of the desired effect or results with minimum time, effort or skill (Freshwater & Maslin-Prothero, 2005:199).
- Surgical face mask: a device that fits over the nose and mouth by the operating room staff and certain other health-care personnel (Freshwater & Maslin-Prothero, 2005:224).
- Operating room or theatre: is the area where surgical procedures are performed under strict sterile techniques (Phillips, 2007:198).

4.3 CONCLUSION STATEMENTS

From the results that crystallised through the steps of the systematic review on the question: What is the evidence of the effectiveness of surgical face masks worn during a surgical procedure in the operating room?, the following conclusion statements are formulated:

- In general, it is unclear whether wearing or not wearing of surgical face masks serve as protective devices during a surgical procedure in the operating room.
- The selected evidence could not conclude on the effectiveness of wearing surgical face masks in the operating room during a surgical procedure.
- Surgical face masks worn during surgical procedures might be a protective measure against body fluid and blood splashes.
- The effectiveness of surgical face masks as a protective measure is influenced by the type of face masks used, the application thereof and how regularly the face mask is replaced.
- The temperature and humidity of the operating room are two aspects of the operating room that impact on the efficiency of surgical face masks worn during a surgical procedure in an operating room.

4.4 SUMMARY

In this chapter, the realisation of data extraction and data synthesis was done. A summary of the research findings from the included studies (final sample) was reflected and the characteristics of the final sample were provided. Lastly, definitions of the keywords e.g. effectiveness, efficient, surgical face mask and operating room or theatre were explained.

CHAPTER 5

CONCLUSIONS, LIMITATIONS AND RECOMMENDATIONS

5.1 INTRODUCTION

Chapter five serves as the final chapter of this study and will be dedicated to the following: final conclusion, reflective evaluation of the study, identifying limitations and formulate recommendations for nursing education, - research and – practice.

5.2 FINAL CONCLUSIONS

In Chapter 1 of this study a focus question was stated: “What evidence is available regarding the effectiveness of surgical face masks as a protective device during a surgical procedure in the operating room?” In Chapter 4 conclusion statements were formulated. In order to answer this question the concluding statement was formulated as there is insufficient evidence that surgical face masks are effective during a surgical procedure in the operating room. The findings from studies including in this investigation revealed the same results, namely that wearing of surgical face masks during a surgical procedure is still unclear whether it protects both patient and the surgical team. The authors strongly agree that further robust research is needed to determine conclusively the effectiveness of the surgical face mask as a protective device (Lipp & Edwards, 2005:38).

5.3 EVALUATION

In this systematic review rigour was ensured in various ways in order to reach a proper conclusion, considering different stages in the review namely the problem identification stage, the literature search stage, the critical appraisal stage, the data synthesis stage and presentation (Whitemore & Knafl, 2005:548–552). Rigour maintained in these stages will be explained below:

5.3.1 Problem–identification stage

The problem and purpose in this systematic review were clearly defined and were supported by the evidence collected during the literature review. The review question was formulated and a PICOT(S) format was used (see Table 3.1). A systematic review was chosen in this study as the relevant design that answers the review question stated (see paragraph 1.7). A methodological model for research in nursing referred to as the Botes' model (Botes, 1995) and the theoretical framework (model for evidence-based clinical decisions) were used as a basis and guided the researcher to conclude with the problem stated (Rothrock, 2007:5).

5.3.2 Literature search stage

The literature search strategy (sampling) was conducted comprehensively by identifying complete and unbiased relevant studies in order to increase internal validity. A combination of key words e.g. effective/ efficient, surgical masking, operating room/ theatre were used. Various sources which clearly stated the inclusion and the exclusion criteria were searched in order to ensure that no relevant data that is relevant to the review topic is missed. An experienced librarian at the Ferdinand Postma Library at the NWU (Potchefstroom Campus) had input in literature searches by assisting with articles where only abstracts could be opened. Only articles that were written in English were used in order to reduce publication bias in this study (O'Mathuna *et al.*, 2008:105).

5.3.3 Critical appraisal stage

In the critical appraisal stage, the focus was on choosing an appropriate study design in relation to the research question. The critical appraisal was done in order to ensure that included studies were of high quality evidence before data extraction was conducted. "High quality" types of research designs can be conducted in an appropriate and unbiased way (CDR, 2009:33). Below are the tools used to appraise the relevant study designs:

- The evaluation tool for quantitative research studies (Long *et al.*, 2002).
- Critical appraisal instrument for reviews (CASP, 2006).
- Critical appraisal instrument for RCTs (CASP, 2006).
- Critical appraisal instrument for cohort studies (CASP, 2006).
- BMC (Bio Medical Central) Medical Research (Development of AMSTAR) (Shea, *et al.*, 2007).
- PRISMA statement checklist (Moher, *et al.*, 2009:6).

These tools were chosen because they could fit well to the study design for the included studies. To ensure that only studies that contain high quality evidence are included, the critical appraisal process was conducted by the reviewer under supervision of the supervisor (see paragraph 3.4). Auditability was taken into consideration by maintaining the inclusion and the exclusion criteria before data was critically appraised. Internal validity was put into consideration to ensure that no data was missed and the search was updated before the final report was submitted (see paragraph 3.2). Lastly with regard to transparency and repeatability, the entire search strategy was documented including decisions concerning inclusion and exclusion of data and reasons and presented in tables and flow charts (see figures 3.1, 3.2 and 3.4, 3.6)

5.3.4 Data synthesis stage

Items included in the study were appraised in order to be able to provide rigorous conclusions and recommendations which were derived from the evidence. For an overview of the data analysis process see paragraph 4.2.3.

5.3.5 Presentation

The entire systematic review was made transparent with clearly defined tables where applicable and flowcharts where also provided. A separate Chapter was provided where conclusions, limitations and recommendations are reflected. Finally, the outcomes of this study will be submitted for publication in a peer review journal.

5.4 LIMITATIONS

In this study the following limitations were identified:

- Various search engines were used in an extensive and rigorous manner, (see paragraph 3.2) but it was impossible to obtain full texts, in some instances only abstracts of the articles could be obtained, and this resulted in missing the data could be relevant to the current study. Studies that could not be obtained are outlined in Table 3.4.
- It was difficult to use sources from other Universities. Other multiple sources were also used in order to get more published and relevant studies such as electronic

databases (were used in the study) and, papers and catalogues (not used in the study).

- One of the articles was written in Italian although the abstract indicated a valuable contribution; the researcher was unable to access the Italian article.
- No independent reviewer conducted the critical appraisal.

5.5 RECOMMENDATIONS

In this study a systematic review was conducted in order to provide recommendations whether a surgical face masks are worn for the protection of both the surgical team and the patient during a surgical procedure in the operating room. The recommendations provided below, are based on the conclusion statement derived from the findings of this systematic review and also related to the levels of evidence (see paragraph 2.3.3.1)

5.5.1 Recommendations for further research

- From the limited results on this topic it is clear that there is a need to conduct more research regarding the effectiveness of surgical mask regarding protecting the surgical team from contracting infectious diseases during a surgical procedure and preventing post-operative wound infection to operated patients.
- Reading scientific papers is partly a matter of experience and skill and partly learning the specific vocabulary. It is recommended that the nursing leaders in the operating rooms should fully support EBP by providing the surgical team with knowledge and skills necessary to appraise research evidence regarding the effectiveness of surgical face masks during a surgical procedure in the operating room. Only through continuous learning that the surgical team can gain confidence needed to incorporate the evidence from research into day to day care of the individual surgical patient.

5.5.2 Recommendations for nurses' training and education

- In this study, it was clear that surgical masks were worn and used incorrectly by the surgical team thus resulting in uncertainty and inconsistent practice based on inadequate rationale (Lipp & Edwards, 2005:24). Therefore it is recommended that in service training and workshops are to be conducted in order to equip and develop the surgical team on the importance of wearing a surgical mask for protection during a surgical procedure.

- It is recommended that the manufactures should demonstrate the filter performance and the fit characteristics of surgical face masks for surgical face masks to be considered effective,

5.5.3 Recommendations for nursing practice

- Although it was clear from the critical appraisal conducted from various studies, that there is insignificant evidence supporting whether to continue wearing a surgical mask to protect both the surgical team and the patient during a surgical procedure. It is difficult to alter the current clinical practice of wearing surgical masks on the basis of current evidence (Bahli, 2009:170). The reviewer accepts that wearing of a surgical mask be continued by the surgical team during a surgical procedure, (considering the distance from the operation site) e.g. the scrub nurse, the surgeon and the assistant surgeon.
- In the absence of available evidence, local operating theatre policies should be established to promote wearing of surgical masks during a surgical procedure.

5.6 REFLECTION BACK TO THE RESEARCH AIM

In this study, a research question was answered, namely what is the evidence about the effectiveness of surgical face masks as a protective device during a surgical procedure in the operating room? It was evident from studies that were appraised, that very limited results in this field were revealed. In order to determine conclusively the benefit of a surgical face masks as a protective device for both the health care professional and the patient, during a surgical procedure in the operating room, further research is necessary.

5.7 SUMMARY

In this chapter an overview of the conclusion of statement of findings regarding the following important factors in this study such as the effectiveness of surgical face masks as a protective device, operating room, the evaluation of rigor, and the limitations during the process of conducting the study were well defined. The explanation about the achievement of the aim was provided. Lastly, recommendations regarding the need for further research were provided; in order to equip the nursing professionals towards enhanced informed decision-making on wearing a surgical mask during a surgical procedure.

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CASP **see** Critical Appraisal Skills Programme

CDC **see** Centers for Disease Control and Prevention

CRD **see** Centre for Reviews and Dissemination.

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